



Comparison of the AdvaMed Code of Ethics and the Eucomed Code of Business Practice

Note: The Eucomed Code also contains Guidelines on Competition Law. These principles discuss trade association rules and anti-trust principles and as such are not included in this analysis.

<p>AdvaMed Code of Ethics on Interactions with Health Care Professionals</p>	<p>Eucomed Code of Business Practice Includes:</p> <ul style="list-style-type: none"> • Guidelines on Interactions with Healthcare Professionals • Guidelines on Competition Law
<p>Approved: December 18, 2008, Effective July 1, 2009</p>	<p>Approved September 11, 2008</p>
<p style="text-align: center;">I. Preamble</p> <p>1. Defines the terms: “Companies”: companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities. These products, technologies and services are defined as “Medical Technologies”.</p> <p>“Health Care Professional”: (HCP) those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in the United States.</p> <p>2. Medical Technologies: makes a distinction between Medical Technologies which are highly dependent on “hands on” HCP interaction, and drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means.</p> <p>3. Interactions with HCPs: explains the scope and types of interactions with HCPs.</p> <ol style="list-style-type: none"> a) Promote the advancement of Medical Technologies b) Enhance the Safe and Effective use of Medical Technologies c) Encourage Research and Education d) Foster Charitable Donations and Giving <p>4. The Purpose of the Code of Ethics: recognizes that HCP’s first duty is to act in the best interest of patients, and the obligation to facilitate ethical interactions between Companies and HCPs.</p>	<p style="text-align: center;">I. Preamble</p> <p>Defines Health Care Professionals (HCPs) as: Individuals (clinical or non-clinical including physicians, Nurses, technicians and research coordinators, or Entities (hospitals or group purchasing bodies) that directly or indirectly purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members’ medical devices.</p> <p>Interactions with HCPs advance medical science or improve patient care through:</p> <ul style="list-style-type: none"> • Advancement of Medical Technology • Safe and Effective Use of Medical Technologies, and, • Research and Education. <p>The Preamble sets forth four key principles:</p> <ul style="list-style-type: none"> • Separation: interactions must not be misused to influence purchasing decisions nor should they be contingent upon sales transactions. • Transparency: interactions must comply with national and local laws, regulations or professional codes of conduct. In countries where such provisions are not made, prior written notification is required to be made to the hospital administration or the HCP’s superior or other designated competent authority. (This concept is referenced throughout the Code.) • Equivalence: remuneration paid by a member to an HCP must be commensurate with fair market value for the services performed, • Documentation: including a written agreement related reports, invoices, etc. to support the need for and materiality of the services and reasonableness of the remuneration paid.



<p>5. A footnote notes that the principles are derived from a number of authorities, including the federal Anti-Kickback Statute. Reference to “unlawful inducement” relates to the Anti-Kickback Statute prohibitions.</p>	<p>Third-party intermediaries Members should require third-party intermediaries to comply with standards equivalent to these guidelines</p> <p>The Code is not intended to supplant national laws or regulations or professional codes that impose more stringent requirements. Members should ascertain that their interactions with HCPs comply with current national and local laws, regulations and professional codes.</p>
<p style="text-align: center;">II. Code of Ethics Compliance New Section</p> <p>All Companies are strongly encouraged to adopt the Code and implement effective compliance programs.</p> <p>1. Annual Certification Companies that adopt the Code are strongly encouraged to submit an annual certification that the Company has adopted the Code and has implemented an effective compliance program. Certification should be signed by the CEO and Chief Compliance Officer. AdvaMed will publish a list of Companies that have certified.</p> <p>2. Contact Information AdvaMed member Companies must, and non-members may supply contact information for the Company’s Compliance Department or anonymous hot line to facilitate reporting of possible violations. AdvaMed will publish this information.</p> <p>3. Elements of an Effective Compliance Program: Companies are strongly encouraged to follow the seven elements of an Effective Compliance Program.</p> <ul style="list-style-type: none">a) Written policies and procedures;b) Designated compliance officer and compliance committee;c) Conduct effective training and education;d) Develop effective lines of communication (including an anonymous reporting function);e) Conducting internal monitoring and auditing;f) Enforcing standards through well-publicized disciplinary guidelines; andg) Responding promptly to detected problems and undertaking corrective action. <p>4. Note: Companies adopting the Code shall communicate the principles of the Code to their employees, agents, dealers and distributors with the</p>	<p style="text-align: center;">No equivalent section.</p>



