

**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 Members 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 inducement 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 with 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 arrangement 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 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 consultant 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 protocol.

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.

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 laws 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 it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations.

FREQUENTLY ASKED QUESTIONS

REGARDING ADVAMED'S CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

SECTION I: PREAMBLE & GENERAL QUESTIONS

Q₁ Why did AdvaMed develop a code distinct from the PhRMA Code on Interactions with Health Care Professionals?

AdvaMed's Revised Code ("Code," updated from AdvaMed's 1993 Code of Ethics) reflects the unique interactions between medical technology 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 Members interact with Health Care Professionals because of the complexity of medical technology and the importance of having Health Care Professionals understand how to use the technology safely and effectively. In other ways, however, AdvaMed's Revised Code of Ethics reflects similarities in the interactions between Health Care Professionals and medical technology companies as compared with other elements of the health care industry.

Q₂ Who are "Health Care Professionals"? Does the term include non-clinical people who make product purchasing decisions? Does it include decision-makers within GPOs?

The term "Health Care Professional" includes those "individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Member's medical technology products in the United States." This includes both clinical and non-clinical people who make product-related decisions of the sort listed. It also includes decision-makers within group purchasing organizations (GPOs). This is a broad definition, intended to encompass anyone with material influence over purchasing decisions. Note that there may be laws and other codes applicable to relationships with Health Care Professionals, including relationships with government employees.

Q₃ 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 products in the United States. This would include interactions with Health Care Professionals who work in the United States, even if the interaction occurs outside the country (such as at a conference or other event). Of course, there are other laws and ethical requirements

that may pertain to interactions with Health Care Professionals located both inside and outside the United States.

Q4 Are combination products covered by the Code?

Yes, interactions related to combination products (e.g., those that are both biologics and devices or drugs and devices) are covered by the Code. Interactions related to combination products also may be subject to the codes of other trade associations to which some AdvaMed Members belong.

Q5 Does the Code address arrangements between a Member and a Health Care Professional relating to licensing a new medical technology to the Member?

Interactions relating to product development and intellectual property would be subject to the general principle that Members shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of, their products.

Q6 What do the terms “modest,” “occasional,” and “hospitality” mean?

The Code seeks to balance an interest in civility with the desire to avoid even the appearance that hospitality may be used as an inducement to purchase or refer for product. Accordingly, the Code differentiates, depending on the type of meeting, the type of meals and other hospitality that may be extended to Health Care Professionals by Members.

In light of regional differences, “modest” means moderate or low value and “occasional” means infrequent. Meals and hospitality should be ancillary to a legitimate documented purpose. Members should consider establishing limits on the frequency and amount of expenditures.

The Code contemplates that any “hospitality” extended by a host would be “modest and occasional.” For example, hospitality might include modest and occasional receptions. The Code contemplates that any hospitality should be subordinate in time and focus to the purpose of the meeting. The Code addresses meals, travel, and lodging separately.

Q7 May a Member offer to provide laptop computers with independent value to any purchasing manager whose hospital purchases at least 1,000 medical devices that the Member has just introduced?

No. It is not appropriate for a Member to provide any item of value to a Health Care Professional that takes into consideration the value or volume of the business that is or may be generated by the Health Care Professional, unless permitted by law (e.g., appropriate discounts).

SECTION II: MEMBER-SPONSORED TRAINING AND EDUCATION

Q₈ Why may it be appropriate under the Code for Members to pay for travel to training and education sessions?

In order to efficiently deliver training at appropriate facilities, the Code contemplates that Members 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 Member products, and only for persons who could legitimately benefit from the training. (Meetings focused on sales and promotion are treated under Section IV.)

Q₉ May a Member pay for travel to a Member-sponsored general educational program (not specific to the Member's products)?

It may be appropriate for Members to conduct general educational sessions, but these are not the types of programs for which Member-supported travel would be appropriate under the Code. In contrast, paying for Health Care Professionals' travel may be appropriate when the Member is conducting training and education on the safe and effective use of its products.

SECTION III: SUPPORTING THIRD PARTY EDUCATIONAL CONFERENCES

Q₁₀ May a Member designate attendees or faculty who will speak at third-party educational conferences?

No. The Code contemplates that an independent third party will select faculty and attendees. The Code does not preclude a Member from recommending a knowledgeable faculty member. The ultimate selection should be made by the conference sponsor.

Q₁₁ Can a Member 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 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.

