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A graphic with the words "IN PRINT" in large, white, sans-serif capital letters. The background is a collage of orange-toned images including a stack of books, a magnifying glass, a keyboard, and a document.

## ADVAMED'S REVISED CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

Scheduled to Be Effective July 1, 2009

By Frank E. Sheeder III and Keri Tonn

One of the many tasks that health care compliance professionals must be prepared to address regularly revolves around the type and frequency of interactions between health care providers, drug manufacturers, device companies, and other similar company representatives. One of the sources that many compliance professionals might have previously consulted is the Code of Ethics on Interactions with Health Care Professionals ("Code") published by the Advanced Medical Technology Association ("AdvaMed"). 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," broadly defined 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. The Code was first updated in 2003, after the AdvaMed

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directors approved efforts focused on the training and education of Company personnel and Health Care Professionals who deal 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 that 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:

- Companies and Health Care Professionals have collaborative relationships that meet high ethical standards;
- Medical decisions are based on the best interests of patients; and
- 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 article addresses some of the key revisions to the AdvaMed Code. Health care providers and compliance professionals should read the revised Code and develop a strategic plan to implement the guidelines that AdvaMed sets forth. For example, health care compliance officers should consider revising internal policies and procedures regarding interactions with Companies. In addition, compliance professionals may need to provide updated training and education to health care providers and employees who frequently

interact with Company representatives. 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. Consequently, compliance professionals should take a proactive stance to better protect their own organizations from being included in any concerns raised about a Company.

## COMMITMENT AND TRANSPARENCY

One of the striking revisions to the Code is in the section titled "Code of Ethics Compliance." AdvaMed "strongly encourage[s]" all Companies to adopt the revised Code, implement effective compliance programs, and submit annual certifications to AdvaMed to attest that they have taken such actions. AdvaMed will publish on its web site a list of all Companies that have submitted the annual certification. It might be a useful exercise for compliance professionals to compare the list of Companies on AdvaMed's web site to the list of Companies with which the health care organization has relationships.

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

<sup>1</sup> The revised AdvaMed Code is available at <http://www.advamed.org/NR/ronlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>. (Both web sites herein were last visited on May 19, 2009.)

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

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 who enter into, royalty arrangements, it is important to carefully review the revisions in the Code and develop safeguards to prevent potentially inappropriate behavior. For example, compliance professionals should consider surveying all of the parties associated with their organizations that are involved in royalty arrangements, evaluating whether those arrangements would satisfy revisions to the Code and, if not, taking necessary steps to make sure future royalty arrangements meet the AdvaMed Code standards.

## **PROHIBITION ON ENTERTAINMENT AND RECREATION**

The revised Code contains a new section related to Companies that provide 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 nonemployee Health Care Professional. 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. Compliance professionals should take appropriate measures to educate employees about these restrictions and how and to whom to report potential violations of this section in the Code.

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 him- or herself 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 FAQ 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. One way that compliance professionals can better protect their organizations from being involved in questionable conduct under the AdvaMed Code is to carefully track and monitor all social events at their organizations, including where the funds for such events originated.

## **MODEST MEALS AT 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 provide meals only 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 economics 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 about 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 FAQ 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

Health care providers and compliance professionals should review the revised Code and evaluate their interactions, policies and procedures, training and educational programs, 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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