

ACCLARENT U.S. CUSTOMER RELATIONSHIP POLICY
ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

Acclarent, Inc. (the “Company” or “Acclarent”), is committed to complying with all federal, state, and local laws and regulations, and to maintaining a workplace that is free of retaliation for raising matters of legal compliance. As a medical device company, Acclarent is subject to a number of federal laws governing conflicts of interest, including but not limited to the federal anti-kickback statute (42 U.S.C. § 1320(a)-7(b)) and Stark II (Omnibus Budget Reconciliation Act of 1993). Effective July 1, 2009, Acclarent has adopted a U.S. Customer Relationship Policy (“USCRP”), which is based on the AdvaMed Code of Ethics on Interactions with Health Care Professionals (the “AdvaMed Code”), and which regulates the Company’s interactions with health care professionals. In some states, state law imposes additional restrictions on interactions with health care providers.¹ In particular, you are responsible for complying with Massachusetts regulation 105 CMR 970.000 with respect to interactions with health care providers in Massachusetts, a copy of which is attached to this USCRP as Exhibit A and incorporated by this reference. In addition, in creating this USCRP, Acclarent has supplemented the AdvaMed Code with certain provisions necessary to comply with state laws governing these interactions.

Acclarent employees are expected to familiarize themselves with Acclarent’s legal obligations. In addition, all Acclarent employees who interact with those individuals or entities involved in the provision of health care services and/or items to patients, or who purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Acclarent’s products are required to complete regular training on this USCRP.

At all times, you are required to abide by both the spirit and the letter of the USCRP and applicable law. Failure to comply with applicable law can result in serious consequences for both you and the Company, including imprisonment, civil and criminal penalties, and exclusion from participation in federal health care programs.

Should you ever have any question as to whether a particular activity violates applicable law or Acclarent’s USCRP, you are strongly encouraged to contact Human Resources, the Compliance Director, or any member of the Compliance Committee before undertaking such activity.

Reporting and Investigation

The Company is committed to maintaining an atmosphere of open communication and trust between employees and management. If you reasonably believe that you are aware of conduct that violates the Company’s duties under applicable law or the USCRP, you should immediately contact your supervisor, Human Resources, the Compliance Director, and/or any member of the Compliance Committee. You can also make a report via Acclarent’s compliance

¹ As of the date of this version of Acclarent’s compliance code, Massachusetts, Vermont, California and Nevada have imposed compliance and/or reporting requirements on medical device manufacturers.

hotline number, which is monitored by an outside vendor and affords the option of making an anonymous complaint. Reports to the hotline number are forwarded to the Company's Compliance Director for investigation.

All complaints under this policy will be promptly and thoroughly investigated, and all information disclosed during the course of the investigation will remain confidential, except as necessary to conduct the investigation and take any remedial action, in accordance with applicable law. All employees and supervisors have a duty to cooperate in the investigation of reports of any conduct covered by this policy. In addition, an employee will be subject to disciplinary action, including the termination of their employment, if the employee fails to cooperate in an investigation or deliberately provides false information during an investigation.

Once the investigation is complete, the specific action taken in any particular case depends on the nature and gravity of the conduct or circumstances reported and the quality of the information provided. If an investigation determines that conduct in violation of the Company's legal duties has occurred, and, if appropriate, the persons responsible will be disciplined.

Prohibition on Discrimination, Retaliation or Harassment

The Company strictly prohibits discrimination, retaliation or harassment of any kind against any employee who, based on the employee's reasonable belief that a violation of the USCRP or applicable law have occurred or are occurring, reports that information in accordance with this policy. The Company also strictly prohibits any discrimination, retaliation or harassment against any person who participates in an investigation of such complaints.

Any complaint that any managers, supervisors or employees are involved in discrimination, retaliation or harassment related to the reporting or investigation of conduct in violation of the Company's legal duties will be promptly and thoroughly investigated in accordance with the Company's investigation procedures. If a complaint of discrimination, retaliation or harassment is substantiated, appropriate disciplinary action, up to and including termination, will be taken.

The Company may modify this policy as necessary to accommodate organizational changes or to maintain compliance with applicable law and the USCRP. This policy is not intended to supersede any other Acclarent policies relating to whistleblowing, discrimination, harassment or retaliation.

Version 1

Dated: July 1, 2009

CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

I. Preamble: Goal and Scope of AdvaMed Code

The Advanced Medical Technology Association (“AdvaMed”) represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (“Medical Technologies”) in order to enable patients to live longer and healthier lives (collectively “Companies,” and individually “Company”). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in the United States (“Health Care Professionals”).

Medical Technologies

Medical Technologies are often highly dependent upon “hands on” Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician’s hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health Care Professionals. Innovation and creativity are essential to the development and evolution of Medical Technologies, which often occur outside a Company’s laboratory.

- *Enhance the Safe and Effective Use of Medical Technologies.* The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical, or other Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators often require this type of training as a condition of product approval.
- *Encourage Research and Education.* Companies' support of *bona fide* medical research, education, and enhancement of professional skills improves patient safety and increases access to Medical Technologies.
- *Foster Charitable Donations and Giving.* Companies make monetary and Medical Technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to—as well as the quality of—care and treatment in patient populations that may not otherwise be reached.

