

# Sample FAQs

Courtesy of the Advanced Medical Technology Association

## FREQUENTLY ASKED QUESTIONS REGARDING ADVAMED'S CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

### SECTION I: PREAMBLE AND GENERAL PRINCIPLES

#### 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

Any relationship between a Health Care Professional and a Company when services provided by the Company to the Health Care Professional are not covered by the Code... (text continues)

#### Q5 Can the offer of a consultant include fee or honorarium, wage or familiarly with specific Company?

Section V provides that a consultant should be selected on the basis of his or her qualifications and expertise... (text continues)

#### Q6 How are Clinical Study Agreements treated under the Code?

Agreements that are not in the provision of clinical research services by a Health Care Professional to a Company... (text continues)

#### Q7 How can a Company establish "fair market value"?

There are different valuation methods that may be used to establish fair market value... (text continues)

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### SECTION II: CODE OF ETHICS COMPLIANCE

Q1 What form should Companies use to make the certification described in Section II, and when date are such certifications due?

The revised Advamed Code of Ethics will take effect on July 1, 2009. Companies should be advised that the certification should be submitted to the Code of Ethics by July 1 of each year, beginning in 2009. 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, certain compliance policies, procedures and disclosure 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.

Q2 Does the Advamed Code of Ethics have 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 bear an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations.

Q3 Will Advamed address questions about how the Code will affect specific practices?

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

Q4 Does the Code govern the actions of Companies' agents and distributors?

No. Companies adopting the Code are required to communicate the Code's provisions to their employees, agents, distributors and other individuals that they may be subject to. It is important that these entities are informed that Advamed has revised the Code of Ethics and that they are aware of the ethical standards reflected in it.

Q5 What does "aggregating" tabular data mean with respect to implementation of the new elements of an ethics compliance program?

"Aggregating" means that each Company's implementation of the seven elements of an ethics compliance program should take into account the Company's size, resources, particular mix of business, and risk profile. Advamed has revised the Code only with respect to the medical technology industry. There is no single best compliance program. Advamed strongly encourages Companies to identify and implement compliance elements that address the specific types of risks that apply to their operation.

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### SECTION III: COMPANY-CONDUCTED PRODUCT TRAINING AND EDUCATION

Q1 Who may be the appropriate vendor for the Code for Companies to pay for training to attend training and education courses?

In order to effectively 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 include out-of-town travel expenses. Note that this section deals only with meetings focused on training and education of Medical Technologies, and only for persons who could legitimately benefit from the training and education. Always keep records on costs, promotional, and other business meetings as discussed in Section V.

Q2 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 to the extent of programs for which a Company-sponsored vendor would be appropriate under the Code. Instead, paying for Health Care Professionals' travel may be appropriate when the Company is conducting training and education on the safe and effective use of Medical Technologies.

### SECTION IV: SUPPORTING TERTIARY PARTY EDUCATIONAL CONFERENCES

Q1 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 prohibit a Company from recommending a knowledgeable faculty member, whose recommendation is permitted by the conference sponsor's guidelines. The attendee selection should be made by the conference sponsor.

Q2 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 to support attendees, which will allow the attendees. Furthermore, the Code contemplates that the benefited attendees would be medical students, residents, fellows, or other Health Care Professionals in training.

Q3 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.

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Q5 May a Company indirectly provide meals, meals or refreshments that not conform to a distributor who provides these meals with Technology?

No. Companies should always promote adherence to the Code of Ethics. The Code of Ethics encourages and condones an intermediary to be prohibited by the Code of a Company engaged in a

### SECTION V: CONFLICT OF INTEREST

Q1 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. Advamed has been instructed to ensure the charitable organization is bona fide. The entity's corporate status under state law, and whether the organization has a charitable mission or purpose, among other factors.

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### SECTION VI: PROHIBITION ON ENTERTAINMENT AND RECREATION

Q1 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 for his or her own way.

### SECTION VII: MOST MEALS ASSOCIATED WITH HEALTH CARE PROFESSIONAL BUSINESS INTERACTIONS

Q17 Is a general discussion to build good business relationships a "business presentation" within the meaning of the Code?

No. A business presentation may include substantial discussions related to medical technology development and improvement of a medical technology, pricing, or contract negotiation. The business discussion should occur for most of the time spent during the meal. Development of general good will 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 VIII: EDUCATIONAL ITEMS, PROMOTIONAL GIFTS

Q18 May a Company provide a gift such as flowers, gift baskets, meals, meals, wine, or other refreshments to a Health Care Professional at a Health Care Professional's office or staff?

No. Types of gifts and refreshments are not considered educational items for the benefit of patients.

Q19 May a Company give gifts to staff of Health Care Professionals who are not immediate Health Care Professionals?

Health Care Professionals should be treated as though they are guests and are not subject to all applicable provisions of the Code.

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### SECTION IX: EVALUATION AND DEMONSTRATION PRODUCTS

Q22 May a Company provide a recently approved product without charge to a Health Care Professional for evaluation?

Yes, but the Company must provide the Health Care Professional with documentation about the product to allow the Health Care Professional to support any obligation to report to the reimbursement process.

Q23 Is a Health Care Professional has reported that a Company provide 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 necessary to prepare for a Health Care Professional to assess a multiple use product will depend on the frequency of 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 obtain different product features, and similar considerations. A Company should provide a Health Care Professional with documentation and feedback regarding the charge status of evaluation products.

Q24 Is a demonstration or evaluation product that is provided at no charge to a Health Care Professional a Company gift?

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

Q25 May a Company make a charitable contribution to support the construction of a new wing?

Companies have historically supported the delivery of health care services. As with any other contribution, this type of contribution is subject to the requirements of a charitable organization in charitable in nature, and (2) it is an unselfish individual involved in conducting whether such contribution is supported amount of the donation is not dependent upon the volume of combined sales or related to the Company.

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