AdvaMed Issues Revised Code of Ethics on Interactions with Health Care Professionals

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On January 9, 2019, the Advanced Medical Technology Association (AdvaMed) issued a press release announcing approval of an updated *Code of Ethics on Interactions with Health Care Professionals (HCPs) in the U.S.*.[1] The Code provides voluntary guidelines for interactions with HCPs in the medical technology context.

Background

Medical technologies (i.e., tools, devices, and technologies) frequently require training and an in-depth understanding of how a product works to ensure the technology's safe and effective use. Interactions between HCPs and medical technology companies are critical to enabling these trainings and exchanges, and AdvaMed developed guidelines in the form of the Code of Ethics to help facilitate these interactions. While the Code does not create legal rights or obligations, it does help companies make decisions that align with the Code's cornerstone values: innovation, education, integrity, respect, responsibility, and transparency. In turn, compliance with the Code helps to ensure compliance with applicable state and federal requirements.

Prior to the revisions, the Code included sections on the following topics: Company-Conducted Product Training and Education; Supporting Third-Party Educational Conferences; Sales, Promotional, and Other Business Meetings; Consulting Arrangements with Health Care Professionals; Prohibition on Entertainment and Recreation; Modest Meals Associated with Health Care Professional Business Interactions; Educational Items & Prohibition on Gifts; Provision of Coverage, Reimbursement and Health Economics Information; Research and Educational Grants and Charitable Donations; and Evaluation and Demonstration Products. The revised Code retains these sections and adds the following new topics:

- Jointly Conducted Education and Marketing Programs;
- Communicating for the Safe & Effective Use of Medical Technology;
- Consigned Products; and
- Company Representatives Providing Technical Support in the Clinical Setting.

Code Revisions

Jointly Conducted Education and Marketing Programs

The new section on Jointly Conducted Education and Marketing Programs covers education and marketing programs jointly conducted by medical technology companies and HCPs. According to the revised Code, the following guiding principles apply to these programs:

- There must be a bona fide, legitimate need for the company to engage in the activity for its own education or marketing benefit;
- There should be established controls to help ensure decisions to engage in these arrangements are not made as an unlawful inducement;
- The programs should be balanced, meaning the programs promote (1) the company and its

1 A copy of the revised and restated code is available at: https://www.advamed.org/sites/default/files/resource/advamed_u.s._code_of_ethics_final_-_eff._jan_1_2020.pdf

medical technology and (2) the HCP and the services he or she offers related to the medical condition;
- The company and HCP should be bona fide partners in the program and make equitable contributions toward activities and costs; and
- The arrangement should be documented in a written agreement that includes the purpose of the arrangement and the roles, responsibilities, and expectations for the parties involved, including payment of costs.

Communicating for the Safe & Effective Use of Medical Technology

The new section on Communicating for the Safe & Effective Use of Medical Technology applies to communications regarding a product's use, including uses described in the product's labeling, uses consistent with the label, and off-label uses. Receiving information related to a product's on- and off-label uses is critical for HCPs to be able to apply sound medical judgment and provide medical care in the best interest of a patient. The Code provides a number of examples of industry appropriate communications of on and off-label uses of a medical technology, i.e., proper dissemination of peer-reviewed scientific and medical journal articles, and provides the following principles to guide these communications:

- Only authorized personnel should provide company responses regarding unapproved or uncleared uses of a product;
- The communications must be truthful and non-misleading; and
- Information regarding unapproved or uncleared uses should be identified as such.

The Code encourages companies to develop policies based on these principles and that incorporate applicable requirements from the Food & Drug Administration, judicial decisions related to appropriate product communications, and other applicable sources.

Consigned Products

The revised Code also includes information on consigned products and consignment arrangements. The subsection on Consigned Products defines "consigned products" to mean medical technologies that a company provides to an HCP for use in and storage at the HCP's patient care setting and to which the company retains title until the product is used. The Code notes that, in general, consignment arrangements should be the subject of an arrangement that addresses the terms of consignment. Companies using consignment arrangements are also encouraged to consider implementing appropriate controls, such as periodic review of consigned devices inventory for purposes of billing and restocking.

Company Representatives Providing Technical Support in the Clinical Setting

The new section on Company Representatives Providing Technical Support in the Clinical Setting provides guiding principles for companies to follow to help facilitate interactions in the health care setting, while also ensuring that a representative does not interfere or unduly prejudice HCP clinical judgment. The guiding principles include the following:

- Representatives should enter and be present in the clinical setting only upon the request of and under the supervision of an HCP;
- Representatives should make it transparent that they are acting on behalf of the company in a technical support capacity;
- Representatives should not interfere with HCP clinical decision-making;
- Representatives should comply with applicable facility policies and requirements; and
- The company's technical support should not eliminate overhead or another expense that the HCP would otherwise incur.

AGG Observations

- The revisions to the Code go into effect on January 1, 2020, allowing almost a year for companies to align with the revisions.

- The revisions highlight additional scenarios and interactions with HCPs in which it is important to balance the need to educate the HCP on the safe and effective use of a medical technology while avoiding compromising the HCP's clinical decision-making.
- Companies should review existing compliance policies to ensure they are updated to align with the revised Code's changes.

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