The Purpose of the Code of Ethics

AdvaMed recognizes that Health Care Professionals' first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and Health Care Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are the subject of this Code of Ethics.² To that end, AdvaMed restates and amends its Code of Ethics and Frequently Asked Questions (collectively "Code of Ethics" or "Code"), effective July 1, 2009.

II. Code of Ethics Compliance

All Companies are strongly encouraged to adopt this Code and to implement an effective compliance program – one which includes policies and procedures that foster compliance with the Code with respect to their interactions with Health Care Professionals related to Medical Technologies. A Company that adopts the Code is strongly encouraged to submit to AdvaMed an annual certification that the Company has adopted the Code and has implemented an effective compliance program. This certification must be signed by the Company's Chief Executive Officer and Chief Compliance Director or individuals with equivalent responsibilities within the certifying Company. AdvaMed will publish on its website a list of those Companies that have submitted the annual certification.

Companies that are AdvaMed members shall, and Companies that are non-members may, supply contact information for the Company's Compliance Department or an anonymous hotline to

² The principles of the Code are derived from a variety of authorities, including the federal Anti-kickback Statute. Throughout the Code, we refer to the concept of an "unlawful inducement" to reflect Anti-kickback Statute prohibitions.

facilitate reporting of possible violations of the Code. AdvaMed will publish on its website the contact information supplied by each such Company.

Companies are strongly encouraged to follow the seven elements of an effective compliance program, appropriately tailored for each Company, namely: (1) implementing written policies and procedures; (2) designating a Compliance Director and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication (including an anonymous reporting function); (5) conducting internal monitoring and auditing; (6) enforcing standards through well-publicized disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action.

Note. This Amended and Restated Code supersedes and replaces all previous AdvaMed Codes of Ethics. Companies adopting this Code shall communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations. The information provided by the Department of Health and Human Services, Office of Inspector General (“OIG”), as well as applicable laws or regulations, may provide more specificity than this Code, and Companies should address any additional questions to their own attorneys. This Code of Ethics is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations. Any interpretation of the provisions of this Code, as well as Companies’ interactions with Health Care Professionals not specifically addressed in this Code, should be made in light of the following principle: Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

III. Company-Conducted Product Training and Education

Companies have a responsibility to make training and education on their products and Medical Technologies available to Health Care Professionals. Companies may also provide education to Health Care Professionals. “Training” means training on the safe and effective use of Medical Technologies. “Education” means communicating information directly concerning or associated with the use of Companies’ Medical Technologies, *e.g.*, information about disease states and the benefits of Medical Technologies to certain patient populations. Training and Education programs include, but are not limited to, “hands on” training sessions, cadaver workshops, lectures and presentations, and grand rounds. In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain Medical Technologies. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals:

- Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. In some cases, it may be appropriate for a Company representative to provide training and education at the Health Care Professional's location.
- Programs providing "hands on" training on Medical Technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.
- Companies may provide Health Care Professional attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.
- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Companies may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Note under Massachusetts Law: Payment or reimbursement for reasonable expenses necessary for technical training on the use of a medical device is not prohibited, so long as the commitment to provide such expenses, and the amounts or categories of such reasonable expenses to be paid, are *described in the written purchase agreement* between the health care practitioner³ and the device vendor for the purchase of the device.

Note under Vermont Law: Payment or reimbursement for reasonable expenses necessary for technical training of individual health care professionals⁴ on the use of a medical device is not prohibited, so long as the commitment to provide such expenses,

³ Under Massachusetts law, health care practitioner is defined as a person who prescribes prescription drugs for any person and is licensed to provide health care in the commonwealth, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals. Hospitals are not healthcare practitioners. Additionally, full time employees and board members of pharmaceutical or medical device manufacturers are not health care practitioners.

⁴ Under Vermont law, health care professional is defined as (i) a person who is authorized to prescribe or to recommend prescribed products and who either is licensed by this state to provide or is otherwise lawfully providing health care in this state; or (ii) a partnership or corporation made up of the persons described in subdivision (i); or (iii) an officer, employee, agent, or contractor of a person described in subdivision (i) who is acting in the course and scope of employment, of an agency, or of a contract related to or supportive of the provision of health care to individuals. The term shall not include a person described above who is employed solely by a manufacturer

and the amounts or categories of such reasonable expenses to be paid, are *described in the written agreement* between the health care professional and the manufacturer.

IV. Supporting Third-Party Educational Conferences

Bona fide independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Companies may support these conferences in various ways:

- *Conference Grants.* Companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Companies may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with applicable standards established by the conference sponsor and any body accrediting the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

Note under Massachusetts Law: A medical device company may not sponsor CME events that do not meet the Standards for Commercial Support as established by the Accreditation Council for Continuing Medical Education (“ACCME”) or equivalent commercial support standards, or that provide payment directly to a health care professional.