<p>expectation that they will adhere to the Code. Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.</p>	
<p style="text-align: center;">III. Company-Conducted Product Training and Education</p> <p>1. The Code defines: Training: training on the safe and effective use of Medical Technologies Education: communicating information directly concerning or associated with the use of Companies' Medical Technologies, e.g., information about disease states and benefits to certain patient populations.</p> <p>FDA Required Training The Code points out the FDA often mandates training and education to facilitate the safe and effective use of Medical Technologies.</p> <p>2. Companies should adhere to the following principles concerning training and education:</p> <ol style="list-style-type: none"> a) Conducive Setting Programs should be conducted in a setting conducive to the effective transmission of information. Settings may include clinical, educational or conference sites including hotels and other meeting facilities. They may also include the HCPs site. b) Hands on Training Training should be conducted at training facilities, medical institutions or laboratories. Training staff should be qualified. Sales employees may conduct the training if they have the technical expertise. c) Modest meals and refreshments may be provided if they are modest in value and subordinate in time to the training or education. d) Travel and Lodging Out-of-town travel and modest lodging may be provided the HCPs if there are objective reasons to support the need. e) No Guests Meals, refreshments, travel and lodging may be provided only to HCPs with a <i>bona fide</i> reason to attend the training. 	<p style="text-align: center;">II. Member-Sponsored Product Training and Education</p> <p>Product education and training should be made available to HCPs to facilitate the safe and effective use of medical technology.</p> <p>Conducive Settings Programs should be conducted in settings such as clinical, laboratory or conference settings, that are conducive to the transmission of knowledge or any required hands on training.</p> <p>Qualified Staff Training staff should have appropriate expertise.</p> <p>Reasonable Hospitality Any hospitality must be reasonable in price and subordinate in time and focus to the education, including:</p> <ul style="list-style-type: none"> • Reasonable priced meals • Reasonable travel and accommodations when necessitated by the educational program <p>Regulatory Compliance Programs must be in compliance with the regulations of the country where the HCP is licensed to practice.</p> <p>No Guests Members may not pay for any meals, travel, accommodation or other expenses for spouses or guests or HCPs or anyone not having a bona fide professional interest in the education.</p>
<p style="text-align: center;">IV. Supporting Third-Party Educational Conferences</p> <p><i>Bona fide</i> independent, education, scientific and policymaking conferences include educational conferences include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers.</p>	<p style="text-align: center;">III. Supporting Third-Party Educational Conferences</p> <p>Members may support educational conferences whose content promotes scientific knowledge medical advancement and the delivery of effective healthcare and is consistent with guidelines established by professional societies. Members may support such programs by the provision of financial, scientific, technical, organizational and/or logistical assistance.</p>



Companies may support these through:

Conference Grants Grants must be provided to the conference sponsor to reduce conference costs, or to training institutions to allow attendance by medical students, residents, fellows and other HCPs in training.

Grants may be provided when:

- a) The gathering is primarily dedicated to promoting objective scientific and educational activities, and
- b) The training institution or conference sponsor selects the attending HCPs in training.

- Grants should be paid ONLY to organizations with a genuine educational function
- The may be used to reimburse legitimate expenses for *bona fide* educational activities.
- The conference sponsor controls the selection of program content, faculty, methods and materials.

Conference Meals and Refreshments Companies may provide:

- Funding to conference sponsors to support the provision of meals and refreshments to conference attendees
- Meals and refreshments themselves if they are provided:
 - (1) To all HCP attendees (note exception below)
 - (2) Consistent with applicable standards established by the conference sponsor and any accrediting body.

Note: meals and refreshments provided to fewer than all HCP attendees must meet all the principles stated in Section VIII of the Code, and must be modest in value, subordinate in time and focus to the purpose of the conference and separate from the educational portion of the conference.

Faculty Expenses Grants may be made for reasonable honoraria, travel, lodging and modest meals for *bona fide* faculty members

Advertising Companies may purchase advertisements and lease booth space for Company displays.

- **Health Care Professional Sponsorship** Members may provide financial support for attendance of individual HCPs, limited to conference registration fee and reasonable travel, meals and accommodations.

(Note: The Transparency Principle outlined in Section I, Preamble, applies.)

