

## QUESTIONS AND ANSWERS

# Frequently asked questions regarding the revised Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals

The Advanced Medical Technology Association (AdvaMed) developed a list of “*Frequently Asked Questions Regarding AdvaMed’s Code of Ethics on Interactions with Health Care Professionals*.” The list offers a total of 54 questions and answers covering all 12 sections of the code. Selected questions and answers are provided here.

The Advanced Medical Technology Association offers some specific examples regarding items that medical device makers can and cannot provide to health care professionals, when device makers might provide meals for health care professionals, and the manner in which device makers can support health care professional education.

### General questions

**Question:** Why did AdvaMed develop a code distinct from the Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals?

**Answer:** The AdvaMed Code of Ethics is intended to address the unique interactions that occur between health care device 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.

**Question:** Who are “health care professionals”? Does the term include non-clinical people who make medical technology purchasing decisions? Does it include

decision-makers within group purchasing organizations (GPOs)?

**Answer:** The phrase “health care professionals” is intended to be a broad one. It includes individuals or entities: (1) that are involved in the provision of health care services and/or items to patients; and (2) that 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 GPOs.

**Question:** What do the terms “modest” and “occasional” mean?

**Answer:** “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 the section on “Modest meals associated with health care business transactions.” 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.”

**Question:** 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?

**Answer:** 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.

**Question:** May a company provide support for a health care professional-sponsored social event, such as an office holiday party?

**Answer:** No, such support would be inappropriate.

### Compliance

**Question:** What form should companies use to make the certification described in the section on “Code of ethics

This article is based on information from the Advanced Medical Technology Association’s (AdvaMed). Opinions expressed are not necessarily those of the American Optometric Association.

**compliance” and on what date are such certifications due?**

**Answer:** 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.

**Question: Does the AdvaMed Code of Ethics offer legal advice?**

**Answer:** 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.

**Question: Will AdvaMed staff provide advice on how the code would apply to specific practices?**

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

**Question: Does the code govern the actions of manufacturers’ agents and distributors?**

**Answer:** As stated in the “Code of ethics compliance” section, 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.

**Question: What does “appropriately tailored” mean with respect to implementation of the 7 elements of an effective compliance program?**

**Answer:** The 7 elements of a compliance plan are: (1) implementing written policies and procedures, (2) designating a compliance officer 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. “Appropriately tailored” means that each company’s implementation of the 7 elements of an effective compliance program should take into account the company’s size, resources, particular lines of business, and workforce. 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.

## **Company-conducted product training and education**

**Question: Why may it be appropriate under the code for companies to pay for travel to attend training and education sessions?**

**Answer:** 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 “Sales, promotional, and other business meetings.”)

**Question: May a company pay for travel to a company-sponsored general educational program (not related to a medical technology)?**

**Answer:** 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.

## **Supporting third-party educational conferences**

**Question: May a company designate attendees or faculty who will speak at a third-party educational conference?**

**Answer:** 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.

**Question: May a company provide an educational grant to support the attendance of a health care professional at a third-party educational conference?**

**Answer:** 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.

## **Sales promotional and other business meetings**

**Question: Why does the code not allow companies to extend business courtesies to guests/spouses in connection with sales, promotional and other business meetings?**

**Answer:** 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,

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