Note under Vermont Law: (A) A medical device company may make a payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided: (i) the payment is not made directly to a health care provider; (ii) funding is used solely for bona fide educational purposes; and (iii) all program content is objective, free from industry control, and does not promote specific products. (B) A medical device company may make a payment of honoraria or the expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical scientific, or policy-making activities; provided that the content of the presentation, including slides and written materials, is determined by the health care professional.

- *Conference Meals and Refreshments.* Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, Companies themselves may provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are provided: (1) to all Health Care Professional attendees (with the limited exception noted below), and (2) in a manner that

is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. Meals and refreshments may be provided to fewer than all Health Care Professional attendees if the Company providing such meals and refreshments satisfies all other principles related to meals set forth in Section VIII. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.

Note under Massachusetts Law: No medical device company may provide payment for meals directly to a health care practitioner at any CME event, third-party scientific or education conference, or professional meeting, although a CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a medical device company for the event to provide meals for all participants.

- *Faculty Expenses.* Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are *bona fide* conference faculty members.
- *Advertisements and Demonstration.* Companies may purchase advertisements and lease booth space for Company displays at conferences.

V. Sales, Promotional, and Other Business Meetings

Companies may conduct sales, promotional, and other business meetings with Health Care Professionals to discuss, for example, Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Health Care Professional's place of business. It is appropriate to pay for reasonable travel costs of attendees when necessary (*e.g.*, for plant tours or demonstrations of non-portable equipment) and/or to provide occasional modest meals and refreshments in connection with such meetings. However, it is not appropriate to pay for meals, refreshments, travel, or lodging of guests of Health Care Professionals or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. *See* Section VIII for additional principles related to the provision of meals associated with Health Care Professional business interactions.

VI. Consulting Arrangements with Health Care Professionals

Companies engage Health Care Professionals to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:

- Consulting agreements should be written and describe all services to be provided. When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.
- Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented.
- Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.
- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business.
- A Company may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging. **Note under Massachusetts Law:** Any such compensation or reimbursement must be specified in, and paid for under, a written agreement.
- The venue and circumstances for Company meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Company-sponsored meals and refreshments provided in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. Companies should not provide recreation or entertainment in conjunction with these meetings.
- A Company's sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Health Care Professional as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this section.

Note under Massachusetts Law: Medical device companies must maintain records concerning all consulting arrangements with health care practitioners and make appropriate use of the services provided by the health care practitioners.

Provisions on Payment of Royalties. Arrangements involving the payment of royalties to a Health Care Professional should meet the contractual standards set forth above. Health Care Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement. A Company should enter into a royalty arrangement with a Health Care Professional only where the Health Care Professional is expected to make or has made a novel, significant, or innovative contribution to,

for example, the development of a product, technology, process, or method. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

The calculation of royalties payable to a Health Care Professional in exchange for Intellectual Property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, royalties paid in exchange for Intellectual Property should not be conditioned on: (1) a requirement that the Health Care Professional purchase, order or recommend any product or medical technology of the Company or any product or technology produced as a result of the development project; or (2) a requirement to market the product or medical technology upon commercialization. (Companies may, however, elect to enter into separate consulting agreements with Health Care Professionals for marketing services if such services meet the requirements set forth in this Section VI above.) Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the Health Care Professional and/or members of the Health Care Professional's practice.

VII. Prohibition on Entertainment and Recreation

Company interactions with Health Care Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee Health Care Professional. Such activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips. Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether the Company engages the Health Care Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

VIII. Modest Meals Associated with Health Care Professional Business Interactions

A Company's business interactions with Health Care Professionals may involve the presentation of scientific, educational, or business information and include, but are not limited to, the different types of interactions described in Sections III through VI of this Code of Ethics. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section.

Purpose. The meal should be incidental to the *bona fide* presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.

Setting and Location. Meals should be in a setting that is conducive to *bona fide* scientific, educational, or business discussions. Meals may occur at the Health Care Professional's place of

business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Health Care Professional's place of business, for example, (1) where the Medical Technology cannot easily be transported to the Health Care Professional's location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on-site.

Note under Massachusetts Law: Meals should not be offered, consumed or provided outside of the health care practitioner's office or hospital setting.

Participants. A Company may provide a meal only to Health Care Professionals who actually attend the meeting. A Company may not provide a meal for an entire office staff where everyone does not attend the meeting. A Company also may not provide a meal where its representative is not present (such as a "dine & dash" program). A Company may not pay for meals for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Other principles. Depending on the type of business interaction or meeting, additional principles may apply, as described in other sections of this Code of Ethics. Specifically:

- Section III: Company-Conducted Product Training and Education.
- Section IV: Supporting Third-Party Educational Conferences.
- Section V: Sales, Promotional, and Other Business Meetings.
- Section VI: Consulting Arrangements with Health Care Professionals.

IX. Educational Items; Prohibition on Gifts

A Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than \$100. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example, a DVD player or MP3 player/I-Pod.

A Company may not give Health Care Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Health Care Professional's work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have a Company's name, logo, or the name or logo of one of its Medical Technologies. Companies also may not provide Health Care Professionals with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.

This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section XII.

