

**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”) is dedicated to the advancement of medical science, the improvement of patient care, and in particular to the contribution that high quality, cost-effective health care technology can make toward achieving those goals. In pursuing this mission, AdvaMed members (“Members”) recognize that adherence to ethical standards and compliance with applicable laws are critical to the medical device industry’s ability to continue its collaboration with health care professionals. Members encourage ethical business practices and socially responsible industry conduct related to their interactions with health care professionals. Members also respect the obligation of health care professionals to make independent decisions regarding Member products. Consequently, AdvaMed adopts this voluntary Code of Ethics, effective January 1, 2004, to facilitate Members’ ethical interactions with those individuals or entities that purchase, lease, recommend, use, arrange for the purchase Or lease of, or prescribe Members’ medical technology products in the United States (“Health Care Professionals”)

There are many forms of interactions between Members and Health Care Professionals that advance medical science or improve patient care, including:

- *Advancement of Medical Technology.* Developing cutting edge medical technology and improving existing products are collaborative processes between Members and Health Care Professionals. Innovation and creativity are essential to the development and evolution of medical devices; often occurring outside the laboratories of medical device companies. Heart valves, MRI equipment, cardiac rhythm devices, surgical tools, and infusion pumps are just a few examples of the array of complex medical technologies developed through research collaborations and consulting relationships between Health Care professionals and Members.

- *Safe and Effective Use of Medical Technology.* The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical, or other medical technology often requires Members to offer Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval.
- *Research and Education.* Members' support of *bona fide* medical research, education, and enhancement of professional skills serves patient safety and increases access to new technology.

AdvaMed recognizes that Member may interact with Health Care Professionals for many legitimate objectives other than selling, leasing, recommending, arranging for the sale or lease of, or prescribing products, and that some of these relationships are not addressed in this code. Any interpretation of the provisions of this code, as well as Members' interactions with Health Care Professionals not specifically addressed in this Code, should be made in light of the following principle: Members shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducements in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of, their products.

II. Member-Sponsored Product Training and Education

Members have a responsibility to make product education and training available to Health Care Professionals. In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain medical technology. Such programs often occur at centralized locations (necessitating out-of-town travel for some participants), and may extend more than one day. With regard to member programs focused on the education and training in the safe and effective use of Member products:

- Programs and events should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge.
- Programs requiring "hands on" training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff should have the proper qualifications and expertise to conduct such training.
- Members may provide Health Care Professional attendees with hospitality only in the form of modest meals and receptions in connection with these programs. Any such meals and receptions should be modest in value and subordinate in time and focus to the educational or training purpose of the meeting.
- Members may pay for reasonable travel and modest lodging costs incurred by attending health Care Professionals.

- It is not appropriate for members to pay for the meals, hospitality, 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.

III. Supporting Third Party Educational Conferences

Bona fide independent, educational, scientific, or 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; conferences sponsored by accredited continuing medical education providers; and grand rounds. Members may support these conferences in various ways:

- *Educational Grants.* Members may provide a grant either directly to the conference sponsor to reduce conference costs, or 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. Members may provide educational 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 purpose or function, and may be used only to reimburse the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with relevant guidelines established by professional societies or organizations. The conference sponsor should be responsible for and control the selection of program content, faculty, educational methods, and materials.
- *Modest Meals and Hospitality.* Members may provide funding to the conference sponsor to support the conference's meals and hospitality. Also, Members themselves may provide meals and receptions for all Health Care Professional attendees, but only if it is provided in a manner that is also consistent with the sponsor's guidelines. Any meals, receptions, and hospitality should be modest in value and should be subordinate in time and focus to the purpose of the conference.
- *Faculty Expenses.* Members may make grants to conference sponsors for reasonable honoraria, travel, lodging, and meals for health Care Professionals who are *bona fide* conference faculty members.
- *Advertisements and Demonstration.* Members may purchase advertisements and lease booth space for company displays at conferences.

