



JONES DAY  
**COMMENTARY**

## **ADVAMED'S REVISED *CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS* SCHEDULED TO BE EFFECTIVE JULY 1, 2009**

The Advanced Medical Technology Association (“AdvaMed”) represents companies that develop, provide, market, and manufacture medical products, technologies, and related services and therapies (“Companies”). In conjunction with AdvaMed’s focus on improving patient care and advancing medical science, it aims to facilitate ethical interactions between Companies and Health Care Professionals. AdvaMed broadly defines “Health Care Professionals” as “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.” One of the ways that AdvaMed promotes the need for ethical interactions between Companies and Health Care Professionals is through its *Code of Ethics on Interactions with Health Care Professionals* (“Code”).

The Code was first updated in 2003 after the AdvaMed directors approved efforts focused on training and education of Company personnel and Health Care Professionals dealing with sales and promotions. In 2005, AdvaMed updated the Code to include additional frequently asked questions regarding gifts and types of financial support. It also launched a web site so the public could easily search for contact information for compliance officers at medical technology companies. In 2006, AdvaMed further expanded its efforts to promote ethical interactions between Companies and Health Care Professionals by initiating a logo program whereby AdvaMed member and nonmember Companies could certify compliance with the AdvaMed Code.

Most recently, on December 18, 2008, AdvaMed announced that its board of directors had unanimously

approved revisions to its Code to be effective July 1, 2009.<sup>1</sup> The purpose of the Code is to ensure that (a) Companies and Health Care Professionals have collaborative relationships that meet high ethical standards; (b) medical decisions are based on the best interests of patients; and (c) Companies and Health Care Professionals comply with applicable laws, regulations, and government guidance. AdvaMed's revisions to its Code follow revisions the Pharmaceutical Research and Manufacturers of America ("PhRMA") made to its *Code on Interactions with Healthcare Professionals*, which took effect in January 2009.<sup>2</sup> PhRMA represents research-based pharmaceutical and biotechnology companies. The cumulative revisions to both the AdvaMed Code and the PhRMA Code signify increased limitations on provider interactions.

This *Commentary* addresses some of the key revisions to the AdvaMed Code. Health care providers should read the revised Code and develop a strategic plan to implement the guidelines that AdvaMed sets forth. As more Companies focus on compliance initiatives, it is inevitable that greater attention will be placed on all health care providers. Companies do not operate in silos. Instead, they interact with a variety of health care providers, including hospitals and physician groups. When compliance concerns are raised about a Company, health care providers are often embroiled in the circumstances as well.

## COMMITMENT AND TRANSPARENCY

One of the striking revisions to the Code is in the section titled "Code of Ethics Compliance." AdvaMed "strongly encourages" all Companies to adopt the revised Code, implement effective compliance programs, and submit annual certifications to AdvaMed attesting that they have taken such actions. AdvaMed will publish on its web site a list of all Companies that have submitted the annual certification.

Further, the Code states that "Companies that are AdvaMed members shall, 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." This contact information will be published on AdvaMed's web site. The revised Code also sets forth the seven elements of an effective compliance program, and AdvaMed strongly encourages Companies to follow the seven elements.

## ROYALTY ARRANGEMENTS

The revised Code sets forth guidelines that will allow Companies to enter into royalty arrangements with Health Care Professionals in exchange for contributions that improve medical technologies. If a Health Care Professional intends to enter into a royalty arrangement with a Company, the arrangement should meet the standards AdvaMed sets forth under a section of the Code entitled, "Consulting Arrangements with Health Care Professionals." AdvaMed has also developed specific guidelines related to royalty arrangements. For example, the calculation of royalty payments "should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence." Royalty payments should not be conditioned on a requirement that the Health Care Professional purchase, order, or recommend a product or technology of the Company or that was produced as a result of the development project. Further, royalty payments should not be conditioned on a requirement that the Health Care Professional market the product or medical technology upon commercialization. If your organization enters into, or has physicians that enter into, royalty arrangements, it is important to carefully review the revisions in the Code and develop safeguards to prevent potentially inappropriate behavior.

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1. The revised Code is available at <http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>.

