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Life Sciences Health Industry Alert

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AdvaMed Issues Revised Code of Ethics on Interactions with Health Care Professionals

On December 18, 2008, the Advanced Medical Technology Association ("AdvaMed")—the national trade association of medical technology manufacturers—issued a revised Code of Ethics on Interactions with Health Care Professionals ("HCPs") (the "AdvaMed Code" or "Code"). The revised AdvaMed Code, which becomes effective July 1, 2009, contains several changes that will significantly impact the medical device industry. These include:

- The addition of guidelines for the payment of royalties to HCPs
- The inclusion of a new section on the provision of evaluation and demonstration products to customers at no charge
- More comprehensive guidelines for furnishing reimbursement and health economics information to HCPs
- A prohibition on the provision of entertainment and recreation
- A prohibition on the provision of non-educational branded promotional items, such as pens, notepads, mugs and similar items
- Increased restrictions on the provision of restaurant meals or meals at other off-site venues

More generally, the revisions to the AdvaMed Code seek to strike the appropriate balance between encouraging beneficial, productive interactions between device manufacturers and HCPs, and establishing safeguards to ensure that such arrangements meet high ethical standards and are conducted in a manner that is consistent with fraud and abuse authorities. It is also important to note that the revised AdvaMed Code applies to all medical device "Companies"; the prior version, by its plain terms, applied only to AdvaMed "members." Thus, while each device manufacturer must make its own decision regarding whether to comply with the AdvaMed Code, irrespective of that decision, the revised Code's provisions extend to all medical device manufacturers, and, as such, arguably establish industry standards.

This *Client Alert* contains a summary, in Section I, of the principal changes to each section of the AdvaMed Code (including, where pertinent, comparisons to the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals (the "PhRMA Code"), which was revised in July 2008 with an effective date of January 1, 2009). Section II highlights several compliance considerations related to implementation of the revised AdvaMed Code. Finally, attached to this *Client Alert* is a chart summarizing the original and revised AdvaMed Codes, and highlighting the new provisions that will become effective July 2009.

I. Summary of Revisions to the AdvaMed Code

Revisions to the AdvaMed Code include:

- ***Preamble: Goal and Scope of the AdvaMed Code.*** The revised Code replaces references to "Members" with references to "Companies." The term "Companies" is defined as "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." As noted above, this change means that, by its plain terms, the revised AdvaMed Code extends to all companies, irrespective of whether they are members of AdvaMed. Thus, although individual manufacturers must make a decision about whether to comply, voluntarily, with the Code, the revised Code's guidelines could arguably serve to establish industry-wide standards. The Preamble also expressly recognizes that medical devices—now referred to as "Medical Technologies"—are distinct from drugs and biologics. Although not explicitly stated, this distinction implies that the guidance (and safeguards) for device manufacturers must necessarily be different from that of pharmaceutical manufacturers, at least in certain instances.

- ***Code of Ethics Compliance.*** The revised AdvaMed Code includes a new section on compliance with the Code. All companies are "strongly encouraged" to adopt the Code and to implement an effective compliance program. Those that do are "strongly encouraged" to submit an annual certification of compliance, signed by the CEO and Chief Compliance Officer (or equivalent individuals). AdvaMed will publish on its website a list of companies that submit the annual certification. In addition, AdvaMed will publish the contact information for a company's Compliance Department (or anonymous compliance hotline) for AdvaMed members and non-members that choose to provide this information. Finally, the revised Code provides that all companies are strongly encouraged to follow the seven core elements of an effective compliance program as outlined by the U.S. Department of Health and Human Services, Office of Inspector General. Unlike the revised PhRMA Code, the revised AdvaMed Code does not require or recommend that companies seek regular external verification of compliance. (As part of its recent revisions, the PhRMA Code now encourages companies to seek external verification—at least every three years—that they have policies and procedures in place to foster compliance with the PhRMA Code.)
- ***Company-Conducted Product Training and Education.*** The revised AdvaMed Code includes a more detailed section on company-conducted product training and education. Specifically, the revised Code includes definitions of "training" and "education." It also recognizes that training staff "may include qualified field sales employees who have the technical expertise necessary to perform the training." Finally, the revised Code also specifies—as did the original Code—that payment for out-of-town travel associated with product training is permitted; however, the revised Code permits such payment only where the need for out-of-town travel is supported by objective reasons.
- ***Supporting Third-Party Educational Conferences.*** The revised Code provides additional details with respect to support for third-party educational conferences. Of note, the Code changes references to "hospitality" to "meals and refreshments," and clarifies that companies may provide funding to a conference sponsor in support of this. Companies may also provide meals and refreshments directly to conference attendees, with certain restrictions. Finally, the Code makes clear (in FAQ 21) that a company can sponsor off-site sales, promotional or other business meetings ancillary to a third-party educational conference, provided that there is a legitimate business purpose and provided that the company complies with the conference sponsor's guidelines.
- ***Sales, Promotional and Other Business Meetings.*** This section of the Code remains substantially the same. Revised FAQ 23 (former FAQ 18), however, clarifies that companies should select a location and venue for sales, promotional and other business meetings that is appropriate for, and conducive to, accomplishing the purpose of the meeting. The FAQ explains that selection of a resort location for these types of meetings would likely not meet these standards and may give rise to an appearance of impropriety.
- ***Consulting Arrangements and Royalties.*** The revised Code expands on the original Code's guidelines for consulting arrangements by, among other things, refining the standards for consulting agreements. In particular, the revised Code is explicit that sales personnel may provide input as to the suitability of a proposed consultant, but cannot control or unduly influence the decision of whether to engage a consultant. Like the current Code, the revised Code indicates that selection of a consultant should be on the basis of his or her qualifications and expertise to meet a defined need. New FAQ 32 notes that this could include experience with, usage of, or familiarity with, a company's products/medical technologies.