IV. Sales and promotional Meetings

It is appropriate for members to meet health Care professionals to discuss product features, contract negotiations, and sales terms. Often, these meetings occur close to the Health Care Professional's place of business. It is appropriate for Members to pay for occasional hospitality

only in the form of modest meals and receptions for Health Care Professional attendees that are conducive to the exchange of information. It is also appropriate to pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment). However, it is not appropriate to pay for meals, hospitality, 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.

V. Arrangements with Consultants

Many Health Care professionals serve as consultants to members, providing valuable *bona fide* consulting services, including research, participation on advisory boards, presentations at Member-sponsored training, and product collaboration. It is appropriate to pay Health Care Professionals reasonable compensation for performing these services. The following factors support the existence of a *bona fide* consulting arrangements between Members and Health Care Professionals:

- Member consulting arrangements should be written, signed by the parties and specify all services to be provided.
- Compensation paid to consultants should be consistent with fair market value for the services provided.
- Consulting agreements should be entered into only where there is a legitimate need and purpose for the services is identified in advance.
- Selection of consultants should be on the basis of the consultant's qualifications and expertise to address the identified purpose, and should not be on the basis of volume or value of business generated by the consultant.
- The venue and circumstances for member meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other setting, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Member-sponsored hospitality that occurs in conjunction with a consulting meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting.
- Members may pay for reasonable and actual expenses incurred by consultants in carrying out the subject of the consulting arrangement, including reasonable and actual travel, modest meals and lodging costs incurred by consultants attending meetings with, or on behalf of, Members.
- When a member contracts with a consultant for research services, there should be a written research proposal.

VI. Gifts

Members occasionally may provide modest gifts to health Care professionals, but only if the gifts benefit patients or serve a genuine educational function. Other than the gift of medical textbooks or anatomical models used for educational purposes, any gift from a Member should have a fair market value of less than \$100.

In addition, Members may occasionally give Health Care Professionals branded promotional items of minimal value related to the Health Care Professional's work or for the benefit of patients. Gifts may not be given in the form of cash or cash equivalents.

This section is not intended to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation.

VII. Provision of Reimbursement and Other Economic Information

Members may support accurate and responsible billing to Medicare and other payors by providing reimbursement information to Health Care Professionals regarding Members' products, including identifying appropriate coverage, coding or billing of Member products, or of procedures using those products. Members may also provide information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Member's products. However, it is inappropriate for members to provide this technical or other support for the purpose of unlawfully inducing Health Care professionals to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of members' products.

VIII. Grants and Other Charitable Donations

Members may make donations for a charitable purpose, such as supporting genuine independent medical research for the advancement of medical science or education, indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. Donations should be made only to charitable organizations or, in rare instances, to individuals engaged in genuine charitable missions for the support of that mission. It is not appropriate for members to make such donations for the purpose of unlawfully inducing Health Care Professionals to purchase, lease, recommend, use or arrange for the purchase, lease or prescription of Members' products. All donations should be appropriately documented. Examples of appropriate charitable grants and related considerations are:

- *Advancement of Medical Education.* Members may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs, which are charitable or have an academic affiliation or, where consistent with the preamble to this section, other medical personnel. (For additional considerations regarding educational grants, see Section III, supporting Third Party Educational Conferences).

- *Support of Research with Scientific Merit.* Members may make research grants to support genuine medical research. The purpose of the grant must be clearly documented. (For guidance as to the limitations that apply when a Member contracts with a Health Care Professional to provide research on behalf of a Member, see Section V, Arrangements with Consultants).
 - *Public Education.* Members may make grants for the purpose of supporting education of patients or the public about important health care topics.
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Note: This Code supercedes and replaces all previous AdvaMed Codes of Ethics. Members will communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Members have an independent obligation to ascertain 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, as well as applicable law or regulations, may provide more specificity than this Code, and Members 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 be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations.