

COMPANY-CONDUCTED PRODUCT TRAINING AND EDUCATION

Because of the way medical device technologies are used, medical technology companies have a responsibility to make available to HCPs, training on the safe and effective use of their products, and education, i.e., information on the disease state and benefits of their technologies. Companies should follow the following principles when providing training and education to HCPs:

- 3 Programs should be conducted in clinical or educational settings that are conducive to exchange of information, like clinical, educational or conference centers.
- 3 “Hands on” training should be held at facilities suitable for the type of training to be conducted, and instructors should be qualified and have the technical expertise to conduct the training.
- 3 Meals and refreshments may be provided only to attendees and must be modest in nature and subordinate in time and focus to the training and/or education.
- 3 Companies may pay for necessary and reasonable travel, and modest lodging for healthcare professional attendees only. It is inappropriate for companies to pay for meals, refreshments, travel or lodging for any person who does not have a bona fide professional reason to attend the training or education.

EVALUATION AND DEMONSTRATION PRODUCTS

Medical Technology Companies have a unique responsibility to ensure the safe and effective use of their products and technologies. One way this can be accomplished is through the provision of reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes.

Evaluation Products: Evaluation products may be provided for HCPs to evaluate a product to determine whether to purchase that product in the future. Companies may provide single-use products only in sufficient quantity necessary for the adequate evaluation of those products, and furnish capital equipment only for a reasonable period of time sufficient for evaluation of the equipment.

Demonstration Products: Demonstration products are typically unsterilized single use products that are used for HCP and patient awareness, education and training. Such products are not intended to be used in patient care and are typically identified as “Sample,” “Not for Human Use,” or other designation on the product, its packaging and/or documentation accompanying the product.

Companies should provide HCPs with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.



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CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS



WHY A REVISED CODE?

AdvaMed recognizes and respects the obligation of Health Care Professionals (HCPs) to make independent decisions regarding the health care of their patients. Medical technology companies can support this obligation and serve the best interest of patients through ethical interactions with HCPs. As such, AdvaMed has revised its Code of Ethics on Interactions with HCPs—creating ethical principles that govern the interactions between medical technology companies and the individuals or entities that provide healthcare services to patients or that purchase, lease, recommend, use, or prescribe medical technologies in the United States.

CODE OF ETHICS COMPLIANCE

Medical Technology Companies are strongly encouraged to adopt the Code of Ethics and to implement an effective compliance program. Companies that adopt the Code are strongly encouraged to submit to AdvaMed an annual certification to that effect. Member companies shall, and non-member companies may, supply contact information to AdvaMed concerning the company's compliance department or anonymous hotline to facilitate reporting possible violations of the Code. Companies adopting the Code shall communicate its principles to their employees, agents, dealers and distributors with the expectation that they will adhere to the Code.

This brochure is intended to provide a brief overview of the Code's key messages. Please visit www.AdvaMed.org to see the full Code and related FAQs.

SUPPORTING THIRD-PARTY EDUCATIONAL CONFERENCES

Independent educational or scientific conferences impart valuable information to HCPs and promote the advancement of effective health care. Medical technology companies may support these events as follows:

- 3 **Grants:** Companies may provide grants only to conference sponsors to reduce conference costs or to training institutions to allow attendance of HCPs in training. Grants should be paid only to reimburse legitimate expenses for the educational activity, and the conference sponsor is solely responsible for the program content, faculty, educational methods and materials.
- 3 **Conference Meals and Refreshments:** Companies may provide meals and refreshments to all attendees provided that they are open to all attendees and consistent with the standards established by the conference sponsor or the accrediting body. Meals or refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and should also be clearly separate from the education portion of the conference.
- 3 **Faculty Expense:** Companies may provide grants to conference sponsors for reasonable honoraria, travel, lodging and modest meals for HCPs who are bona fide conference faculty members.
- 3 **Advertisement and Demonstration:** Companies may purchase advertisement and lease booth space for company displays at conferences.

SALES, PROMOTIONAL AND OTHER BUSINESS MEETINGS

It is appropriate for companies to conduct sales, promotional and other business meetings with HCPs to discuss product features, sales terms or contracts. These meetings typically occur close to the health-care’s place of business. Companies may pay for occasional modest meals in connection with such meetings. In addition, in cases where it is necessary to demonstrate non-portable equipment, or conduct plant tours, companies may pay for reasonable travel costs, lodging and modest meals of attendees (but not their guests).

