



Client Alert



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AdvaMed Issues Revised Code of Ethics

Recently, the Advanced Medical Technology Association (“AdvaMed”), a national trade association of medical technology manufacturers, released a revised version of its “Code on Ethics on Interactions with Health Care Professionals.” The revised AdvaMed Code establishes best practices for its medical device industry members that engage in interactions with Health Care Professionals (HCPs), as they relate to the marketing of medical technology products. The revised AdvaMed Code is more rigorous and restrictive than the version originally adopted in 2005. The AdvaMed Code, while voluntary for its members, will become effective on July 1, 2009, and contains several changes that we anticipate will have a significant impact on the medical device industry. Only the most significant revisions and expansions to the original AdvaMed Code are provided below.

SUMMARY OF REVISED CODE SECTIONS

Revisions to the AdvaMed Code include:

- **Supporting Third-Party Educational Conferences.** Like the original code, the revised Code permits companies to provide support for conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited Continuing Medical Education (CME) providers. Specifically, companies may provide grants to the conference sponsor to reduce conference costs. Grants, however, should be consistent with a sponsor’s standards and standards established by accrediting body and the sponsor must independently control the content, faculty, and materials. Notably, “grand rounds,” which are formal meetings at which physicians discuss the clinical case of one or more patients, are no longer considered third-party conferences in the revised Code and are not eligible for such grants, but may be conducted, and funded, as part of company-sponsored training and education. Where grants for third-party conferences are permitted, the revised Code authorizes a company to provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Further, companies may provide meals and refreshments to HCP attendees directly if: (1) provided to all HCP attendees (with a limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. Meals and refreshments may be provided to fewer than all HCP attendees if the company providing such meals and refreshments satisfies all other principles related to meals described in the “Modest Meals” section of

the revised Code. Moreover, meals and refreshments must also be clearly separate from the CME portion of the conference. A Frequently Asked Questions (FAQ) section of the revised Code concerning ancillary off-site meetings clarifies that a company is permitted to 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 the company complies with the conference sponsor's guidelines.

- **Consulting Arrangements with Health Care Professionals.** The revised Code sets forth compliance standards focused on increased documentation and ensuring that compensation is consistent with the fair market value for the services performed as part of an arm's length transaction. While sales personnel may provide input as to the suitability of a proposed consultant, they cannot control or unduly influence the decision of whether to engage a consultant. The revised Code contains a new section on the payment of royalties to HCPs. All royalty arrangements must meet the same standards as other consulting arrangements (*e.g.*, written contract, services clearly specified) 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 calculation of royalties payable to a HCP in exchange for intellectual property should be based on factors that preserve the objectivity of medical decision making and avoid the potential for improper influence by the company. Further, royalties should not be conditioned on an HCP's marketing of products upon commercialization, and companies are "strongly encouraged" to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units of a product purchased, used or ordered by the HCP or the HCP's practice.
- **Prohibition on Entertainment and Recreation.** The revised Code includes a new section that a company should not provide or pay for any entertainment or recreational activities. The Code currently in effect permits modest consultant entertainment under certain circumstances, while the revised Code imposes a strict prohibition on entertainment and recreation that extends to theater tickets, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips. In an FAQ, the revised Code, however, provides that it may be appropriate, depending on the circumstances, for an employee or agent of a company to engage in certain entertainment or recreation activities with a HCP if each pays his or her own way.
- **Modest Meals Associated with HCP Business Interactions.** The revised Code adds a new section on meals associated with HCP business interactions and specifies that meals can be provided to HCPs in connection with the presentation of scientific, education or business information. The meal should be incidental to the bona fide presentation of scientific, educational, or business information; provided in a manner consistent conducive to the presentation of such information; and should not be part of an entertainment or recreational event. A company may provide a meal only to HCPs who actually attend the meeting. Further, a company may not provide a meal for an entire office staff where everyone does not attend the meeting or at a meeting where a company's representative is not present (often referred to as "dine & dash" program). Such meals need not be provided exclusively in the physician office or hospital setting. Rather, meals off-site are permitted if (1) an on-site setting is not conducive to the presentation of scientific, education or business information, or (2) it is impracticable or inappropriate to provide meals at an on-site setting.

- **Educational Items and Prohibition on Gifts.** The 2005 AdvaMed Code permitted occasional gifts of branded promotional items of minimal value related to the HCP's work or for the benefit of patients. Under the revised AdvaMed Code, however, non-educational, branded promotional items are explicitly prohibited, even if an item is of minimal value and related to the HCP's practice, or even if the item is for the benefit of patients. Prohibited branded items include pens, notepads, mugs or similar "reminder" items that are branded with the company's name or with occasional reminder items that are branded with the company's name or logo. The revised Code, however, permits companies to occasionally provide modest items to HCPs that benefit patients or serve a genuine educational function for HCPs (e.g., medical textbooks or anatomical models used for educational purposes). Further, a company may not provide items that a HCP could use for non-educational or non-patient-related purposes (e.g., a DVD player or MP3 player/I-Pod).
- **Provision of Coverage, Reimbursement and Health Economics Information.** The revised Code has significantly expanded and modified the current provisions on reimbursement information and related activities. Companies may provide accurate, objective, timely and complete coverage, reimbursement and health economics information on their products. Moreover, companies may collaborate with HCPs, patients, and organizations that represent their interests to achieve government and commercial payor coverage decisions, guidelines, and policies, as well as adequate reimbursement levels that allow patients to access device products. Permissible activities recognized under the revised Code include, but are not limited to: identifying the 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 to HCPs about a company's product; 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. The provision of such information, however, cannot interfere with the HCP's prescribing or referral decisions and cannot involve providing free services that would eliminate an HCP's overhead or other expenses.
- **Evaluation and Demonstration Products.** The revised 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 products that may be provided to HCPs for evaluation such as single-use products and multiple use products and demonstration products. Specifically, for single use products (e.g., consumable or disposable products), the company must not provide more products than are needed for the evaluation. For multiple use products (e.g., capital equipment), the company should not provide the equipment for any longer than necessary to evaluate the products and should set the terms in advance and in writing. The company should retain title to the equipment, and have a process to immediately remove the equipment from the HCP at the end of the evaluation period. A demonstration product is generally an unsterilized, single-use product or mock up used for HCP or patient awareness, education, and training. Under the revised Code, companies should provide documentation of the free nature of evaluation and demonstration products.
- **Sales, Promotional, and Other Business Meetings.** This section of the revised Code has essentially remained the same as the original Code. However, in an FAQ, AdvaMed makes clear that companies

should select a location and venue for sales, promotional and other business meetings that are appropriate for, and conducive to, accomplishing the purpose of the meeting. Further, the selection of a resort location would not likely be appropriate and may give rise to an appearance of impropriety.

COMPLIANCE

The revised AdvaMed Code includes a new section on compliance. All companies are strongly encouraged to adopt the Code and to implement an effective compliance program. Companies that adopt the Code are strongly encouraged to submit an annual certification to AdvaMed that the company has implemented the Code and has adopted a compliance program. The certification must be signed by the company's Chief Executive Officer and Chief Compliance Officer (or equivalent individuals). Further, companies that are AdvaMed members must, and companies that are non-members may, supply contact information for the company's Compliance Department or an anonymous hotline to facilitate reporting of possible violations of the Code. AdvaMed will publish on its website a list of companies that have submitted the annual certification and contact information supplied for each company. Companies are also strongly encouraged to follow the seven elements of an effective compliance program which include: (1) written policies and procedures; (2) compliance officer and committee; (3) effective training and education; (4) effective lines of communication; (5) internal monitoring and audit; enforcement through well-publicized disciplinary guidelines; and (7) prompt response to problems and corrective action.

PRACTICAL CONSIDERATIONS

Companies that choose to adopt the revised AdvaMed Code must review and, where applicable, amend their compliance policies and procedures by July 1, 2009. Device companies that adopt the revised Code will also need to update their training programs. Finally, device companies should evaluate how the revised Code will affect sales and marketing policies and practices.

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