  The Code also adds a new section dedicated to the payment of royalties to HCPs. In this regard, the revised Code indicates that all royalty arrangements must meet the same standards as other consulting arrangements (*e.g.*, written contract, services clearly specified, etc.) and can only be entered into when an HCP is expected to make or has made a novel, significant or innovative contribution to the development of a product, process or method associated with a company's product. The revised Code also indicates that royalties should not be conditioned on an HCP's marketing of products upon commercialization, and also notes that companies are "strongly encouraged to consider whether it is appropriate and practicable" to exclude from royalty calculations the number of units of a product purchased, used or ordered by the HCP or his/her practice.
- ***Prohibition on Entertainment and Recreation.*** The revised Code adds a new section on entertainment and recreation that states that a company should not provide or pay for any entertainment or recreational activities. The current Code permits modest consultant entertainment under certain circumstances, whereas the revised Code incorporates a strict

prohibition on entertainment and recreation that extends to theater tickets, sporting events, golf, skiing, hunting, sporting equipment, vacations and similar items. Note, however, that FAQ 36 provides that it may be appropriate in certain cases for a company's employee or agent to engage in entertainment or recreation activities with an HCP, so long as each pays his or her own way.

- ***Modest Meals Associated with HCP Business Interactions.*** The revised Code also adds a new section on meals associated with HCP business interactions. In this new section, the revised Code specifies that meals can be provided to HCPs in conjunction with the presentation of scientific, educational or business information. Unlike the revised PhRMA Code, however, such meals need *not be provided exclusively in the physician office or hospital setting*. Rather, if (1) an on-site setting is not conducive to the presentation of scientific, educational or business information, or (2) it is impracticable or inappropriate to provide meals in an on-site setting (*e.g.*, technology cannot be transported easily to the HCP's location, confidential product information being discussed, etc.), then meals in off-site settings are permitted.
- ***Educational Items: Prohibition on Gifts.*** The revised AdvaMed Code explicitly prohibits non-educational, branded promotional items, even if an item is of minimal value and related to the HCP's practice, or even if an item is for the benefit of patients. This would include items such as pens, notepads, mugs or similar "reminder" items that are branded with the company's name or logo. Whereas the original AdvaMed Code permitted companies to provide HCPs and their staff with occasional branded reminder items of minimal value, the revised AdvaMed Code allows only educational or patient benefit items to be provided to HCPs. Accordingly, educational items such as textbooks, subscriptions to relevant scientific journals or copies of clinical treatment guidelines are permitted, as are anatomical models. A $100 cap is applied to all such items, except for textbooks and anatomical models.
- ***Provision of Coverage, Reimbursement and Health Economics Information.*** The revised Code substantially expands and revises the current provisions on reimbursement information and related activities. The revised Code identifies several key permissible activities, such as identifying clinical value of a company's product; collaborating with HCPs on joint advocacy for coverage, reimbursement and health economics concerns; providing accurate and objective coverage, coding and billing information; and providing information and training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims, among other items. The provision of such information, however, cannot interfere with HCP decision-making and cannot involve providing free services that would eliminate an HCP's overhead or other expenses.
- ***Research and Educational Grants and Charitable Donations.*** The revised AdvaMed Code provides more detail on awarding grants for research, educational and charitable purposes. Among the changes in the revised Code is an explicit statement as to the role of sales personnel in the grant-making process. Whereas the revised PhRMA Code requires a strict firewall between the sales and marketing functions and the grant-making process, the revised AdvaMed Code notes that sales personnel may provide input about the suitability of a grant or donation recipient or program, but may not control or unduly influence the decision of whether a particular HCP will receive a grant or donation or the amount.
- ***Evaluation and Demonstration Products.*** The revised AdvaMed Code adds a new section on evaluation and demonstration products that permits companies to provide products to HCPs at no charge, and includes guidelines specific to single-use products (consumable or disposable), multiple use products (capital equipment) and demonstration or unsterilized products. The revised Code also includes standards for determining the duration of the demonstration and evaluation period, and the appropriate amount of product that should be provided to HCPs.

