AdvaMed Updates Code of Ethics on Interactions with Health Care Professionals

Thursday, February 7, 2019

For the first time since 2008, the Advanced Medical Technology Association ("AdvaMed") has updated its "Code of Ethics on Interactions with Health Care Professionals." These updates were announced on January 9, 2019, and will become effective on January 1, 2020.

AdvaMed’s goal in updating the Code was to address the evolving nature of interactions between the medical device industry and health care professionals ("HCPs"), bring existing examples up-to-date, and enhance user-friendliness. Topics that were previously covered in multiple areas of the Code are now consolidated into more comprehensive sections on Company programs, Third-Party Programs, Travel, and Meals. There are also three new sections on: Jointly Conducted Education and Marketing Programs, Communicating for the Safe and Effective Use of Medical Technology, and Company Representatives Providing Technical Support in the Clinical Setting. Additionally, the updated Code includes language that clarifies when it is acceptable to provide evaluation products and adds additional detail to the section on Consulting. These changes are explained in further detail below.

Consulting Arrangements with HCPs

While the updated section on consulting arrangements retains much of the same content as the previous version, it also provides additional clarity on determining whether there is a legitimate need for consulting services, explaining that a legitimate need arises when a company requires the services of an HCP to achieve a specific objective. It also specifies that rewarding an HCP for referrals, or designing an arrangement to generate business, are not considered legitimate needs. Additionally, the updated section includes criteria on how manufacturers can establish fair market value compensation rates for consulting services. These include the HCP’s specialty, years and type of experience, geographic location, practice setting, and the type of service performed.

Third-Party Programs

The updated Code consolidates existing language on providing support for third-party educational, charitable, and research programs into one section on grants, donations, and commercial sponsorships. This section includes a checklist that companies can use to review requests for educational grants, and adds language on whether companies can host satellite symposia. It also expands and clarifies the requirements for supporting independent research grant requests or charitable donations.

Travel and Meals

The updated Code also consolidates its previous guidance on travel and lodging into one section and provides clarity on situations for which a company may pay for travel and lodging expenses (e.g., consulting, training, legitimate need for meeting, HCP presence) and when such payments are prohibited (e.g., general education,
attending a third-party program, no legitimate need). It also includes additional information on evaluating appropriate venues for meetings, taking into consideration whether the venue is in a central location and whether it is conducive to an exchange of information. The added language also places a limit on “top category” or luxury hotels.

**Jointly Conducted Education and Marketing Programs**

The Code’s new section on Jointly Conducted Education and Marketing Programs explains that these types of programs are typically educational programs that are aimed at highlighting a medical technology as well as an HCP’s ability to treat a condition using that technology (e.g., a manufacturer promotes its surgical implant device while a surgeon discusses his or her ability to perform the implant procedure using the device.) AdvaMed acknowledges the benefits of such jointly conducted programs; however, it also advises manufacturers to follow certain principles to ensure that the program does not unduly benefit the HCP in a manner that violates the Anti-Kickback Statute. For example, the manufacturer and the HCP must establish a bona fide partnership, meaning the arrangement should be documented in a written agreement and any contributions and costs should be shared equitably between them.

**Communications & Technical Support**

The updated Code also features a new section on communicating for the safe and effective use of medical technology, which sets forth principles for communicating information on unapproved or uncleared uses. For example, communications should be truthful and non-misleading, provided by authorized personnel, and appropriately identified as off-label. AdvaMed advises that companies develop policies on the dissemination of off-label information based on existing guidance.

The final new section added to the Code is on the provision of technical support in the clinical setting. This section provides guidelines for company representatives who provide technical support in this setting to follow. This includes, but is not limited to, being transparent that they are acting on behalf of the company and not interfering with an HCP’s clinical decision-making.

Although only certain states, such as California, Nevada, and Connecticut, have required device manufacturers to model their compliance programs after principles set forth in AdvaMed’s Code of Ethics, the Code has long been relied upon as the industry standard for maintaining ethical and compliant relationships between device manufacturers and HCPs. As such, manufacturers should carefully review the changes that have been made to the Code and update their internal policies and procedures as necessary. Manufacturers in states like California, Nevada, and Connecticut should also look out for any updates in their states’ legislation to adopt the changes made to the Code.

The updated Code is available [here](https://www.natlawreview.com/article/advamed-updates-code-ethics-interactions-health-care-professionals) and a brief overview of the changes can be found [here](https://www.natlawreview.com/article/advamed-updates-code-ethics-interactions-health-care-professionals).  

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