

AdvaMed Releases Updated Code of Ethics on Interactions with Health Care Professionals

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Key Points

- Revisions to the Code go into effect on January 1, 2020, giving companies nearly a year to review their compliance policies, training and strategic planning to ensure that their compliance programs align with the revised Code's requirements.
- The revised Code includes a glossary with enhanced definitions, as well as six core industry values.
- Companies should raise awareness about the Code revisions with their customers, important medical and specialty societies, sales organizations and other key business partners.

The Advanced Medical Technology Association (AdvaMed) recently updated its longstanding Code of Ethics on Interactions with U.S. Health Care Professionals ("Code").¹ In addition to changes that are designed to improve the look and feel of the Code, the revisions introduce several new topics and clarify existing guidance. The updated version will take effect January 1, 2020, and can be located [here](#).

The Code provides voluntary guidelines for medical technology companies on proper interactions with health care professionals (HCP), and is designed to help companies comply with federal and state laws and regulations that cover interactions between companies and HCPs (e.g. the federal Anti-Kickback Statute). Although the Code provides informal industry guidelines regarding HCP interactions, and therefore is not directly binding on entities in the industry, federal and state regulators may nonetheless take the Code into account when evaluating HCP interactions.² The Code aims to "promote socially and ethically responsible business practices" within the industry.³ To that end, AdvaMed President and CEO Scott Whitaker has stated that the revisions "reflect our industry's continued commitment to ethics, integrity and transparency."⁴

The updated Code introduces four 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.

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1. **Jointly Conducted Education and Marketing Programs (New Section V):** The updated Code covers joint activities between HCPs and medical technology companies that educate, demonstrate or otherwise market new medical technology. For example, this section would cover an agreement in which an HCP would demonstrate how to use a company's new surgical product. The Code sets forth the following guidelines:

- The company should engage in joint educational or marketing activities only if there is a **bona fide** legitimate need for the company to do so for its own educational or marketing benefit.
- The company should implement controls, including policies and procedures to decrease any risk of the relationship morphing into an unlawful inducement.
- The company should ensure that HCPs comply with company guidelines governing the provision of product labeling information, health care economic information and any other information required by the company.
- Jointly conducted programs should be balanced and promote both the company and the HCP. In addition, the company and the HCP should equitably share all contributions of activities or costs related to the program.
- The arrangement should be set out in a written agreement, which should cover the roles, responsibilities and contributions of all parties involved.

2. **Communicating for the Safe and Effective Use of Medical Technology (New Section X):** The Code permits certain communications that relay "truthful and non-misleading" information about a product's on- and off-label uses, recognizing that such communications will better enable HCPs to provide efficient care. The updated Code encourages companies to draft policies that reflect the following:

- Company responses to inquiries containing information about unapproved or uncleared uses should be provided by authorized personnel.
- Information about unapproved or uncleared uses should be identified as such.
- Communications should never be untruthful or misleading.

Proper communications include: distribution of peer-reviewed journals, articles and guidelines; presentations that cover data related to clinical trials and investigational use, so long as the communication makes no claim about the safety and effectiveness of the product; and discussions to obtain advice and feedback.

3. **Consigned Products (Updated Section XII):** The updated Code covers products that an HCP may store for use in its facility, but to which the company retains title. Specifically, the Code suggests that consigned agreements should cover issues such as the number of products stored with the HCP, segregation requirements and space rental terms. Further, the updated Code suggests that companies should take periodic inventory of these products, resolve record discrepancies, and address procedures for the return and removal of expired products, if applicable.

4. **Company Representatives Providing Technical Support in the Clinical Setting (New Section XIII):** The updated Code recognizes that medical technology employees and representatives can provide meaningful technical and educational support in a clinical setting. Companies should abide by the following principles:

- Company representatives should enter clinical settings only when HCPs request support.
- Company representatives should be transparent about their roles within a clinical setting.
- Company representatives should never interfere with an HCP's medical decisions.
- Company representatives should always comply with facility policies and procedures.
- Companies should not engage in activities that would eliminate overhead or ancillary expenses associated with patient care.

The updated Code also provides clarification and additional guidance on a number of topics contained in the current Code:

1. **Applicability:** The updated Code clarifies that it applies to: all companies that interact with U.S. HCPs, regardless of where the interaction takes place; interactions between a company's agents or employees and HCPs, even if the agents or employees independently pay for the interaction; and all combination products.
2. **Consultants:** While the updated Code leaves the substantive principles governing consulting agreements largely untouched, it does provide additional guidance on what constitutes a "legitimate need" for an HCP consultant. Specifically, a company should use a consultant only to accomplish a "specific objective" (e.g. training other HCPs to use a product or providing expertise for research and development). Importantly, a company should never use a consultant to generate future business or to reward past usage. The updated Code also provides examples of what qualifications should govern the selection of an appropriate consultant: specialty, years of experience, location, practice setting, clinical research experience, podium presence, speaking and publication experience, and familiarity with certain medical technologies.
3. **Satellite Symposium:** The updated Code explicitly allows companies to host satellite symposiums, but cautions that companies should be transparent in promoting them and should treat them as any other Third Party Program.
4. **Travel:** The updated Code now includes a consolidated section on travel, providing companies with a comprehensive discussion of when HCP travel and lodging expenses can be covered under the Code and offering guidance for selecting appropriate venues and locations for holding company meetings.
5. **Meals:** The updated Code consolidates the guidelines covering reimbursements for meals, and encourages companies to create policies that will govern how meals will be provided to HCPs.

Medical technology companies should consider revisiting and updating current policies and procedures within the next year to ensure compliance and consistency with the best practices set forth in the updated Code. Importantly, many companies will likely need to adopt new policies to reflect the Code's new sections, notably those related to communications, technical support and joint programs, and will likely need to tweak old ones to reflect the additional guidance on consultants and meals. This will be especially important for those companies that do business under state laws that explicitly reference industry codes.

¹ Press Release, *AdvaMed Approves Updated Code of Ethics* (Jan. 9, 2019) (available at: <https://www.advamed.org/newsroom/press-releases/advamed-approves-updated-code-ethics>).

² For example, Connecticut explicitly references the AdvaMed Code in its law governing the interactions between HCPs and medical technology companies. Conn. Gen. Stat. § 21a-70e (2010). Indeed, Nevada requires the adoption of marketing codes based on the AdvaMed and PhRMA codes. See Nev. Rev. Stat. § 639.570 (2017); Nev. Admin. Code § 639.617 (2016).

³ Advanced Medical Technology Association, *AdvaMed Code of Ethics On Interactions with U.S. Health Care Professionals 3* (2018).

⁴ Press Release, *AdvaMed Approves Updated Code of Ethics* (Jan. 9, 2019) (available at: <https://www.advamed.org/newsroom/press-releases/advamed-approves-updated-code-ethics>).