Note under Vermont Law: It is unlawful for any manufacturer of a prescribed product or any wholesale distributor of medical devices, or any agent thereof, to offer or give any gift⁵ to a health care provider. This prohibition does not apply to: (A) product samples, (B) the loan of medical devices for evaluation purposes for a period not to exceed 90 days, (C) the provision of reasonable quantities of medical device demonstration or evaluation units, (D) the provision of peer-reviewed journal articles and other items that serve a genuine educational function for the benefit of patients, (E) scholarships or other support for medical students, residents and fellows to attend certain professional association conferences or seminars if the recipient is selected by the professional association, (F) rebates and discounts, and (G) approved labels.

X. Provision of Coverage, Reimbursement and Health Economics Information

As Medical Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Medical Technology may be dependent on Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, a Company may provide such information regarding its Medical Technologies if it is accurate and objective. A Company also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Medical Technologies.

⁵ Under Vermont law, a gift is defined as (A) anything of value provided to a health care provider for free; or (B) any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider, unless (i) it is an “allowable expenditure;” or (ii) the health care provider reimburses the cost at fair market value.

“Allowable expenditures” means: (A) Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided: (i) the payment is not made directly to a health care provider; (ii) funding is used solely for bona fide educational purposes; and (iii) all program content is objective, free from industry control, and does not promote specific products.

(B) Honoraria and payment of the expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, provided: (i) there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities; and (ii) the content of the presentation, including slides and written materials, is determined by the health care professional.

(C) For a bona fide clinical trial: (i) gross compensation for the Vermont location or locations involved; (ii) direct salary support per principal investigator and other health care professionals per year; and (iii) expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.

(D) For a research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry: (i) gross compensation; (ii) direct salary support per health care professional; and (iii) expenses paid on behalf of each health care professional.

(E) Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals 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 a written agreement between the health care provider and the manufacturer.

(F) Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.

Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- Identifying the clinical value of the Company's Medical Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payors.
- Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Health Care Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Health Care Professionals regarding the Company's Medical Technologies, including identifying coverage, codes and billing options that may apply to those Medical Technologies or the services and procedures in which they are used.
- Providing accurate and objective information about the economically efficient use of the Company's Medical Technologies, including where and how they can be used within the continuum of care.
- Providing information related to the Company's Medical Technologies regarding available reimbursement revenues and associated costs.
- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Health Care Professional's decision to buy or use the Company's Medical Technologies.
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Medical Technologies.
- Facilitating patient access to the Company's Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of a Health Care Professional to facilitate patient access to the Company's Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a Company's own Medical Technology; however such assistance should not be provided as an unlawful inducement.

A Company may not interfere with a Health Care Professional's independent clinical decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement. Further, a Company should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

XI. Research and Educational Grants and Charitable Donations

A Company may provide research and educational grants and charitable donations. However, a Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should: (a) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented. A Company's sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular Health Care Professional or institution will receive a grant or donation or the amount of such grant or donation. Companies should consider implementing procedures to monitor compliance with this section.

a. Research Grants

Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of health care, and otherwise benefits patients. In furtherance of these objectives, a Company may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies.

Company-initiated or directed research involving a Company's Medical Technologies (such as clinical study agreements) is addressed separately in Section VI.

b. Educational Grants

Educational grants may be provided for legitimate purposes, including, but not limited to, the examples below. As noted in Section IV, a Company may make educational grants to conference sponsors or training institutions. A Company may not make educational grants to individual Health Care Professionals.

- *Advancement of Medical Education.* A Company may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel. (For additional considerations regarding educational grants, see Section IV.)

- *Public Education.* A Company may make grants for the purpose of supporting education of patients or the public about important health care topics.

c. Charitable Donations

A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

XII. Evaluation and Demonstration Products

Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating Health Care Professional regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Health Care Professionals at no charge for evaluation and demonstration purposes.

This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement.

Company products that may be provided to Health Care Professionals for evaluation include single use (*e.g.*, consumable or disposable products) and multiple use products (sometimes referred to as “capital equipment”). These products may be provided at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Company products provided for evaluation are typically expected to be used in patient care.

Single Use/Consumables/Disposables. The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

Multiple Use/Capital. Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the Health Care Professional’s location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products.

Demonstration. Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. For example, a Health Care Professional may use a demonstration

product to show a patient the type of device that will be implanted in the patient. Demonstration products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as “Sample,” “Not for Human Use,” or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

A Company should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

F**R****E****Q****U****E****N****T****L****Y** **A****S****K****E****D** **Q****U****E****S****T****I****O****N****S**
R**E****G****A****R****D****I****N****G** **A****D****V****A****M****E****D**'**S** **C****O****D****E** **O****F** **E****T****H****I****C****S**
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SECTION I: PREAMBLE AND GENERAL QUESTIONS

Q1 Why did AdvaMed develop a code distinct from the PhRMA Code on Interactions with Health Care Professionals?

The AdvaMed Code of Ethics is intended to address the unique interactions that occur between Companies and Health Care Professionals, just as the PhRMA Code reflects the nature of interactions between pharmaceutical companies and Health Care Professionals. Distinguishing features in AdvaMed's Code arise primarily from the fact that Companies interact with Health Care Professionals because of the complexity and "hands on" nature of Medical Technologies and the importance of having Health Care Professionals understand how to use the technologies safely and effectively.