- **Advertisements and Demonstrations** Members may purchase advertising and lease booth space for displays
- **Conference Support** Members may provide financial grants directly to conference sponsor to reduce overall cost of attendance, and reasonable honoraria, travel, meals and accommodation of HCP faculty.
 - Requires written request by conference organizer
 - Conference sponsor alone is responsible for content, and faculty selection
 - May recommend speakers or comment on the program only where requested to do so
- **Satellite Symposia** Members may sponsor satellite symposia at third-party conferences and provide fair, balanced and scientifically rigorous presentations consistent with overall content of conference. Members may determine content and select faculty if documented with a written contract and disclosed.
- **Scholarships** Members may provide financial support to institutions or societies for fellowships and scholarship awards. Grantee is selected by, and payment is made to, the institution where grantee is enrolled or to be trained. Payment can be made directly to the grantee only with a written request by the institution. Grants should not be based upon an institution's purchase or use of a company's products.

V. Sales, Promotional, and Other Business Meetings

Companies may conduct business meetings with HCPs:

IV. Sales and Promotional Meetings

In the countries where it is appropriate, members may meet with HCPs :



<ul style="list-style-type: none"> a) Business Discussion Discuss Medical Technology features, sales terms or contracts b) Meals Occasional modest meals and refreshments may be provided c) Travel When necessary, (e.g., plant tours or demonstration of non-portable equipment) reasonable travel costs and lodging may be provided d) No Guests Meals, refreshments, travel or lodging may not be provided for guests of HCPs or anyone without a <i>bona fide</i> interest in the information being shared at the meeting. 	<p>Business Discussion Discuss product features, conduct contract negotiations or discuss sales terms.</p> <ul style="list-style-type: none"> a) Location Meetings should occur close to the HCP’s place of business b) Meals May pay for reasonably priced meals c) Venue Environment must be conducive to exchange of information d) Travel When necessary (plant tours, demonstration of non-portable equipment) may pay for reasonable travel and accommodation of HCPs e) No Guests Meals, travel, accommodation or other expenses may not be provided for guests of HCPs or anyone without a <i>bona fide</i> interest in the information being shared at the meeting.
<p style="text-align: center;">VI. Consulting Arrangements with Health Care Professionals</p> <p>Companies may pay HCP consultants fair market value for services that fulfill a legitimate business need and do not constitute an unlawful inducement. The following standards apply:</p> <ul style="list-style-type: none"> • Agreements should be written and describe all the services to be provided. Clinical research services should have a written research protocol. • Legitimate need for the services should be identified and documented in advance of any arrangements. • Selection should be based on the consultant’s qualifications and expertise to meet the defined need. • Compensation should be fair market value and not based on past, present or anticipated business. • Expenses Companies may pay for actual, reasonable and documented expenses, including travel, modest meals and lodging, incurred by the consultant to carry out the arrangement. • Venue and circumstances of any meetings should be appropriate for the subject of the consultation, and conducive to the effective exchange of information. • Meals and refreshments should be modest in value and subordinate in time and focus to the primary purpose of the meeting. Recreation or entertainment should not be provided. • Sales Involvement Sales personnel may provide input about the suitability of proposed consultant, but should not control or unduly influence the selection decision. <p style="text-align: center;">Provisions on Payment of Royalties</p>	<p style="text-align: center;">V. Arrangements with Consultants</p> <p>It is appropriate to pay HCPs reasonable compensation for meaningful <i>bona fide</i> services, including research, participation on advisory boards, presentation at member-sponsored training or third-party conferences and product development. The following factors support <i>bona fide</i> consulting arrangements:</p> <ul style="list-style-type: none"> • Legitimate Need There must be a legitimate purpose for the services and should be identified in advance. • Selection must be based on the consultant’s qualifications and expertise to address the identified purpose, not the volume or value of business generated by the consultant. • A written agreement, signed by the parties, must specify the services to be provided, and must be consistent with the regulations of the country where the HCP is licensed to practice. • Compensation must be fair market value and must not be tied to the value of products which the consultants may use in their own practice. Members may pay for reasonable and actual expenses for travel, meals and accommodations, and these should be described in the written agreement. • (Note: The Transparency Principle outlined in Section I, Preamble, applies.) • Documentation All arrangements must be documented in writing even if no payment is required or the arrangement only involves a one-day event. • Venue and circumstances for meetings should be appropriate to the subject matter of the consultation, and conducive to the effective exchange of information. • Hospitality should be modest in value and subordinate in time and focus for the primary purpose of meetings.



