



CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS



COMPANY-CONDUCTED PROGRAMS & MEETINGS WITH HCPs

Because of the way medical device technologies are used, medical technology companies have a legitimate need to conduct training and education for HCPs on the safe and effective use of their products and to hold other important business meetings. Companies should follow the following principles when training and meeting with HCPs:

Company-Conducted Training & Education

- Programs should be conducted in clinical or educational settings that are conducive to the effective transmission of information, like clinical, educational, conference, or other settings such as hotels or other commercially available meeting facilities.
- “Hands-on” technical training should be held at training facilities, medical institutions, laboratories or other appropriate facilities, and instructors should be qualified and have the technical expertise and experience necessary to perform the training.
- Companies should only engage faculty that have proper qualifications and expertise.
- HCPs must have a legitimate need to attend Company-conducted training or education programs.

Company Business Meetings

- Companies must have a legitimate need to conduct the meeting.
- Companies may hold meetings at or close to an HCP’s place of business as appropriate for the meeting; the setting must be conducive to the discussion of relevant information.
- Each HCP must have an objective, legitimate need to attend the meeting.

DEMONSTRATION, EVALUATION AND CONSIGNED 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 and education. Such products are not intended to be used in patient care and are typically identified as “sample” or “not for human use,” on the product, its packaging and/or documentation accompanying the product.

Companies should provide HCPs with appropriate documentation on the no-charge status of evaluation and demonstration products to permit the HCP to address reimbursement and reporting obligations.

Consigned: Consigned products are medical technologies provided to HCPs for use and storage pursuant to a consignment arrangement. Company retains title until the product is used and maintains inventory control of the consigned devices for purposes of billing and restocking; verification of product inventory; and the return or removal of expired product.



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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. Since the last revision of AdvaMed’s Code of Ethics in 2009, new government and industry guidance has been issued and medical technology has advanced rapidly. AdvaMed has revised its Code of Ethics on Interactions with HCPs to better reflect the evolving standards and business models affecting the 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, including training of company representatives that interact with HCPs. Companies that adopt the Code are strongly encouraged to submit to AdvaMed an annual certification to that effect, available at www.advamed.org/ethics. Companies that certify their compliance with the Code 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/ethics to see the full Code and access related resources.



EDUCATIONAL & RESEARCH GRANTS, CHARITABLE DONATIONS & SPONSORSHIPS

Companies may provide monetary, in-kind and other contributions to third parties in support of their educational, charitable and research programs, 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. 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.

Supporting Third-Party Programs Through Educational Grants and Commercial Sponsorship

Third-party programs allow companies to support HCP and patient training; to participate in clinical, research and scientific exchanges related to their products and to advertise their services. Medical technology companies may support these activities as follows:

- providing patient-related training and education;
- participating in clinical, research and scientific exchanges related to medical technologies; and
- advertising and promoting their products and services

Supporting Independent Third-Party Research

Companies may provide in-kind or monetary research grants in support of independent research with scientific merit. The research must have defined objectives and milestones outlined by clinical protocols documenting the nature and scope of the research, the budget and other independent approvals as needed. Companies should have a process to review research grant requests that limits involvement of the sales team, ensures researcher control and defines the types of expenses and quantities of product used in the research study.

Supporting Charitable Programs

Companies may donate money, product or equipment for charitable purposes to charities with bona fide philanthropic missions provided companies ensure donations are used for charitable purposes and that sales personnel do not influence the choice of charity.

COMMUNICATIONS ON THE SAFE & EFFECTIVE USE OF MEDICAL TECHNOLOGY

Truthful and non-misleading information related to medical technologies is critical to an HCP's ability to provide high-quality care through the effective use of available medical technology. Industry communications may include: scientific journal articles, clinical practice guidelines and reference texts; educational presentations; or discussions with HCPs for feedback in support of product development.

PROVISION OF HEALTH ECONOMICS & REIMBURSEMENT INFORMATION

To facilitate patient access to medical technology, Companies may provide accurate and complete coverage, reimbursement and health economics information. Companies may also collaborate with HCPs and HCP organizations to achieve government and commercial payor coverage decisions.

COMPANIES PROVIDING TECHNICAL SUPPORT IN THE CLINICAL SETTING

Company representatives may explain a product's settings and technical controls function and make related recommendations. Company representatives may assist a clinical or operating room team to ensure the appropriate devices are available during a procedure. Company representatives should enter the clinical setting only at the request of an HCP and should never interfere with the HCP's independent clinical decision-making.

JOINTLY CONDUCTED EDUCATION & MARKETING PROGRAMS

Companies may partner with HCPs to jointly conduct education and marketing programs that serve to educate patients and HCPs on medical conditions and the range of testing or treatment options, including the availability of medical technology and the HCPs ability to diagnose or treat related medical conditions.

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. Companies should follow these standards with respect to consulting arrangements with HCPs:

- There should be a legitimate need for the services identified and documented in advance,
- Consultants should be selected based upon their qualifications relative to the defined need,
- Companies should engage only as many consultants as are necessary to fulfill the requirements,
- Compensation should be at fair market value without regard to the value of the consultant's business,
- Companies may pay for reasonable and actual expenses, such as travel, modest meals and lodging, incurred by the consultant,
- Consulting arrangements should be governed by a written agreement,
- 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.

AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation.

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 or recreation of HCPs.

TRAVEL & LODGING, VENUE

The Code provides that Companies may pay for an HCPs travel and lodging costs provided: there is an objective, legitimate reason to support out-of-town travel; the costs of the travel and lodging accommodations are modest and reasonable under the circumstances in an appropriate setting; and that costs associated with personal travel or costs related to HCP guests are not borne by the Company.

MODEST MEALS & REFRESHMENTS

Companies may provide HCPs with modest meals and refreshments, provided the meal and refreshments are subordinate in time and in focus to the bona fide discussion and presentation of scientific, educational or business information. Further, the food should be provided in a setting that is conducive to bona fide scientific, educational or business discussions.

A company may not provide meals to an entire office staff attendee, or to an attendee's guest, or to a Company representative that is not present.

EDUCATIONAL ITEMS, PROHIBITION ON GIFTS

Companies may occasionally provide modest, appropriate educational items to HCPs that benefit patients or serve a genuine educational function. Other than medical text books or anatomical models used for educational purposes, these items should have a fair market value of less than \$100, and should not be capable of use for non-educational purposes.

Companies may not provide gifts.

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.