Q₁₂ What section of the Code applies to Member-sponsored off-agenda activities (e.g., sales and promotional meetings or educational programs) that are ancillary to a conference sponsored by a third party?

Sales and promotional meetings should be evaluated under Section IV. However, Member-sponsored product-related educational programs should be evaluated under Section II. In either case, it should be determined whether the conference sponsor has guidelines that cover that type of off-agenda activity, and if so, the sponsor's guidelines should also be honored.

SECTION IV: SALES & PROMOTIONAL MEETINGS

Q₁₃ Why does the Code not allow Members to extend business courtesies to guests/spouses in connection with sales and promotional meetings?

AdvaMed's Code is mindful of the desire to avoid even the appearance that business courtesies are being given as improper inducements to promote a Member's products. On the other hand, it is appropriate for Members, as a matter of common courtesy and civility, to provide modest meals and receptions for Health Care Professionals in connection with these types of meetings. To balance these considerations, the Code allows Members to provide "occasional hospitality only in the form of modest meals and receptions for Health Care Professional attendees that are conducive to the exchange of information." Under the Code, such meals and hospitality are to be incidental and conducive to the underlying business purpose. The Code precludes the extension of these courtesies to persons, such as guests/spouses, without a *bona fide* professional interest in the meeting.

Q₁₄ May a Member conduct a product sales or promotional meeting at a resort location and pay for a Health Care Professional's travel to the meeting for purposes of providing product information and negotiating sales terms?

Generally, this would not be appropriate. The location should be evaluated for consistency with the provisions in Section IV, which state that it may be appropriate at a sales or promotional meeting to provide occasional hospitality only in the form of "modest meals and receptions" and "conducive to the exchange of information," and, with respect to providing travel, that the travel be "necessary." Furthermore, the Code provides for limited special circumstances of "plant tours and demonstrations of non-portable equipment" as specific examples of when travel might be necessary.

SECTION V: ARRANGEMENTS WITH CONSULTANTS

Q₁₅ Is a clinical investigator considered a "consultant" under Section V?

Yes.

Q₁₆ Is there a limit to the number of consultants a Member may retain under Section V?

Members may retain only as many consultants as are legitimate and appropriate to provide *bona fide* services; moreover, the requirements of Section V must be satisfied for each consultant.

Q₁₇ May a consultant be placed under retainer with services provided as requested?

Yes, provided the requirements of Section V are met.

Q₁₈ What happens if a consultant is engaged but the project is cancelled or modified without using the consultant's services?

The Code contemplates that if the requirements of Section V were met when the consultant was engaged and then unanticipated circumstances prevented performance, then the question of whether or how much payment is made to a consultant would be a matter determined by the underlying consulting agreement.

Q₁₉ What factors should a Member consider when evaluating the venues and circumstances for meetings with consultants?

A Member should assess (a) whether there is a *bona fide* business justification for holding the meeting; (b) whether the location and venue are suitable for and conducive to the exchange of information between Member and consultant; (c) whether the value of any member-sponsored lodging is modest; (d) whether any ancillary meals and hospitality are modest in value (or alternatively, the fair market value of such meals and hospitality are taken into consideration when determining the fair market value of the compensation to be provided to the consulting Health Care Professional) and are subordinate in time and focus to the business part of the meeting; and (e) whether the overall meeting has a genuine business purpose and tenor and does not represent improper inducement of the Health Care Professional.

SECTION VI: GIFTS

Q₂₀ What are some examples of branded promotional items of minimal value that are “related to a Health Care Professional’s work or for the benefit of patients”?

Pens and notepads that could be used in the Health Care Professional’s work environment are examples of minimal value, branded promotional items appropriate as gifts. Golf balls and tee-shirts would not be allowed, as they are neither related to the Health Care Professional’s work nor for the benefit of patients.

Q₂₁ May a Member provide a gift such as flowers, gift baskets, meals, snacks, wine, or other refreshments to a Health Care Professional or a Health Care Professional's office or staff?

No. These types of gifts and refreshments are not considered related to the Health Care Professional's work or for the benefit of patients. However, if food is provided in connection with either sales and promotional meetings, conferences, or training and education, see Sections II, III, and IV to evaluate when meals and receptions may be appropriate.

Q₂₂ Is the \$100 limit determined on a per-gift or per-year basis?

