LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D. C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329

www.hpm.com

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MEMORANDUM

Re: Revised AdvaMed Code

On December 18, 2008, the Advanced Medical Technology Association (AdvaMed) released a revised "Code on Ethics on Interactions with Health Care Professionals."[1] The revised AdvaMed Code, which will become effective on July 1, 2009, is more restrictive and detailed than the 2005 version of the AdvaMed Code.

The AdvaMed revision adopts some of the new restrictions in the updated Pharmaceutical Research and Manufacturers of America (PhRMA) "Code on Interactions with Healthcare Professionals," which will become effective on January 1, 2009.[2] The most significant changes to the AdvaMed Code, and a brief comparison of the AdvaMed update to the PhRMA Code, are provided below.

Evaluation and Demonstration Products

- The revised Code includes a new section that allows companies to provide single or multiple use products at no charge to allow health care professionals to evaluate the product. 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

1 The revised AdvaMed Code is available on AdvaMed's web site at http://www.advamed.org/MemberPortal/About/code.

2 The revised PhRMA Code is available on PhRMA's web site at http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf.

4819 EMPEROR BOULEVARD
SUITE 400
DURHAM, NORTH CAROLINA 27703
(919) 313-4750
FAX (919) 313-4751

health care professional at the end of the evaluation period. A demonstration product generally is an unsterilized, single-use product or mock up used for health care professional or patient awareness, education, and training. Companies should provide documentation of the free nature of evaluation and demonstration products.

Provision of Coverage, Reimbursement, and Health Economics Information

- Although the 2005 version of the AdvaMed Code contained provisions regarding the provision of reimbursement information, the revised Code substantially expands that discussion. Companies may provide accurate, objective, timely, and complete coverage, reimbursement, and health economic information regarding their products. Moreover, companies may collaborate with health care professionals, 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 Medical Technologies.

- *Enumerated Permissable Activities Related to Coverage, Reimbursement and Health Economics Issues*: The Code provides a list of examples of permissible activities related to coverage, reimbursement, and health economics issues. These explicitly sanctioned activities related to coverage, reimbursement, and health economics issues include the following:
    - Identifying clinical value of Medical Technologies
    - Collaborating with health care professionals and others to engage in joint advocacy on coverage, reimbursement, and health economics issues
    - Providing accurate and objective information and materials to health care providers regarding Medical Technologies, including identifying potentially applicable coverage, codes, and billing options, thus promoting accurate Medicare and other payor claims
    - Providing accurate and objective information on economically efficient Medical Technology use
    - Providing information on reimbursement revenues and costs
    - Providing information on changes to coverage or reimbursement amounts, methodologies, and policies
    - Providing accurate and objective information intended to offer technical and other support
    - Assisting health care providers with obtaining patient coverage decisions from payors

- *Prohibition against Using Reimbursement Support As Inducement*: The AdvaMed Code cautions that companies cannot provide reimbursement support as an unlawful inducement. For example, companies should not provide free services that eliminate an overhead or other expense that a health care professional would have incurred as part of its business operations if doing so would amount to an unlawful inducement.

Consulting Arrangements with Health Care Professionals

- *Compliance Standards*: AdvaMed added significant detail to the compliance standards. The amended compliance standards focus on increased documentation, including requiring a written protocol for clinical research services, and ensuring that compensation is consistent with the fair market value in an arm's length transaction for the services rendered. While sales personnel may provide input regarding the suitability if a proposed consultant, they may not control or unduly influence the decision to engage a particular health care professional as a consultant.

- *Royalties*: The revised Code adds a new section related to royalty payments. Royalty payments, according to the Code, must meet the general compliance standards for consultant arrangements with health care professionals. In addition, the company should enter royalty arrangements only when the health care professional is expected to make, or has made, a novel, significant, or innovative contribution. That contribution could include a contribution to the development of a product, technology, process, or method. The company should appropriately document a significant contribution of an individual or group if that contribution is the basis for compensation.