<p>Companies should enter into a royalty arrangement only where the HCP makes a novel, significant or innovative contribution to the development of a product, technology, process or method.</p> <p>Calculation of royalties should preserve the objectivity of medical decision-making and avoid the potential for improper influence and should not be conditioned on a requirement to purchase, order or recommend the Company's product or technology or a requirement to market the product or technology upon commercialization.</p> <p>Companies may elect to enter into separate agreements with HCPS for marketing services and are strongly encouraged to consider the appropriateness and practicality of excluding the HCP consultant's purchases from the calculation of royalty payments.</p>	<p>There is not a separate sub-section on royalties, but a final bullet contains pertinent information.</p> <p>There must be a written agreement providing for fair market value compensation for the development of intellectual property. Under no circumstances may HCPs receive compensation for the purchase of products, (including devices which contain the intellectual property. All required consents and approvals should be obtained.</p> <p>(Note: The Transparency Principle outlined in Section I, Preamble, applies.)</p>
<p>VII. Prohibition on Entertainment and Recreation</p> <p>Note: this is a new section of the Code.</p> <p>Companies should not provide or pay for any entertainment or recreational event or activity for any non-employee HCP. Examples include: golf, skiing. Hunting, sporting equipment and leisure or vacation trips.</p> <p>Such events or items should not be provided regardless of: (1) Their value, (2).whether the HCP is a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.</p>	<p>No equivalent section.</p>
<p>VIII. Modest Meals Associated with Health Care Professional Business Interactions</p> <p>Note: this is a new section of the Code. It provides a summary of the provision of modest meals to HCPs in various types of interactions described in Sections III, IV, V and VI of the Code.</p> <p>Modest meals may be provided as an occasional business courtesy involving the presentation of scientific, educational, or business information, consistent with the following limitations:</p>	<p>No equivalent section.</p>



<p>Purpose The meal should be incidental to the <i>bona fide</i> presentation of scientific, educational or business information, and should provided in a manner conducive to the presentation. It should not be part of an entertainment or recreation event.</p> <p>Setting and Location The setting should be conducive to <i>bona fide</i> scientific, educational or business discussion. Meals may occur at the HCP’s place of business, however, if that place is not available or conducive to such discussions, meals may be provided off-site. Examples include: (1) where the medical technology cannot easily be transported to the HCP’s location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on site.</p> <p>Participants (No Guests) Meals may be provided only to HCPs who actually attend the meeting, and may not be provided for an entire staff where everyone does not attend the meeting, i.e., no “dine and dash” programs. Meals may not be provided for guests of HCPs or any one not having a <i>bona fide</i> professional interest in the information being shared.</p>	
<p style="text-align: center;">IX. Educational items; Prohibition on Gifts</p> <ul style="list-style-type: none"> • Gifts that benefit patients or serve a genuine educational function occasionally may be provided to HCPs. • Items should have a FMV of less than \$100, except text books and anatomical models. • Items must not be capable of non-educational or non-patient-related uses. • Non-educational branded promotional items may not be given to HCPs, even if of minimal value and related to the HCPs work or benefit patients. • Gifts such as wine, flowers, cookies, gift baskets, holiday gifts etc., or cash or cash equivalents are not permitted. 	<p style="text-align: center;">VI. Gifts</p> <p>Members may provide inexpensive, branded or non-branded items if they are modest in value and in accordance with the national and local laws and regulations and professional codes of conduct of the country where the HCP is licensed to practice.</p> <p>Gifts must relate to the HCPs practice, benefit patients or serve a genuine educational function and must not be given in the form of cash or cash equivalents.</p>
<p style="text-align: center;">X. Provision of Coverage, Reimbursement and Health Economics Information</p> <p>Companies may provide accurate and objective reimbursement information on their products to HCPs, professional or patient organizations, patients and payors as follows:</p> <ul style="list-style-type: none"> • Identifying the clinical value of their technologies and services • Collaborating on joint advocacy on coverage, reimbursement and health economics issues 	<p style="text-align: center;">VII. Provision of reimbursement and other economic information</p> <p>Members should support accurate and responsible billing by providing economic efficiency and reimbursement information to HCPs and third-party payors regarding members’ products. Information should be limited to identifying appropriate coverage, coding and billing of, or procedures using, members’ products, or to encourage efficient delivery of members’ products.</p> <p>Note: This section excludes the provision of technical support regarding the</p>



- Providing information indentifying coverage, codes and billing options regarding technologies on which they may be used
 - Providing information about the economically efficient use of their technologies
 - Providing information related to available reimbursement revenues and associated costs
 - Providing information relating to changes in coverage or reimbursement amounts
 - Providing support in the appropriate and efficient use of their technologies
 - Assisting to obtain coverage decisions and in the preparation and submission of coverage requests, prior authorizations and appeals.
- Companies may not interfere with HCPs independent clinical decision making or provide information as an unlawful inducement or suggest mechanisms for billing for unnecessary services or fraudulent practices to achieve inappropriate payment.

appropriate use or installation of members' products.