2. The revised PhRMA Code is available at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.

## PROHIBITION ON ENTERTAINMENT AND RECREATION

The revised Code contains a new section related to Companies providing entertainment and recreation to Health Care Professionals. Specifically, Companies should not provide or pay for any activity or recreation (e.g., theater, sporting events, skiing, or sporting equipment) for any Health Care Professional who is not an employee of the Company. The revised Code emphasizes the strict prohibition on entertainment and recreational events by stating that these items should not be provided regardless of “(1) their value; (2) whether the Company engages the Health Care Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.” All Health Care Professionals should be mindful of this strict prohibition and refuse any type of entertainment and recreation that a Company may offer. The answers to the Frequently Asked Questions (“FAQs”) in the revised Code say that a Company’s employee or agent may not skirt around the meal and refreshment restrictions by paying for the benefit themselves and not receiving reimbursement from the Company. However, “[d]epending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.” In the FAQs section of the revised Code, AdvaMed states that it would be inappropriate for a Company to provide support for a Health Care Professional-sponsored social event, such as a holiday party.

## MODEST MEALS ASSOCIATED WITH HEALTH CARE PROFESSIONAL BUSINESS INTERACTIONS

AdvaMed acknowledges that many beneficial exchanges regarding scientific, educational, and business information between Companies and Health Care Professionals happen in conjunction with meals. Therefore, AdvaMed sets forth limitations that, if met, allow for modest meals to be provided to Health Care Professionals as an occasional business courtesy. The meal must be incidental to the *bona fide* presentation of scientific, educational, or business information and should not be part of an entertainment or recreational event. Further, the meal should be in a setting that is conducive to *bona fide* scientific, educational, or

business discussions, which, depending on the type of technology needed for the demonstration or the confidentiality required for the discussion, may or may not be the Health Care Professional’s place of business. Companies may only provide meals to Health Care Professionals who attend the meeting, a Company representative must be present, and a Company may not provide meals for guests of Health Care Professionals or people who do not have a *bona fide* interest in the content of the meeting.

## PROVISION OF COVERAGE, REIMBURSEMENT, AND HEALTH ECONOMICS INFORMATION

AdvaMed greatly expands on the concept of coverage, reimbursement, and health economics information in the revised Code. The revised Code contains distinct examples of permissible activities. For example, Companies may collaborate with “Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economic issues.” In addition, Companies may provide objective information about the “economically efficient” use of their medical technologies, available reimbursement revenues and associated costs, or technical or other support related to the use or installation of the Company’s medical technology.

## EVALUATION AND DEMONSTRATION PRODUCTS

The revised Code also contains a new section that sets forth guidelines on how Companies may provide products to educate Health Care Professionals and patients on newer and improved technologies. AdvaMed acknowledges that there is a benefit to patients when products are provided to Health Care Professionals at no charge for evaluation and demonstration purposes. In order to balance the potential risks that may arise when Companies provide products for evaluation and demonstration projects with a potential benefit to patients, AdvaMed sets forth guidelines for the provision of single-use products, multiple-use products, and company demonstration products. For example, for single-use products, the number of products provided at no charge “should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.”

In the FAQs section of the revised Code, AdvaMed states that when a Company provides a product at no charge to a Health Care Professional, the period for which the Health Care Professional may keep the product depends on the “frequency of anticipated use, the duration of required training, the number of Health Care Professionals who will need to evaluate the product, [and] the length of time necessary to evaluate different product features.” Health care providers who receive evaluation and demonstration products should evaluate all of the aforementioned factors when they receive products from Companies.

## CONCLUSION

All health care providers should review the revised Code and evaluate their interactions, policies and procedures, and possible risk areas related to interactions and arrangements with medical device companies. If your organization interacts with such companies, you should expect greater limitations on your relationships with them. The FAQs in the revised Code are helpful because they provide concrete examples

and present scenarios that many health care providers might face. As the demand for transparency in the health care industry increases, more health care organizations will need to confront the reality that their daily operations and strategic decisions are influenced by a variety of constituents, and will in turn be analyzed by various stakeholders for compliance.

## LAWYER CONTACTS

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our “Contact Us” form, which can be found at [www.jonesday.com](http://www.jonesday.com).

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