CONSULTING ARRANGEMENTS WITH HCPs

Medical technology companies face certain unique challenges regarding the use of HCPs as consultants in such areas as research, product development, advisory boards and company-sponsored training. The Code identifies important standards that companies should follow with respect to consulting arrangements with HCPs:

- 3 Consulting agreements should be for bona fide services and should describe all the services that are to be provided. There should be a written research protocol when clinical research services are being provided,
- 3 There should be a legitimate need for the services identified and documented in advance,
- 3 Consultants should be selected based upon their qualifications relative to the defined need,
- 3 Compensation should be at fair market value without regard to the value of the consultant’s business,
- 3 Companies may pay for reasonable and actual expenses, such as travel, modest meals and lodging, incurred by the consultant,
- 3 The venue and circumstances of any meetings should be conducive to the exchange of information, and any meals or refreshments provided by companies should be modest in value and subordinate in time and focus to the purpose of the meeting. Companies should not provide recreation or entertainment, and
- 3 Company’s sales personnel may provide input regarding the suitability of proposed consultants, but should not control or unduly influence the selection process.

Provision on Payment of Royalties: Companies should enter into royalty arrangements only when HCPs make significant contributions to a product, technology, process or method. Royalties paid in exchange for intellectual property should not be conditioned upon the purchase or recommendation of the technology developed, or a requirement that the HCP market the new technology. When calculating royalties, Companies are strongly encouraged to consider the appropriateness of excluding the number of units purchased by the HCP or their staff. All royalty payments should be adequately documented.

PROHIBITION ON ENTERTAINMENT AND RECREATION

The Code contemplates that all interactions between Companies and HCPs should be professional and facilitate the exchange of information that will benefit patient care. To avoid the appearance of any impropriety, Companies should not provide or pay for any entertainment of HCPs.

MODEST MEALS ASSOCIATED WITH HEALTH CARE PROFESSIONAL BUSINESS INTERACTIONS

These principles apply to a wide range of interactions, including training and education, third-party conferences and sales and promotional meetings:

Purpose: Meals should be incidental to the presentation of bona fide scientific, educational or business information.

Setting and Location: Meals may occur at the HCP’s place of business, or when such venues are not available, at a location conducive to such exchanges.

Participants: Companies may provide meals only to those HCPs who have a professional interest in, and actually attend, the meeting.

EDUCATIONAL ITEMS, PROHIBITION ON GIFTS

Companies may provide items to HCPs that either benefit patients or serve a genuine educational function. Other than medical text books or anatomical models used for educational purposes, the value of such gifts should have a fair market value of less than \$100, and should not be capable of use for non-educational purposes. Companies may not give to HCPs non-educational branded promotional items, even if they are of minimal value and related to the HCPs work or benefit patients.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments.

PROVISION OF COVERAGE, REIMBURSEMENT AND HEALTH ECONOMICS INFORMATION

Companies may provide accurate and objective coverage, reimbursement and health economics information regarding their products to HCPs. Companies may also collaborate with HCPs, patients and organizations to achieve payor coverage, obtain guidelines and policies, or receive adequate reimbursement levels. The Code lists several types of information that Companies may provide regarding their products, such as coverage codes and billing options, changes in coverage or reimbursement amounts and the efficient use or installation of its products or technologies.

At the request of an HCP , Companies may assist patients by facilitating the preparation and submission of requests for coverage, prior authorizations, pre-certifications and appeals of denied claims.

Companies should not suggest any mechanisms for billing for medically unnecessary services nor engage in fraudulent practices to achieve inappropriate payment. Companies must not interfere with an HCP’s independent clinical decision making and may not provide any free services that eliminate or reduce expenses that would otherwise be the responsibility of the HCP as part of its normal cost of doing business.

RESEARCH AND EDUCATIONAL GRANTS AND CHARITABLE DONATIONS

Provision of research and educational grants and charitable donations by Companies are worthwhile undertakings provided they are not offered as an unlawful inducement. Companies should adopt objective criteria for the provision of grants and charitable donations that do not take into account purchasing criteria, implement appropriate procedures to ensure that grants and charitable donations are not used as an unlawful inducement.

Company’s sales personnel may provide input about the suitability of a grant or charitable donation recipient or program, but they should not control or unduly influence such decisions.