XI. Research and Educational Grants and Charitable Donations

- Companies may provide such grants and donations but not as an unlawful inducement. Companies should:
- Adopt objective criteria that exclude purchasing value of the recipient
 - Implement procedures to ensure such grants are not used as an unlawful inducement
 - Document such grants and donations.

Companies' sales personnel may provide input to, but not unduly influence grant and donation decisions or recipient selection.

Research Grants should have well-defined objectives and milestones and may not be linked to purchases of Medical Technologies

- Educational Grants** companies may make such grants to conference sponsors or training institutions but not to individual HCPs
- *Advancement of Medical Education* Companies may make grants to support genuine education of medical students, residents and fellows (See also Section IV)
 - **Public Education-** Companies may make grants to support patient or public education on health care topics

VIII. Donations for Charitable and Philanthropic Purposes

Members may make donations for philanthropic purposes only to charitable organizations or non-profit entities entitled to receive them under national or local laws and regulations. They may be made to support the general activities or general fund raising drives of a *bona fide* organization.

Donations must not be tied to past, present or future use of members' products.

Donations should be documented i.e., with a written request detailing the purpose of the charity and nature of its activities. Payments should be in the name of, and paid directly to, the charity. Donations made to HCPs should only occur when the HCP is an employee or officer of the organization and submits the request on their behalf. It is inappropriate for members to support the favorite charity of an HCP in response to a request from that HCP.



<p>Charitable Donations Companies may make donations to organizations with <i>bona fide</i> charitable missions such as supporting indigent care, or patient and public education.</p>	
<p style="text-align: center;">Included in Section XI.</p>	<p style="text-align: center;">IX. Educational Grants</p> <p>Members may provide funds to support genuine independent medical research, advancement of medicals science or education, or patient and public education, but it is important that they not be viewed as a price concession or inducement or be tied in any way to use of members' products. Appropriate documentation should be maintained.</p> <p>May be made only to organizations (not to individual HCPs) entitled to receive educational grants under applicable national or local laws and regulations.</p> <p>Examples of appropriate educational programs are: Scholarships provided to organizations, hospitals and universities where HCPs are in training. Advancement of Healthcare Education Members may support institutions or organizations for either accredited or non-accredited healthcare education. Research Members may support clinical or non-clinical customer-initiated studies in areas of legitimate interest of the member.</p> <ol style="list-style-type: none"> a) <i>Bona Fide Research</i> Members may provide funds for documented expenses, in-kind services or free product for clearly defined <i>bona fide</i> research activities of HCPs where permitted by national or local laws and professionals codes of conduct. b) <i>Written</i> Requests must be in writing stating the nature and objective of the research. c) <i>Agreement</i> There must be a written agreement, signed by the parties with provision for adverse event reporting before support is provided. d) <i>Full disclosure</i> must be made to various authorities and the recipient shall be required to acknowledge the member's support in all oral or written presentations of the results. <p>Public Education may make grants to support patient or public education about important healthcare topics.</p> <p>Note: Cross reference is made throughout this section to Section III, supporting third-Party Educational Conferences.</p>
<p style="text-align: center;">XII. Evaluation and Demonstration Products</p>	<p style="text-align: center;">No equivalent section.</p>



This section of the Code discusses the provision of evaluation and demonstration products and is not intended to address any other arrangement.

Evaluation Products:

- Provided at no charge to assess functionality and to determine future purchase and use of that product
- Expected to be used in patient care
 - a) *Single Use/Consumable/Disposable*- may be provided in quantity reasonably necessary for adequate evaluation
 - b) *Multiple Use/Capital*- furnished only for the time reasonably necessary for adequate evaluation. The terms of such an evaluation should be set in writing, Companies should retain title to the product, and the product should be removed promptly upon completion of the evaluation.

Demonstration Products:

- Typically unsterilized single-use products typically used for HPC and patient awareness, education and training.
- Not expected to be used in patient care.
- Identified as not intended for patient use and typically designated as "Sample," or "Not for Human Use," on the packaging and/or other documentation that accompanies the product.

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