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. The \$100 limit is intended to be a per-gift amount; however, consideration should be given to the frequency of providing gifts to any one individual (note the requirement that the gifts only be occasional). Repeated gifts to the same person, each with a value below the \$100 threshold, could violate the spirit of the Code, the purposes of which are set forth in the Preamble. Similarly, gifts to multiple members of a physician practice group or to multiple members of a hospital materials management or faculty department could also violate the spirit of the Code.

Q₂₃ May a Member give gifts to staff of a Health Care Professional who are not themselves Health Care Professionals?

Gifts given to the staff of a Health Care Professional should be treated as though they are given to the Health Care Professional and are subject to the provisions of Section VI.

SECTION VII: REIMBURSEMENT SUPPORT PROGRAMS

Q₂₄ Is it appropriate to demonstrate that a product can be used in an economically efficient manner?

It may be appropriate for Members to provide accurate information relating to the costs, savings and revenues associated with the use of a particular product. Without this information, it may be difficult for a Health Care Professional to properly evaluate whether it is economically feasible or desirable to purchase any particular product.

Q₂₅ What is an example of a grant or donation to “individuals engaged in genuine charitable missions for the support of that mission”?

One example is providing medical devices to individuals who perform volunteer disaster relief abroad. Supporting disaster relief work may be appropriate under the Code, notwithstanding that the individuals or group are acting as independent volunteers and not under the umbrella of a not-for-profit, charitable organization.

Q₂₆ May grants be given to a for-profit organization, such as a legitimately sponsored research grant to a for-profit hospital? What about a research grant to an individual Health Care Professional?

This section of the Code addresses charitable giving. Funding a research project at a for-profit institution, or paying an individual researcher, would not qualify as a charitable gift. However, that does not, by itself, mean that the funding would violate the Code. For example, if the funding constituted payment for a legitimate service, it could be appropriate under Section V: “Arrangements with Consultants” (which should be consulted in evaluating proposed arrangements to make payments for the performance of services).

Q₂₇ May a Member make a charitable contribution to a not-for-profit institution to pay the registration or seminar fees and travel expenses for one or more of its affiliated Health Care Professionals to attend a third-party educational conference?

This contribution should be evaluated under Section III: “Supporting Third Party Educational Conferences.” Because Section III does not permit a Member to pay directly for the registration or seminar fees and travel expenses of a Health Care Professional’s attendance at a third-party educational conference (except for Health Care Professionals in training), this type of support should not be provided indirectly as a charitable contribution to the Health Care Professional’s not-for-profit institution for the purpose of defraying the costs of particular individuals’ attendance. However, it would not be inappropriate for a Member to provide funding to a third-party conference that the conference sponsor could apply to defray the reasonable travel expenses of faculty selected by the Sponsor, or to reduce the registration or seminar fees for all attendees.

Q₂₈ May a Member make a charitable contribution to a not-for-profit hospital for construction of a new wing?

Members have historically supported the delivery of health care services through charitable contributions. As with any other contribution, this type of contribution may be appropriate if (a) the recipient of the contribution is a charity; (b) the purpose of the donation is charitable in nature and (c) it is not offered with the intent of providing an inducement to order, sell, lease, recommend, arrange for the sale or lease of, or prescribe Members’ products. Many factors

would be involved in considering whether such a contribution is appropriate, including ensuring that the amount of the donation is not dependent upon the volume of business or anticipated business conducted with or referred to the Member.

Q₂₉ May a Member make a charitable contribution to pay for a clinical fellow?

A Member may make a charitable contribution to subsidize a clinical fellow if he/she is in a genuine fellowship program affiliated with a teaching institution.

NOTE

Q₃₀ Does the AdvaMed Code offer 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 Members have an independent obligation to ascertain that their interactions with Health Care Professionals comply with all current laws and regulations.

Q₃₁ Will AdvaMed staff provide advice on how specific provisions of the Code would apply to specific practices that a Member is contemplating?

This FAQ is designed to provide information regarding the Code. Members should address any questions about specific practices to their own attorneys or advisors, rather than to AdvaMed staff.

Q₃₂ Does the Code govern the actions of Members' agents and distributors?

As the Note to the Code states, Members will communicate the Code's principles to their employees, agents, dealers and distributors with the expectation that they will adhere to the Code. It is important that these entities be informed that AdvaMed has a revised Code of Ethics on Interactions with Health Care Professionals, and that these entities be made aware of the ethical business practices reflected in the Code's provisions.