Q2 Who are "Health Care Professionals"? Does the term include non-clinical people who make Medical Technology purchasing decisions? Does it include decision-makers within GPOs?

The phrase "Health Care Professionals" is intended to be a broad one. It includes individuals or entities: 1) which are involved in the provision of health care services and/or items to patients; and 2) which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States. The phrase Health Care Professional includes both persons providing services (such as licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease, or recommend a Medical Technology. These individuals include, for example, purchasing agents, physician's practice managers and management within group purchasing organizations ("GPOs").

Q3 Does the Code apply to gifts, meals, refreshments, and other benefits provided by Companies to government employees?

Yes, the Code applies to gifts, meals, refreshments, and other benefits provided by Companies to government employees if the employees are Health Care Professionals. Companies also should be aware that there may be specific legal restrictions on providing gifts and other benefits to government employees, and that these restrictions may, in some cases, be more restrictive than the Code.

Q4 Does the Code cover interactions with Health Care Professionals whose primary place of work is outside the U.S.? Does it cover interactions outside the U.S. with Health Care Professionals who work in the U.S.?

The Code applies to interactions with Health Care Professionals to the extent that they provide services or Medical Technologies in the United States. This would include interactions with

Health Care Professionals who work in the United States, even if the interaction occurs outside the country (such as at a conference or other event). Of course, there are other laws and ethical requirements that may pertain to interactions with Health Care Professionals located both inside and outside the United States.

Q5 Are combination products covered by the Code?

Yes, interactions related to combination products (*e.g.*, those that are both biologics and devices or drugs and devices) are covered by the Code. Interactions related to combination products also may be subject to the ethical codes of other trade associations.

Q6 Does the Code address arrangements between a Company and a Health Care Professional relating to licensing a new product to the Company?

If these arrangements involve providing services to a Company, they are a type of consulting arrangement addressed in Section VI.

Q7 What do the terms “modest” and “occasional” mean?

“Modest” means moderate value, but may differ depending on regional differences.
“Occasional” means infrequent.

The provision of meals is subject to the limits discussed in Section VIII. A Company should consider establishing limits on the frequency and costs of meals provided to Health Care Professionals to comply with the requirements that the meals must be “modest” and “occasional.”

Q8 May a Company’s employee or agent pay for meals or refreshments for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the meals or refreshments nor reimburses the employee or agent?

No. The Code should be viewed as applying to a Company’s employees and agents even if they pay for benefits themselves. Depending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.

Q9 May a Company offer to provide laptop computers with independent value to any purchasing manager whose hospital purchases at least 1,000 units of the Company’s medical technology that the Company has just introduced?

No. A Company may not provide any item of value to a Health Care Professional that takes into consideration the value or volume of the business that is or may be generated by the Health Care Professional, unless permitted by law (*e.g.*, appropriate discounts).

Q10 May a Company provide support for a Health Care Professional-sponsored social event, such as an office holiday party?

No, such support would be inappropriate.

SECTION II: CODE OF ETHICS COMPLIANCE

Q11 What form should Companies use to make the certification described in Section II, and on what date are such certifications due?

The revised AdvaMed Code of Ethics will take effect on July 1, 2009. Company certifications should be submitted no later than July 1 of each year, beginning in 2010. AdvaMed will publish the certification form that Companies should use. While it may take a period of time for Companies to adopt the revised Code, create and implement policies, procedures and effective compliance programs to comply with the Code, and educate and train employees whose job responsibilities make the information relevant, Companies should endeavor to accomplish these tasks as diligently as reasonably possible.

Q12 Does the AdvaMed Code of Ethics offer legal advice?

No. The Code is intended to facilitate ethical behavior and is not intended to be, nor should it be, construed as legal advice. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations.

Q13 Will AdvaMed staff provide advice on how the Code would apply to specific practices?

No. Companies should address questions about specific practices to their own attorneys or advisors.

Q14 Does the Code govern the actions of Companies' agents and distributors?

As stated in Section II, Companies adopting the Code are required to communicate the Code's provisions to their employees, agents, dealers and distributors with the expectation that they will adhere to them. It is important that these entities are informed that AdvaMed has revised its Code of Ethics and that they are aware of the ethical standards reflected in it.

Q15 What does "appropriately tailored" mean with respect to implementation of the seven elements of an effective compliance program?

"Appropriately tailored" means that each Company's implementation of the seven elements of an effective compliance program should take into account the Company's size, resources, particular lines of business, and work-force. AdvaMed recognizes that, given the wide diversity within the medical technology industry, there is no single best compliance program. AdvaMed strongly encourages Companies to develop and implement compliance elements that address the specific types of risks that apply to their operations.

SECTION III: COMPANY-CONDUCTED PRODUCT TRAINING AND EDUCATION

Q16 Why may it be appropriate under the Code for Companies to pay for travel to attend training and education sessions?