II. COMPLIANCE CONSIDERATIONS

Companies that choose to comply with the revised AdvaMed Code will need to amend their compliance policies and procedures by July 1, 2009. In addition to the operational challenges associated with revising, approving and distributing policies and procedures, companies will need to update—and roll out—updated training programs.

In addition, as a practical matter, device companies that do business in California and Nevada will likely have to adopt the changes reflected in the revised AdvaMed Code to ensure adherence to those states' legal requirements that device companies maintain comprehensive compliance programs. We also note that recently proposed regulations in Massachusetts—designed to restrict

sales and marketing activities by both drug and device companies—are based, in part, on the AdvaMed Code, and accordingly, it is unclear how the state will decide to incorporate the revised AdvaMed Code into its final regulations.

Finally, device manufacturers will need to assess how the revised Code impacts their sales and marketing practices. For example, companies will need to determine whether, and under what specific circumstances, sales representatives can take HCPs to a restaurant. Companies will also need to determine what types of "gifts" fall within the AdvaMed Code's standard that companies may only provide HCPs with items that either benefit patients or serve a genuine educational function.

These, and a host of other compliance considerations, will likely garner significant company resources in the months leading up to July 1, 2009.

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Reed Smith was honored to serve as outside counsel to AdvaMed in connection with drafting both the current and the revised Code, and would be pleased to answer any questions or provide additional information.

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Comparison Chart: Revisions to the AdvaMed Code of Ethics on Interactions with Health Care Professionals ("HCPs")

Subject[1]	AdvaMed Code (2005)	Revised AdvaMed Code (effective 7/1/2009)[2]
I. Preamble	1. General. Notes that adoption of the AdvaMed Code is to facilitate Members' ethical interactions with Health Care Professionals ("HCPs"). 2. HCP Interactions. Describes different types of Member and HCP interactions, including: a. Advancement of medical technology; b. Safe and effective use of medical technology; and c. Research and education. 3. Effective Date. Includes effective date (January 1, 2004). 4. Interpretive Standard. States the standard that should be applied if the Code does not address a specific type of interaction: "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." 5. Definition of HCPs. FAQs 2 & 3 define HCPs to include "individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Members' medical technology products in the United States." This further includes clinical and non-clinical people, decision-makers within GPOs, and any other people in a position to make product-related decisions, such as hospital purchasing agents, and physician practice managers.	1. **Medical Technologies. Distinguishes between (1) Medical Technologies,[3] which are dependent upon hands-on HCP interaction, and (2) drugs and biologics, which achieve their principal intended action by pharmacological, immunological or metabolic means.** 2. Interactions with HCPs. Describes different types of Company[4] and HCP interactions, including those intended to: **a. Promote** the Advancement of Medical Technologies, **b. Enhance** the Safe and Effective Use of Medical Technologies, **c. Encourage** Research and Education; and **d. Foster Charitable Donations and Giving.** 3. The Purpose of the Code of Ethics. To ensure HCP-Company collaborative relationships meet high ethical standards. 4. **Footnote. Notes that the principles of the Code are derived from the federal Anti-Kickback Statute, among other authorities. In addition, throughout the Code, reference to "unlawful inducement" reflect the Anti-Kickback Statute prohibitions.** 5. Effective Date. Effective date is July 1, 2009. 6. Interpretive Standard "Note." Moved to new Section II (described below). 7. Definition of HCPs. Defined substantially the same as in the original AdvaMed Code; however, the revised Code broadens the definition of HCPs to include any individuals or entities "**involved in the provision of health care services and/or items to patients."** Like the original Code, HCPs include those individuals who purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies. **Includes (in FAQ 2) persons who provide services (licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease or recommend Medical Technology** (*e.g.*, purchasing agents, practice managers, and GPO management). 8. Preamble and General FAQs. i. FAQ 7: Modest, Occasional, Hospitality. **The revised Code removes use of the word "Hospitality" from the Code. The revised Code now reads in terms of meals and refreshments instead of**

[1] Based on subject headings in the revised AdvaMed Code.

[2] Revisions to the AdvaMed Code appear in **bold**.

[3] The revised AdvaMed Code replaces the term "product" with the defined term, "Medical Technologies." Specifically, the revised Code defines "Medical Technologies" to include "medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities."

[4] All references to "Members" in the revised AdvaMed Code have been changed to "Companies."

Subject[1]	AdvaMed Code (2005)	Revised AdvaMed Code (effective 7/1/2009)[2]
	6. Modest, Occasional, Hospitality. The current AdvaMed Code defines "modest" to mean moderate or low value (depending upon regional differences) and "occasional" to mean infrequent. "Hospitality" (undefined) should be modest and occasional.	**"hospitality." FAQ 7 indicates that meals and refreshments should be modest.** FAQ 7 defines "modest" as moderate value**,** accounting for regional differences and "occasional" (infrequent). **FAQ 7 also states that Companies should consider establishing limits on frequency and costs of meals to comply with requirements that they be modest and occasional.** ii. FAQ 8: Employee Payment for Meals and Refreshments. **New FAQ 8 provides that a Company's employee or agent cannot pay for meals or refreshments for an HCP, even if out of pocket. However, the FAQ notes there may be situations where an employee or agent may engage in certain activities with an HCP so long as the HCP and the employee or agent each pays his/her own way.**
II. Code Compliance	1. Code Compliance. The current AdvaMed Code states that Members will communicate the Code's principles to employees, agents, dealers and distributors with the expectation that they will adhere to the Code.	1. Code Compliance. **Companies are strongly encouraged to adopt the Code and implement an effective compliance program to foster compliance with the Code.** 2. Certification. **Companies that adopt the revised Code are strongly encouraged to submit to AdvaMed an annual certification that the Company has adopted the revised Code and implemented an effective compliance program (signed by the CEO and Chief Compliance Officer or individuals with equivalent responsibilities). AdvaMed will publish (on its website) a list of Companies that have submitted the annual certification.** 3. Compliance Contact Information. **Companies that are AdvaMed members must (and non-members may) provide contact information for their compliance department or anonymous hotline to facilitate reporting violations. AdvaMed will publish this information on its website.** 4. Elements of Compliance Program. **Companies are strongly encouraged to follow the seven elements of an effective compliance program:** **a. Written policies and procedures;** **b. Compliance officer and committee;** **c. Effective training and education;** **d. Effective lines of communication (including an anonymous reporting function);** **e. Internal monitoring and auditing;** **f. Enforcement through well-publicized disciplinary guidelines; and** **g. Prompt response to problems and corrective action.** 5. "Note." Includes a similar standard as original Code: "Members shall encourage ethical business practices and socially responsible industry conduct and shall not **engage in any unlawful inducement**."
III. Company-Conducted	Existing title for this section is "Member-	1. Definition of Training Education. **Defines "training" as "training on the safe and effective use of Medical Technologies" and "education" as "communicating information directly concerning or associated with the**

Subject[1]	AdvaMed Code (2005)	Revised AdvaMed Code (effective 7/1/2009)[2]
Product Training and Education	Sponsored Product Training and Education." 1. Definition of Training. None. 2. Need for Training. Indicates that the FDA mandates training and education to facilitate the safe and effective use of medical technology. 3. Standards on Training: a. Must be conducted in clinical, educational, conference or other settings, including hotel or other meeting facilities conducive to the effective transmission of knowledge. b. Hands-on training should be held at training facilities, medical institutions, laboratories, or other appropriate facilities with training staff that have proper qualifications and expertise. c. Hospitality for attendees is permissible in the form of modest meals and receptions (modest in value, subordinate in time and focus to the educational or training purpose of the meeting). d. Payment for reasonable travel and modest lodging costs by attendees is permitted. e. Payment for meals, hospitality, travel or other expenses of guests of HCPs or any other person without a *bona fide* professional interest in the information being shared is not permitted.	**use of Companies' Medical Technologies" (*e.g.*, disease states, patient benefits). Training and education programs include "hands on" training sessions, cadaver workshops, lectures and presentations, and grand rounds.** 2. Need for Training. Indicates that the FDA mandates training and education to facilitate the safe and effective use of Medical Technology. 3. Standards on Training. **Refines standards on training and education:** a. Must be conducted in a setting that is conducive to the effective transmission of information. Such settings may include clinical, educational, conference or other settings, including hotels or other meeting facilities, **(this can include training and education at the HCP's site)**; b. Hands-on training should be held at training facilities, medical institutions, laboratories, or appropriate facilities with training staff with appropriate qualifications and expertise **(this can include qualified field sales employees with necessary technical expertise)**; c. Modest **meals and refreshments are permissible so long as subordinate in time and focus to the training or educational purpose;** d. Payment for out-of-town travel **(to efficiently deliver Training and Education on Medical Technologies)** is permitted **where the need is supported by objective reasons**. e. Payment for meals, **refreshments**, travel or other expenses of guests of HCPs or any other person without a *bona fide* professional interest in the information being shared is not permitted.
IV. Supporting Third-Party Educational Conferences	1. Types of Conferences. Conferences sponsored by national, regional, or specialty medical associations; conferences sponsored by accredited continuing medical education ("CME") providers; and grand rounds. 2. Types of Conference Support. a. Educational grants to conference sponsors to reduce conference costs, or to training institutions to permit attendance by students, residents, fellows:	1. Types of Conferences. *Bona fide* independent, educational, scientific and policy making conferences typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited CME providers primarily dedicated to promoting objective scientific and educational activities and discourse. **(Grand rounds removed from list of "third-party educational conferences" and inserted in Company-Conducted Product Training and Education section.)** 2. Types of Conference Support. a. Conference Grants. May be provided to conference sponsors to reduce conference costs or to training institutions to permit attendance by students, residents, fellows and other HCPs in training:

Subject[1]	AdvaMed Code (2005)	Revised AdvaMed Code (effective 7/1/2009)[2]
	• training institution must select attendees; and • sponsor must control content, faculty, materials. b. Modest meals and hospitality may be provided to conference sponsor or Member may provide meals and receptions for all HCP attendees if consistent with sponsor's guidelines. c. Meals, receptions and hospitality must be modest in value and subordinate in time and focus to the conference. d. Grants to conference sponsors for faculty expenses including honoraria, travel, lodging and meals. e. Advertisements and demonstrations for Member displays.	• gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; • training institution or conference sponsor must select attendees; • paid only to organizations with a genuine educational function; • **grants should be consistent with sponsor's standards and standards established by accrediting body; and** • sponsor must **independently** control content, faculty, materials**.** b. **Conference Meals and Refreshments. Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to attendees. Companies may provide meals and refreshments if: (1) provided to all HCP attendees (with one exception) and (2) provided in a manner consistent with sponsor's and accrediting body's standards. Meals and refreshments can be provided to fewer than all attendees if the Company satisfies all other principles related to meals set forth in Section VIII.** Meals and **refreshments** should be modest in value, subordinate in time and focus to the purpose of the conference, **and clearly separate from CME portion of program.** c. Faculty Expenses. Grants to conference sponsors for *bona fide* faculty members' expenses including honoraria, travel, lodging and meals. d. Advertisements and Demonstration. Companies may purchase advertisements and lease booth space for Company displays. 3. Sales Meetings at Third-Party Educational Conference. **FAQ 21 permits a Company to sponsor an off-site sales, promotional or other business meeting that is ancillary to a third-party educational conference, provided that there is a legitimate business purpose and the Company complies with the conference sponsor's guidelines.**
V. Sales, Promotional and Other Business Meetings	1. Meeting Topics. Members may meet with HCPs to discuss product features, contract negotiations, and sales terms. 2. Meals, Receptions. Permits Members to provide occasional modest meals and receptions that are conducive to the exchange of information. 3. Travel Costs. Members can pay reasonable travel costs of attendees when necessary (*e.g.*, for plant tours or demonstrations of non-portable equipment). 4. HCP Guests. No meals, hospitality, travel or lodging for HCP guests or those without a *bona fide* professional interest.	1. Meeting Topics. Companies may meet with HCPs for a variety of sales, promotional and other business purposes, to discuss for example, Medical Technology features, sales terms, or **contracts.** 2. Meals, **Refreshments.** Permits Companies to provide occasional **modest meals and refreshments**. 3. Travel Costs. Companies can pay reasonable travel costs of attendees when necessary (*e.g.*, for plant tours or demonstrations of non-portable equipment). 4. HCP Guests. No meals, **refreshments**, travel or lodging for HCP guests or those not having *bona fide* professional interest. Note: Meals are also discussed in Section VIII.

Subject[1]	AdvaMed Code (2005)	Revised AdvaMed Code (effective 7/1/2009)[2]
VI. Consulting Arrange-ments with Health Care Professionals	1. General. Appropriate to pay HCPs reasonable compensation for providing valuable *bona fide* consulting services, including research, participation on advisory boards, presentations at Member-sponsored training, and product collaboration. 2. Standards. Factors that support the existence of a *bona fide* consulting arrangement between Members and HCPs include: a. Written arrangements signed by the parties specifying the services provided; b. Compensation consistent with FMV for the service provided; c. Legitimate need for the services and purpose for the services identified in advance; d. Selection of consultants based on qualifications and expertise, not on volume or value of business; e. Venue and circumstances for meetings should be appropriate to subject matter and conducted in clinical, educational, conference or other setting (including hotel or other commercial facility) conducive to the exchange of information; f. Member-sponsored hospitality should be modest in value and subordinate in time and focus to the purpose of the meeting; g. Members may pay for reasonable and actual expenses, including travel, modest meals, and lodging costs incurred by consultants attending meetings with, or on behalf of, Members (including modest hospitality, per FAQ 25). h. There should be a written research protocol for research services.	1. General. Appropriate to provide **fair market value** ("FMV") compensation for services intended to fulfill a legitimate business need **and which do not constitute an unlawful inducement**. 2. Standards. **Compliance standards associated with consulting arrangements**: a. Should be written and describe all services to be provided **(for clinical research services, must have a written research protocol)**; b. Should be legitimate need for the consulting services, which is identified in advance of **the services and documented**; c. Selection of consultants should be on the basis of the consultant's qualifications and **expertise to meet the defined need**; d. **Compensation should be consistent with FMV in an arm's length transaction and should not be based on the volume or value of a consultant's past, present or anticipated business;** e. Companies may pay for **documented,** reasonable and actual expenses, including reasonable and actual travel, modest meals and lodging costs; f. Venue and circumstances for Company meetings with consultants should be appropriate to subject matter and conducted in clinical, educational, conference or other setting (including a hotel or other commercial facility) conducive to the exchange of information; g. Company-sponsored **meals and refreshments** should be modest in value and subordinate in time and focus to the purpose of the meeting **(no recreation or entertainment may be provided)**. h. **Sales personnel may provide input about the suitability of a proposed consultant but should not control or unduly influence the decision of whether to engage a particular HCP as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this provision.** 3. **Royalties. New section on royalty payments:** **a. Arrangements involving royalties paid to an HCP should meet the contractual standards above.** b. **Royalty arrangements should be entered only where the HCP is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method.** c. **A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.** **d. Calculation of royalties should be based on factors that preserve the objectivity of medical decision-making and avoid improper influence. For example, royalties should not be conditioned on (i) a requirement that the HCP purchase, order or recommend any product or Medical Technology of the Company or any product or technology produced as a result of the project, or (ii) a requirement to market the product or medical technology upon**

Subject[1]	AdvaMed Code (2005)	Revised AdvaMed Code (effective 7/1/2009)[2]
		commercialization. e. **Companies can enter separate consulting agreements with HCPs (to whom they pay royalties) for marketing services if the services meet the requirements of Consulting Arrangements described above.** f. **Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from royalty calculations the number of units of a product purchased, used or ordered by the HCP or his/her practice group.** 4. **NEW/REVISED FAQs:** **a. Company should hire only as many consultants as are "necessary to fulfill" the Company's requirements for *bona fide* services (FAQ 26).** **b. The AdvaMed Code's restrictions apply to interactions with consultants in the same way as they do for interactions with other HCPs (FAQ 30).** **c. Defines consulting arrangement as any relationship in which services are provided to a Company by an HCP in exchange for remuneration (FAQ 31).** **d. Examples of consulting arrangements include education and training services, speaking engagements, proctoring and preceptorships, reference center or center of excellence relationships, advisory boards and focus groups, product development and research service, arrangements for the development or transfer of intellectual property (FAQ 31).** **e. Selection of consultants must be based on qualifications and expertise to meet a defined need, and this may include, among others, experience with, or usage of, or familiarity with a specific Medical Technology (FAQ 32). However, neither selection nor compensation should be used to reward past usage or constitute an unlawful inducement.** **f. Establishing FMV may include a variety of methods, but in all cases, FMV should be established with objective, verifiable criteria and methodology should be documented (FAQ 34).** **g. Criteria for "legitimate need" for consultant services are separate from generating business, and typically exist if a consulting arrangement would have been entered into absent the opportunity to generate business directly from the HCP who will be serving as the consultant (FAQ 35).**
VII. Prohibition on Entertainment and Recreation	No comparable provision.	1. **Companies should not provide or pay for any entertainment or recreational events or activities for non-employee HCPs.** 2. **Examples include theater, sporting events, golf, skiing, hunting, sporting equipment and leisure or vacation trips.** 3. **Entertainment and recreational items should not be provided regardless of (a) their value, (b) whether the HCP is a speaker or consultant, or (c) whether the entertainment is secondary to an**

Subject[1]	AdvaMed Code (2005)	Revised AdvaMed Code (effective 7/1/2009)[2]
		educational purpose. 4. **New FAQ 36 notes that the restriction applies to a Company's employee or agent, even if the employee pays. There may be situations where an employee or agent can engage in certain activities with an HCP if each pays his/her own way.**
VIII. Modest Meals Associated with Health Care Professional Business Interactions	1. Current AdvaMed Code states that Members can pay for modest meals that are conducive to the exchange of information at a sales and promotional meeting. 2. No meals for guests of HCPs or other persons who do not have a *bona fide* professional interest in the information being shared at the sales and promotional meeting.	1. **Modest meals may be provided as an occasional business courtesy in connection with business interactions with HCPs that involve the presentation of scientific, educational or business information.** 2. **Purpose. The meal should be incidental to the *bona fide* presentation of scientific, educational or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.** 3. **Setting and Location. Meals should be offered in a setting conducive to *bona fide* scientific, educational or business discussions. Meals may occur at the HCPs site. However, if such site is not conducive to exchange of information or is impractical or inappropriate, meals may be provided off-site, for example (1) Medical Technology cannot easily be transported to the HCP's location; (2) confidential product development or improvement information is being discussed; or (3) a private space cannot be obtained.** 4. **Participants. Meals can only be provided to HCPs who actually attend; no meals for office staff where everyone does not attend. No "dine and dash" or take out meals. No meals for guests of HCPs or any other person without a *bona fide* professional interest in the information.** 5. **Other Principles. Additional principles from other sections of the Code may apply depending upon the business interaction or meeting.** 6. **FAQ 37 indicates that a business presentation includes substantial discussion of product development/improvement, pricing, contract negotiation. Development of good will and business relationships should not be the primary purpose.**
IX. Educational Items: Prohibition on Gifts	1. Patient Benefit, Educational Function. Permits modest gifts to HCPs if gifts benefit patients or serve a genuine educational function. 2. $100 Cap. Any gifts should have a FMV of less than $100 unless medical textbook or anatomical model used for educational purposes. 3. Branded Items. Permits occasional gifts of branded promotional items of minimal value related to HCP's work or for the benefit of patients. 4. No Cash/Cash Equivalents. Gifts may not be given as cash or cash equivalents. 5. Food, Wine. Prohibits gifts of food or	1. Patient Benefit, Educational Function. Permits Companies to occasionally provide modest **items** to HCPs that benefit patients or serve a genuine educational function. 2. $100 Cap. Any items should have a FMV of less than $100, except for medical textbooks or anatomical models used for educational purposes. 3. **HCP Benefit. No items intended for the non-educational or non-patient-related benefit of HCPs, office staff, or family/friends (*e.g.*, DVD player or MP3 player/I-Pod).** 4. Branded Items. **No non-educational, branded promotional items may be provided, even if the item is of minimal value and related to the HCP's work or for the benefit of patients (*e.g.*, pens, notepads, mugs, and other items with Company name, logo or logo of product).** 5. Food/Cash: No gifts **such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts** or cash or cash equivalents.

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	wine. 6. Gifts to Office Staff. Prohibits gifts such as flowers, gift baskets, meals, snacks, wine or other refreshments to HCPs or HCP's office staff, because not considered related to HCP's work or for the benefit of patients. 7. Significant Life Events. Permits Members to determine whether it is appropriate to provide a small gift (valued at less than $100) (flowers, fruit baskets) to an HCP upon a significant life event (*e.g.*, birth, death, serious illness).	6. Gifts to Office Staff. Revised FAQ 38 prohibits gifts such as flowers, gift baskets, meals, snacks, wine or other refreshments to HCPs or office staff because not considered educational or for the benefit of patients. **Revised FAQ 39 indicates that gifts to staff are treated under the Code the same as gifts to HCPs.** 7. Significant Life Events. **FAQ 40 prohibits Companies from giving flowers, fruit baskets, etc. to recognize HCP life events (wedding, birth, anniversary, death, etc.).** 8. Raffles. **FAQ 41 prohibits raffling off or giving away at a trade show items that otherwise would not appropriately be provided to HCPs.** 9. Examples of Patient Benefit Items. **FAQ 42 provides examples of items intended for the benefit of patients (starter kits, educational brochures) and items that are not intended for the benefit of patients (scrubs, office supplies). FAQ 42 notes that with respect to starter kits, Companies should adopt appropriate safeguards to ensure they are not offered as an unlawful inducement.**
X. Provision of Coverage, Reimburse-ment, and Health Economics Information	1. Provision of Reimbursement Information. Members may support accurate and responsible billing to Medicare and other payors by providing reimbursement information to HCPs. 2. Coverage, Coding, Billing Information. Information may be about Members' products, appropriate coverage, coding or billing of products, or procedures using those products. 3. Technical Support. Members may provide information that gives technical or other support intended to aid in the appropriate and efficient use or installation of the Member's products. Such support may not be to unlawfully induce HCPs to purchase, lease, recommend, use or arrange for the purchase, lease or prescription of a Member's products.	1. Accurate, Objective Information. Companies may provide accurate and objective, **timely and complete coverage, reimbursement and health economics information** on their products. 2. **Collaboration with Other Persons/Entities. Companies may collaborate with HCPs, patients and organizations that represent their interests to achieve government and commercial payor coverage decisions, guidelines and policies, and adequate reimbursement levels that allow patients to access Medical Technologies.** 3. **Permissible Activities. Permissible activities identified include (but are not limited to):** **a. Identifying clinical value of Medical Technologies;** **b. Collaborating with HCPs and others to conduct joint advocacy on coverage, reimbursement and health economics issues;** **c. Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to HCPs regarding Medical Technologies, including identifying coverage, codes and billing options that may apply;** **d. Providing accurate and objective information on economically efficient Medical Technology use;** **e. Providing information on reimbursement revenues and costs;** **f. Providing information on changes to coverage or reimbursement amounts, methodologies and policies;** **g. Providing accurate and objective information designed to offer technical and other support; and** **h. Facilitating access to Medical Technologies by assisting HCPs with obtaining patient coverage decisions from payors.** **i. This includes providing information and training on**

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		policies and procedures for obtaining prior authorization and providing sample letters and information on medical necessity and appeals of denied claims. **ii. In addition, at the request of an HCP and subject to privacy safeguards, a Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals; however, such assistance should not be provided as an unlawful inducement.** **i. Companies cannot interfere with an HCP's decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement (*e.g.*, providing a free service that eliminates an HCP's overhead or other expense). A Company should not suggest mechanisms for billing services that are not medically necessary or for engaging in fraudulent practices to achieve inappropriate payment.**
XI. Research and Educational Grants and Charitable Donations	1. General. Permits donations for a charitable purpose, such as supporting independent medical research, indigent care, patient education, public education, or sponsorship of events where the proceeds are intended for charitable purposes. 2. Charitable Donations. Donations should be made only to charitable organizations or individuals engaged in charitable missions for the support of that mission. 3. No Unlawful Inducement. Donations may not be made to unlawfully induce HCPs to purchase, lease, recommend, use or arrange for the purchase, lease or prescription of Members' products. 4. Documentation. Donations should be appropriately documented. 5. Types of Grants. Examples of appropriate charitable grants include: a. Advancement of medical education of medical students, residents, and fellows; b. Support of research with scientific merit where the purpose of the grant is clearly documented; and c. Education of patients or the public about important health care topics.	1. General. Permits research and educational grants and charitable donations. 2. No Unlawful Inducement. Grants or donations may not be provided as an unlawful inducement. **Companies should implement procedures to ensure no unlawful inducement via grants and donations.** 3. Objective Grant Criteria. **Companies should (a) develop objective criteria for making grant and donation decisions that do not account for the volume or value of purchases made by or anticipated from the recipient; (b) implement procedures to ensure grants and donations are not used as an unlawful inducement; and (c) ensure appropriate documentation of grants and donations.** 4. Sales Involvement. **Sales personnel may provide input about the suitability of grant or donation recipient or program, but may not control or unduly influence the decision of whether a particular HCP will receive the grant or donation or the amount. Companies should consider implementing procedures to monitor compliance with this provision.** 5. Research Grants. **a.** Companies may provide research grants to support **independent medical** research with scientific merit, with well-defined objectives and milestones, and no direct or indirect link to purchases. **New FAQ 49 prohibits unrestricted grants, stating that research must have defined goals, objectives, and milestones.** **b. Company-initiated or directed research involving a Company's Medical Technologies (*e.g.*, clinical studies) are addressed separately in Section VI (Consulting Arrangements).** 6. Educational Grants. Companies may provide educational grants for advancement of medical education and public education; **no grants may be given to individual HCPs**. 7. Charitable Grants. **a.** Company may make monetary or donations of Medical Technologies

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		for charitable purposes **(such as supporting indigent care, patient education, public education or the sponsorship of events where proceeds are intended for charitable purposes).** **b.** Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations **or, in rare instances, to individuals engaged in charitable activities for the support of a *bona fide* charitable mission**. **c. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or mission. New FAQ 51 indicates that relevant factors include: (1) the entity's tax status; (2) the entity's corporate status under state law; and (3) whether the organization has a charitable mission or purpose, among other factors.** **d. New FAQ 50 permits contributions to charitable events such as golf tournaments or galas but states that Companies may not pay for individual HCPs to play or participate.**
XII. Evaluation and Demon-stration Products	No comparable provision.	1. **<u>General.</u> Company products that may be provided to HCPs for evaluation include (a) single use products (consumable or disposable), and (b) multiple use products (capital equipment), provided at no charge to allow HCPs to assess the appropriate use and functionality and to determine whether/when to use, order, purchase or recommend the product. Products provided for evaluation are typically expected to be used in patient care.** 2. **<u>Single-Use/Consumables/Disposables.</u> Number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation.** 3. **<u>Multiple Use/Capital.</u> Multiple use products should be provided without transfer of title and should be furnished only for a period of time that is reasonable to allow an adequate evaluation. Terms should be set in advance in writing. Company should have process for promptly removing the product from HCP's location at the end of the evaluation period, unless HCP purchases or leases the product.** 4. **<u>Demonstration.</u> These are typically unsterilized, single use products or mock-ups used for HCP and patient awareness, education and training. Demonstration products are not intended to be used in patient care and are typically identified as such ("Sample," "Not for Human Use," or other designation).** 5. **<u>Documentation.</u> Companies should provide HCPs with documentation of the no charge status of evaluation and demonstration products.** 6. **<u>Duration of Evaluation Period.</u> New FAQ 53 describes the factors to consider in calculating the length of time reasonably necessary for HCP to assess a multiple use product (*e.g.*, frequency of anticipated use, duration of required training, number of HCPs who will evaluate the product, and length of time to evaluate different product features, etc.).**