PUBLICATION

AdvaMed Issues a New Code of Ethics a Decade Later

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Advanced Medical Technology Association (AdvaMed) has released the first update to its Code of Ethics on Interactions with U.S. Health Care Professionals (the Code) since July 2009. The new Code, announced January 9, 2019, goes into effect on January 1, 2020, allowing the industry to prepare for the changes.

The Code updates "reflect evolving legal standards, care delivery models and best practices over the last decade." AdvaMed produced an overview of the changes to the Code, which explains that the update consolidates many of the 2009 Code sections, adds clarifying language and definitions in some sections, and introduces new sections. In addition, the Code provides several formatting changes that enhance the look of the Code and result in a more user-friendly document – adding key concepts for each section, takeaways, visuals and graphics, helpful explanations, and FAQs.

The Code is a guidance document for medical technology companies on proper interactions with health care professionals that comply with the federal and state laws and regulations that govern such interactions, but also provides useful guidance that can be transferred to or applied to other health care industries. While not a formal binding guidance document issued by the government, adherence to the Code can form a baseline for the government in evaluating whether business practices are both ethically and socially responsible and in compliance with applicable federal and state laws. In addition, certain states have adopted laws that provide explicit reference to the Code and/or mandatory compliance with the Code requirements (i.e., California, Connecticut, and Nevada).

The key updates are discussed below.

New Sections

The Code contains new sections on jointly conducted education and marketing, communications for safe and effective use of technology, and guidelines for providing technical support in clinical settings.

Jointly Conducted Education and Marketing Programs (New Section V)

A Health Care Professional (HCP) and a Medical Technology Company (Company) may partner to provide education and marketing programs. However, the Code encourages the Company to apply the following guidelines:

1. There should be a bona fide need for the services.
2. The Company should implement some controls to ensure that the arrangement does not become an unlawful inducement.
3. The programs should be balanced and should promote both the Company and the HCP services.
4. The HCP and the Company should equitably share the contributions for cost and program activities.
5. The arrangement should be in writing and should set forth the roles, responsibilities, and contributions of each party.

Communicating for the Safe and Effective Use of Medical Technology (New Section X)

This new section highlights the importance of communications that provide "truthful and non-misleading" information about the use of medical technologies. The Code encourages access to information about on- and off-label technologies and states that such communication often leads to high-quality patient care and the safe use of medical technologies. Examples of communications include: distribution of peer-reviewed scientific and medical journals, texts, and practice guidelines; presentations about clinical research and data for investigational use (as long as the data does not make claims of safety and effectiveness); and discussions with HCPs and consultants to obtain advice and feedback.

The Code also lists three principles for responsible communication:

6. The information communicated must be truthful and not misleading.
7. Information related to unapproved or uncleared uses should be identified as such.
8. Responses that contain information about unapproved or uncleared uses should be provided by authorized personnel.

The Code encourages Companies to develop controls and policies based on these principles.

Company Representatives Providing Technical Support in the Clinical Setting (New Section XIII)

This section acknowledges the value of Company representatives in providing technical support in the clinical setting. In such settings Companies should adopt these five principles:

9. Company representatives should enter the clinical setting only at the HCP's request and must be under the HCP's supervision.
10. Company representatives should identify themselves as a technical support representative for the Company.
11. Company representatives should not interfere with an HCP's clinical decisions.
12. Company representatives should comply with facility policies and requirements.
13. Company representatives' technical support should not eliminate the HCP's overhead expenses related to patient care.

Code Clarifications, Consolidations, and Other Useful Updates

The Code clarifies and consolidates different portions of the Introduction and the sections addressing consulting, third-party programs, travel, meals, and demonstrations and evaluations of product. Some of the key highlights are below:

Introduction (Section I)

The Introduction defines new terms including *satellite symposium*, *commercial sponsorship*, *educational grant*, *third-party program*, and *third-party program organizer*.

Consulting (Section II)

The consulting section provides clarification to the term *legitimate need*, gives further guidance on fair market value (FMV) methodologies, and provides guidance on conflicts of interest.

14. The Code clarifies that a *legitimate need* for a consulting service arises when the HCP's services are needed for a particular objective. The Code notes that creating an agreement to generate business or referrals is not a legitimate need.

15. The Code provides examples of the qualifications that should be factored into the selection of a consultant. Examples of objective factors include: the HCP's specialty and years of experience, the location of the HCP, and the type of practice setting.
16. Companies should use a FMV methodology based on objective criteria and should document the methodology used.
17. The consulting section also cautions Companies to be mindful of potential conflicts of interest that may arise from their relationship with an HCP.

Third-Party Programs (Section IV)

Section IV consolidates the old sections on third-party educational, research, and charitable programs and adds some new provisions.

18. The Code now provides a six-item checklist for evaluating requests to support third-party programs.
19. Companies may now host satellite symposia as long as they promote the symposia in a transparent manner.
20. Education grant funds can be used to purchase permissible items of value under the Code for HCPs (such as modest meals, refreshments, and educational items).

Travel and Lodging (Section VI)

The travel and lodging section consolidates the old guidance. In addition, it provides detailed guidance on when an HCP's travel expenses are covered and guidance for assessing appropriate meeting venues and locations.

Meals (Section VII)

The meals section consolidates the old guidance on meals into one section and encourages Companies to develop policies governing the provision of meals to HCPs.

Demonstration and Evaluation Product (Section XII)

The Code introduces a new provision about consigned products. A *consigned product* is a medical technology that a Company provides for the HCP's use that the HCP stores at its location, even though the Company holds the title to the product. The Code advises Companies to implement controls around consigned products and to draft agreements for their consigned products arrangements. This section also highlights the appropriate reasons for providing evaluation products.

Next Steps

AdvaMed's Code has been and continues to be an important guidance document for the medical technology industry. The Code not only guides the industry's interactions with HCPs, but serves as a baseline for the government and related enforcement entities when evaluating the business practices of the medical technology industry. As such, the issuance of the updated Code is notable and warrants careful review and consideration. AdvaMed has provided ample time over the next year for the industry to adjust to the changes before the January 1, 2020 effective date. Medical technology companies and others that utilize the Code as guidance for shaping interactions with HCPs should take advantage of the time to carefully review the Code and revisit existing policies, procedures, and practices, and develop and implement additional policies and procedures as warranted to address the Code's new sections.