- *Calculating Royalties*: The company should calculate the royalties based on factors that preserve the objectivity of medical decision-making and avoid improper influence. For example, the company should not condition royalties on a requirement that the health care professional purchase, order, or recommend any product or Medical Technology of the company or any product or technology produced as a result of the project. The company also should not condition royalties on a requirement to market the product or Medical Technology upon commercialization. The Code strongly encourages companies to consider whether it is appropriate and practical to exclude from royalty calculations the number of units of a product that a health care professional or his group purchased, used, or ordered.

Modest Meals Associated with Health Care Professional Business Interactions

- *Meals Incidental to the Bona Fide Presentation of Scientific, Educational, or Business Information*: The revised Code includes a new section on such meals. The Code states that the company may provide modest meals as an occasional business courtesy in connection with the business interactions with health care professionals that involve the presentation of scientific, educational, or business information. The meal should be incidental to the *bona fide* presentation of scientific, educational, or business information and be presented in a manner conducive to the presentation of the information. A business presentation includes a substantial discussion of product development/improvement, pricing, and contract negotiation, but it does not include development of good will or business relationships (FAQ 37). The meal should not be part of an entertainment or recreational event.

- *Setting and Location of Meals Incidental to the Bona-Fide Presentation of Scientific, Educational, or Business Information*: The company should offer meals in a location conducive to *bona fide* scientific, educational, or business discussions. Such meals may occur at the health care professional's site. A company can provide meals off-site if the health care professional's site is inappropriate or impractical. For instance, a company can provide meals off-site if the company cannot easily transport the Medical Technology to the health care professional's location; the company is discussing confidential product development or improvement information; or the company cannot obtain a private space.

- *No Take-out or Meals for Guests*: The company may only provide meals for health care professionals who actually attend the meals. The company also may not provide meals for guests of health care professionals or any other person without a *bona fide* professional interest in the information.

Supporting Third-Party Education Conferences

- *Types of Conferences*: As with the prior Code, the revised Code states that the company may provide support for conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education (CME) providers. However, under the revised Code, grand rounds are no longer considered third-party educational conferences.

- *Conference Grants*: The revised Code provides more detail regarding the requirements for providing a grant to a conference sponsor to reduce conference costs or to a training institution or conference sponsor to allow attendance by medical students, residents, fellow, and others who are in health care professionals in training.

- *Conference Meals and Refreshments*: The revised Code clarifies that a company may only provide meals and refreshments under certain circumstances (and no longer allows the company to provide receptions and hospitality). The company may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. The company may provide meals and refreshments directly if provided to all health care professional attendees and in a manner consistent with the standards of the sponsor of the conference and the body accrediting the educational activity.[3] As before, meals and refreshments must be modest in value and subordinate in time and focus to the purpose of the conference. Under the revised Code, the meals and refreshments must also be clearly separate from the CME portion of the conference.

- *Ancillary Off-site Meetings*: The revised Code FAQ states that a company may sponsor an off-site sales, promotional, or other business meeting that is ancillary to a third-party educational conference, provided that the activity has a legitimate business purpose, meets all applicable requirements of the Code, and complies with applicable conference sponsor guidelines (FAQ 21).

Educational Items: Prohibition on Gifts

- *Non-educational Branded Items Prohibited*: The revised Code no longer permits a company to provide non-educational branded promotional items, such as pens, note pads, mugs, or other items with the company's logo, even if the item is of minimal value and related to the health care professional's work or for the benefit of patients.

- *Modest Value Items for Patient Benefit or Educational Function*: The Code permits companies to occasionally offer to health care professionals modest value items if they benefit patients or serve a genuine educational function. Any items

[3] The company may provide meals and refreshments to fewer than all health care professional attending the conference if the company providing the meals complies with all the requirements in the section of the revised Code relating to meals.

should have a value of $100 or less, except for medical textbooks or anatomical models used for educational purposes. Items for the benefit of patients include starter kits and educational brochures, but do not include scrubs or office supplies (FAQ 42).

- *Significant Life Events*: Unlike the 2005 AdvaMed Code, the revised Code prohibits the company from giving small gifts to a health care professional upon a significant life event (FAQ 40).

Prohibition on Entertainment and Recreation

- The revised Code adds a provision that prohibits companies from providing or paying for entertainment or recreational events or activities for non-employee health care professionals. Entertainment or recreational activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips. The prohibition is a categorical one: a company should not provide entertainment or recreational items regardless of the items' value, whether the health care professional is a speaker or consultant, or whether the entertainment is secondary to an educational purpose.

Code Compliance

- *Compliance Program*: AdvaMed's Code "strongly encourages" companies to adopt the Code and to implement an effective compliance program that incorporates seven elements outlined in the Code, as appropriately tailored for each company's size, resources, particular lines of business, and workforce (FAQ 15). The seven elements of an effective compliance program include:
    - Written policies and procedures
    - Compliance officer and committee
    - Effective training and education
    - Effective lines of communication including a mechanism for anonymous reporting
    - Internal monitoring and auditing
    - Enforcement through well-publicized disciplinary guidelines
    - Prompt response to problems and corrective action

- *Certification program*: AdvaMed's Code also "strongly encourages" companies who adopt the Code to certify annually that they have adopted the revised Code and implemented an effective compliance program. The chief executive officer and chief compliance officer, or individuals with equivalent responsibilities, must sign the certification. AdvaMed advises companies to submit certifications no

later than July 1 of each year, starting in 2010. The trade association will provide a certification form the companies should use (FAQ 11).

- *Compliance Department Contact Information*: AdvaMed members must, and non-member companies may, provide contact information for their compliance department or anonymous hotline to facilitate reporting violations. AdvaMed will publish that information on its website.

Comparison to the PhRMA Code

- *General Movement of AdvaMed Code Towards PhRMA Code*: The revised AdvaMed Code incorporates many of the new restrictions added to the revised PhRMA Code, particularly in the areas of prohibitions on promotional items of minimal value such as pens and the prohibition on providing entertainment or recreational events.

    - *AdvaMed Code Essentially Adopts PhRMA Code Prohibition of Non-Educational Branded Items*: Under the most recent version of the PhRMA Code, companies may no longer offer minimal value, practice related items such as pens, clipboards, note pads, mugs, and other reminder items. This prohibition also applies to minimal value items offered at third-party professional or scientific meetings.

    - *AdvaMed Code Essentially Adopts PhRMA Code Prohibition on Entertainment or Recreational Events*: The 2002 version of the PhRMA Code prohibited the offer of entertainment or recreational events to health care professionals except in the context of advisory board and other consultant meetings and speaker training meetings. The revised Code removed this exception and prohibits entertainment, recreational items, and vacation trips from being offered to any health care professional who is not a salaried employee of the company.

    - *AdvaMed Restrictions on Meals Incidental to Scientific Presentations Similar to PhRMA Code*: The PhRMA Code expressly prohibits sales representatives or their immediate supervisors from providing meals off-site, whereas the AdvaMed Code is more permissive on this point.

    - *Compliance Programs, Certification, and External Verification*: Both the PhRMA and AdvaMed Codes now contain provisions for annual certification and easy dissemination of compliance contact information; however, the PhRMA Code does not spell out the seven factors for

effective compliance. The PhRMA Code also encourages companies to seek external verification, at least every three years, that the company has policies and procedures in place to foster compliance with the Code. AdvaMed's Code does not call for external verification of compliance.

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Please contact Alan Kirschenbaum (202-737-4283, amk@hpm.com), Jeff Wasserstein (202-737-9627, jnw@hpm.com), or Michelle Butler (202-737-7551, mlb@hpm.com) if you have any questions about the revised AdvaMed Code.