In order to efficiently deliver training and/or education at appropriate facilities, the Code contemplates that a Company may bring Health Care Professionals together at a central location, which may make out-of-town travel necessary. Note that this section deals only with meetings focused on training and education on Medical Technologies, and only for persons who could legitimately benefit from the training and education. (Meetings focused on sales, promotional, and other business meetings are discussed in Section V.)

Q17 May a Company pay for travel to a Company-sponsored general educational program (not related to a Medical Technology)?

It may be appropriate for a Company to conduct a general educational session, but it is not the type of program for which Company-supported travel would be appropriate under the Code. In contrast, paying for a Health Care Professional's travel may be appropriate when the Company is conducting training and education on the safe and effective use of its Medical Technologies.

SECTION IV: SUPPORTING THIRD-PARTY EDUCATIONAL CONFERENCES

Q18 May a Company designate attendees or faculty who will speak at a third-party educational conference?

No. The Code contemplates that an independent third party will select faculty and attendees. The Code does not preclude a Company from recommending a knowledgeable faculty member, where the recommendation is permitted by the conference sponsor's guidelines. The ultimate selection should be made by the conference sponsor.

Q19 May a Company provide an educational grant to support the attendance of a Health Care Professional at a third-party educational conference?

The Code contemplates that grants would be made to the conference sponsor or training institution, which will select the attendees. Furthermore, the Code contemplates that the benefited attendees would be medical students, residents, fellows, or other Health Care Professionals in training.

Q20 If a Company provides a grant for a medical student to attend an educational conference, may the funds be used to cover both travel expenses and registration fees?

Yes, provided that the grant is given directly to a training institution or a third-party educational conference sponsor.

Q21 May a Company sponsor an off-site sales, promotional, or other business meeting that is ancillary to a third-party educational conference?

Yes, provided that the sales and promotional meeting or other activity has a legitimate business purpose and meets all applicable requirements of the Code. The Company also should comply with applicable conference sponsor guidelines.

SECTION V: SALES, PROMOTIONAL, AND OTHER BUSINESS MEETINGS

Q22 Why does the Code not allow Companies to extend business courtesies to guests/spouses in connection with sales, promotional and other business meetings?

AdvaMed's Code of Ethics is mindful of the desire to avoid even the appearance that business courtesies are being given as improper inducements to promote a Company's Medical Technologies. On the other hand, Companies may, as a matter of common courtesy and civility, provide occasional modest meals or refreshments for Health Care Professionals in connection with these types of meetings that are conducive to the exchange of information. The Code precludes the extension of these courtesies to persons, such as guests/spouses, without a *bona fide* professional interest in the meeting.

Q23 May a Company conduct a sales, promotional, or other business meeting at a resort location and pay for a Health Care Professional's travel to the meeting?

Generally, this would not be appropriate. Companies should be deliberate in selecting the location and venue for such meetings. Like location and venue selection for training and education meetings (discussed in Section III), Companies should select a location and venue that is appropriate for, and conducive to, accomplishing the purpose of the meeting. Selection of a resort location would not likely meet these standards and may give rise to an appearance of impropriety. In addition, the location should be evaluated for consistency with the provisions in Section V, which state that it may be appropriate at sales, promotional, or other business meetings to provide occasional modest meals or refreshments and, with respect to providing travel, that the travel be "necessary." Furthermore, the Code provides for limited special circumstances of "plant tours and demonstrations of non-portable equipment" as specific examples of when travel might be necessary.

Q24 May a Company indirectly provide meals or refreshments when the provision of meals or refreshments does not conform to the Code, for example, by reimbursing a distributor who provides these meals while marketing the Company's Medical Technologies?

No. Companies should always promote adherence to the Code by intermediaries when they are engaged in marketing the Company's Medical Technologies. A Company should never knowingly encourage or condone an intermediary's engaging in conduct that would be prohibited by the Code if a Company engaged in it directly.

SECTION VI: CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS

Q25 Is a clinical investigator considered a “consultant” under Section VI?

If the clinical investigator is providing services to the Company in return for compensation, he or she is a consultant under Section VI.

Q26 Is there a limit to the number of consultants a Company may retain under Section VI?

Companies may retain only as many consultants as are necessary to fulfill the Company’s requirements for *bona fide* services; moreover, the requirements of Section VI must be satisfied for each consultant.

Q27 May a consultant be placed under retainer with services provided as requested?

Yes, provided the requirements of Section VI are met.

Q28 What happens if a consultant is engaged but the project is cancelled or modified without using the consultant’s services?

The Code contemplates that if the requirements of Section VI were met when the consultant was engaged and then unanticipated circumstances prevented performance, then the question of whether or how much payment is made to a consultant would be a matter determined by the underlying consulting agreement. However, any such payment should be reasonable under the circumstances.

Q29 What factors should a Company consider when evaluating the venues and circumstances for meetings with consultants?

A Company should assess (a) whether there is a *bona fide* business justification for holding the meeting; (b) whether the location and venue are suitable for and conducive to the exchange of information; (c) whether the value of any Company-sponsored lodging is reasonable; (d) whether any ancillary meals and refreshments are modest in value and are subordinate in time and focus to the business part of the meeting; and (e) whether the overall meeting has a genuine business purpose and tenor and does not constitute an unlawful inducement.

Q30 Do the restrictions of the AdvaMed Code apply to Company interactions with consultants in the same way as they do to interactions with other Health Care Professionals?

Yes. All interactions with Health Care Professionals must meet the requirements of the Code. These include the requirements of Section VI as well as other applicable sections of the Code.

Q31 When is a Health Care Professional considered a “consultant”? What types of arrangements with consultants are covered under Section VI?

Any relationship between a Health Care Professional and a Company where services provided to the Company by the Health Care Professional are exchanged for remuneration constitutes a consulting arrangement and should comply with Section VI. Examples of consulting arrangements include agreements to provide education and training, speaking engagements, proctoring and preceptorships, reference center or center of excellence arrangements, participation on advisory boards or focus groups, medical technology development and research services arrangements (such as post-market research agreements, research and development agreements and clinical studies), and arrangements for the development and/or transfer of intellectual property. Research and educational grants are not considered consulting arrangements. They are addressed in Section XI.

Q32 Can the selection of a consultant include his or her experience, usage or familiarity with a specific Company Medical Technology?

Section VI provides that a consultant should be selected on the basis of his or her qualifications and expertise to meet a defined need. It is possible that these qualifications could include experience with, usage of, or familiarity with a specific Medical Technology. However, neither selection of, nor compensation paid to, consultants should be to reward past usage or constitute an unlawful inducement.

Q33 How are Clinical Study Agreements treated under the Code?

Arrangements that involve the provision of clinical research services by a Health Care Professional in return for compensation are a type of consulting arrangement and are subject to the same principles as other consulting arrangements under the Code. They should be governed by a written services agreement, and compensation should be based on fair market value for the services provided. The clinical program for which the services are being provided should fulfill a legitimate research purpose.

A Clinical Study Agreement typically is entered into between a Company and a Health Care Professional that is a facility, institution, or practice group, and compensation for the clinical research services is paid to that entity. An individual Health Care Professional may act as a study investigator but also provide related services in his or her individual capacity that is outside the scope of the services covered in the clinical study agreement (*e.g.*, protocol development). In that case, it may be appropriate to enter into a separate consulting arrangement with that Health Care Professional.

Q34 How can a Company establish “fair market value”?

There are different valuation methods that may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria. The method or methods used by a Company should be documented.

Q35 What is considered a “legitimate need” to engage a Health Care Professional as a consultant?

A legitimate need arises when a Company requires the services of a Health Care Professional in order to achieve a proper business objective. There are many proper business objectives. However, engaging a Health Care Professional for the purpose of generating business directly from such Health Care Professional (or a health care provider that is affiliated with the Health Care Professional) is not a proper business objective. Thus, there is a legitimate need to engage a Health Care Professional only if the arrangement would have been entered into absent an opportunity to generate business directly from the Health Care Professional. Further, the level of consulting services to be obtained from a Health Care Professional should not exceed the amount that is reasonably necessary to achieve a Company’s proper business objective.

SECTION VII: PROHIBITION ON ENTERTAINMENT AND RECREATION

Q36 May a Company’s employee or agent pay for entertainment or recreation for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the entertainment or recreation nor reimburses the employee or agent?

No. The Code should be viewed as applying to a Company’s employees and agents even if they pay. Depending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.

SECTION VIII: MODEST MEALS ASSOCIATED WITH HEALTH CARE PROFESSIONAL BUSINESS INTERACTIONS

Q37 Is a general discussion to build good business relationships a “business presentation” such that it is appropriate to provide a business meal?

No. A business presentation may include substantial discussions related to medical technology development and improvement of a medical technology, pricing, or contract negotiations. The business discussion should account for most of the time spent during the meal. Development of general goodwill and business relationships should not be the primary purpose of a business meal, and a business meal should not be used for entertainment or recreational purposes.

SECTION IX: EDUCATIONAL ITEMS; PROHIBITION ON GIFTS

Q38 May a Company provide a gift such as flowers, gift baskets, meals, snacks, wine, or other refreshments to a Health Care Professional or a Health Care Professional’s office or staff?

No. These types of gifts and refreshments are not considered educational items or for the benefit of patients.

Q39 May a Company give gifts to staff of a Health Care Professional who are not themselves Health Care Professionals?

Gifts given to the staff of a Health Care Professional should be treated as though they are given to the Health Care Professional and are subject to all applicable provisions of the Code.

Q40 May a Company or its representative provide a gift to recognize a life event for a Health Care Professional, such as a wedding, birth, anniversary, or death of a family member?

No. A Company, or representative acting on the Company's behalf, may only provide items to Health Care Professionals that are intended for the benefit of patients or serve a genuine educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, etc. do not meet this requirement even if provided to recognize a significant life event.

Q41 May a Company raffle an item during a trade show, such as two round-trip airline tickets, that it could not otherwise give as a gift?

No. A Company may not raffle or give away at a trade show an item that it could not otherwise give a Health Care Professional under Section IX.

Q42 What types of items are considered to be for the benefit of patients?

Items intended for the benefit of patients could include starter kits, and educational brochures, for example. However, “scrubs” and office supplies would not be considered an item for the benefit of patients. With respect to starter kits, a Company should adopt appropriate safeguards regarding the provision of such kits to ensure they are not offered as an unlawful inducement.

SECTION X: PROVISION OF COVERAGE, REIMBURSEMENT, AND HEALTH ECONOMICS INFORMATION

Q43 Is it appropriate to demonstrate that a Medical Technology can be used in an economically efficient manner?

It may be appropriate for Companies to provide accurate information relating to the costs, savings and revenues associated with the use of its Medical Technologies. Without this information, it may be difficult for a Health Care Professional to properly evaluate their economic feasibility or desirability.

SECTION XI: RESEARCH AND EDUCATIONAL GRANTS AND CHARITABLE DONATIONS

Q44 What is an example of a grant or donation to “individuals engaged in genuine charitable missions for the support of that mission”?

One example is providing medical technologies to individuals who perform volunteer disaster relief abroad. Supporting disaster relief work may be appropriate under the Code,

notwithstanding that the individuals or group are acting as independent volunteers and not under the umbrella of a not-for-profit, charitable organization.

Q45 May a Company make a charitable contribution to a not-for-profit institution to pay the registration or seminar fees and travel expenses for an affiliated Health Care Professional to attend a third-party educational conference?

In general, Section IV does not permit a Company to pay directly for the registration, seminar fees or travel expenses of a Health Care Professional's attendance at a third-party educational conference. Consequently, the Company should not provide these benefits indirectly as a charitable contribution to a Health Care Professional's not-for-profit institution for the purpose of defraying the costs of particular individuals' attendance. However, it can provide grants to sponsors to: 1) pay the expenses of faculty members selected by the conference sponsor; 2) support the participation of Health Care Professionals in training; or 3) reduce the costs of participation by all participants.

Q46 May a Company make a charitable contribution to a not-for-profit hospital for construction of a new wing?

Companies have historically supported the delivery of health care services through charitable contributions. As with any other contribution, this type of contribution may be appropriate if: (a) the recipient of the contribution is a charitable organization; (b) the purpose of the donation is charitable in nature; and (c) it is not an unlawful inducement. Many factors would be involved in considering whether such a contribution is appropriate, including ensuring that the amount of the donation is not dependent upon the volume of business or anticipated business conducted with or referred to the Company.

Q47 May a Company make an educational grant to pay for a clinical fellow?

A Company may make an educational grant to an institution to subsidize a clinical fellow if the fellow is in a genuine fellowship program which has a charitable or academic affiliation. A Company may not use the provision of an educational grant as an unlawful inducement.

Q48 May a Company pay for or provide tickets to a Health Care Professional or spouse or guest to attend charitable events, such as galas and golf outings?

No. A Company may not pay for or provide tickets to Health Care Professionals or their spouses or guests to attend charitable events, such as galas and golf outings.

Q49 May a Company give a Health Care Professional a research grant that is unrestricted and can be used for any purpose?

No. A Company should give research grants only if they are in support of research that has defined goals, objectives, and milestones.

Q50 May a Company make a contribution in support of a Health Care Professional’s charitable event (e.g., golf tournament, outing, gala dinner, and the like), where the proceeds earned from the event will be used for charitable purposes?

Yes, so long as the donation is not an unlawful inducement. However, a Company may not pay for an individual Health Care Professional to attend or participate in the charitable event.

Q51 How can a Company determine whether a charitable organization is a *bona fide* charitable organization?

Companies should exercise diligence to ensure the charitable organization is *bona fide*. Relevant factors to consider may include (1) the entity’s tax status, (2) the entity’s corporate status under state law, and (3) whether the organization has a charitable mission or purpose, among other factors.

SECTION XII: EVALUATION AND DEMONSTRATION PRODUCTS

Q52 May a Company provide a recently approved product without charge to a Health Care Professional for evaluation?

Yes, but the Company should provide the Health Care Professional with documentation about the product to allow the Health Care Professional to appropriately address any obligation to report for reimbursement purposes.

Q53 A Health Care Professional has requested that a Company provide it with a multiple use product to evaluate. How long can the Company provide the product at no charge to the Health Care Professional?

The specific length of time reasonably necessary for a Health Care Professional to assess a multiple use product will depend on the frequency of anticipated use, the duration of required training, the number of Health Care Professionals who will need to evaluate the product, the length of time necessary to evaluate different product features, and similar considerations. A Company should provide a Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation products.

Q54 Is a demonstration or evaluation product that is provided at no charge to a Health Care Professional by a Company a gift?

No. Demonstration and evaluation products are not considered gifts under Section IX.

Exhibit A

Massachusetts Regulation

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: Disclosure of Payments
- 970.010: Penalties
- 970.011: Enforcement

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 requires 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 boardmembers 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 pharmacy 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 pharmacy 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 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 Director 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 105 CMR 970.005(2) 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 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, s. 41 and M.G.L. c. 175H, s. 3.
2. Nothing in 105 CMR 970.008 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.

REGULATORY AUTHORITY

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