The 10 Most Important Changes in the New and Improved AdvaMed Code of Ethics

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At the close of 2018, the Advanced Medical Technology Association (AdvaMed) released an updated version of its Code of Ethics governing medical technology manufacturers in their interactions with health care professionals (HCPs) (the Code or the updated Code). This update is the first to the Code since 2009 and addresses key compliance issues underlying the manufacturer-HCP relationship, including manufacturers engaging HCPs as consultants, sponsoring trainings and meetings with HCPs, placing personnel in operating rooms and other clinical settings, providing off-label information about company products, and offering HCPs meals and travel expenses. The Code also adds six "cornerstone values" — innovation, education, integrity, respect, responsibility and transparency — and encourages companies to interpret the Code consistent with these principles. The updated Code will be effective January 1, 2020.

Key Takeaways

- AdvaMed has issued a revised and updated Code of Ethics on Interactions With Health Care Professionals — the first major revision to the Code since 2009. While styled as voluntary guidance, several states have made the Code's provisions mandatory, and prosecutors have cited noncompliance with similar industry codes of conduct when pursuing enforcement actions under the federal Anti-Kickback Statute.
- The new Code adds helpful sections on joint company-HCP education and marketing programs; the provision of truthful, nonmisleading product information; and the presence of company personnel in clinical settings.
- The revisions clarify the scope of the Code to make clear that it applies to all company interactions: (1) with HCPs licensed in the U.S. (even for interactions occurring abroad), (2) involving drug/device combination products, and (3) involving devices in companies with multiple product lines.
- The new Code also includes important revisions and clarifications for consulting agreements, company-conducted meetings, grants, donations and sponsorships, meals, and travel/lodging.

The updated Code comprises 28 pages and provides detailed guidance on a range of company interactions with HCPs. Below, we cover the 10 most important changes.

1. Definition of Health Care Professionals, Geographic Reach and Covered Companies and Agents (Section I)

The new Code clarifies and consolidates the definition of an HCP to include any person or entity who is (1) licensed or authorized in the U.S. to provide health care items or services to patients, or (2) involved in the decision to purchase, prescribe or recommend a medical technology. Thus, the Code now explicitly applies to interactions with nonclinical or administrative personnel involved in purchasing, recommending or ordering decisions. These are important clarifications because medical device companies have faced anti-kickback scrutiny for financial relationships with administrative and nonclinical personnel involved in the purchase or procurement of medical technologies. The Code now also applies to interactions with U.S. HCPs regardless of whether the interaction takes place within or outside the United States.

In addition, the Code now explicitly covers HCP interactions by employees and agents of a device company, making clear that companies are responsible for such interactions, even where the employees or agents pay for the interactions themselves.

Finally, the revisions clarify that, for companies that have multiple business or product lines — including both covered medical technologies and other lines of products, such as pharmaceuticals — the Code applies only to interactions linked to medical technologies. Importantly, however, this includes interactions involving combination products (*e.g.*, drug/device).

2. (New) Joint Education and Marketing Programs With HCPs (Section V)

This section, which is new in the updated Code, provides guidance on education and marketing programs conducted jointly by a company and an HCP for the purpose of educating HCPs and patients. The Code recognizes that such programs can serve important functions by allowing companies and HCPs to provide education on medical conditions and the range of testing or treatment options available. To comply with the Code, companies participating in such joint programs must (among other things): have a bona fide, legitimate need to engage in the program for their own educational or marketing benefit; equitably allocate costs of and contributions to the program between the sponsoring company and HCPs; and include controls to ensure that such programs are not intended to serve as unlawful inducements and that HCPs follow company policies on providing product information. As with other financial arrangements with HCPs, any joint marketing program agreement must be in writing.

3. (New) Communication of Off-Label Information (Section X)

One of the most important new sections in the updated Code addresses the benefit of providing truthful, nonmisleading information to HCPs about medical technologies, including both on- and off-label information. This section also describes the appropriate means and contexts for communicating off-label information, such as in peer-reviewed scientific and medical journal articles, reference texts and clinical practice guidelines; presentations at educational and medical meetings; and discussions with consultants and HCPs, among others. By negative implication, the Code appears to discourage (or at least not endorse) the provision of off-label information by company sales personnel. The Code also calls on companies to adopt policies and controls governing the dissemination of information about company products (including off-label information).

4. (New) Device Personnel in Clinical Settings (Section XIII)

The presence of medical device personnel in operating rooms and other clinical settings has been a hotly debated topic. The updated Code includes a new section that describes why their presence may benefit HCPs and patients, and outlines principles governing when medical device personnel are present in clinical settings. According to these principles, company personnel should: (1) be present in the clinical setting only at the request of and under supervision of an HCP; (2) be transparent to other providers and patients that they are acting on behalf of their company; (3) not interfere with the independent clinical decision-making by the treating HCPs; (4) comply with applicable hospital policies and requirements,including patient privacy and credentialing; and (5) not provide support that would eliminate an overhead expense or other expense that the HCP should otherwise incur.

5. Product Consignment (Section XII)

The updated Code's section on evaluation and demonstration products has been expanded to include guidance to companies providing consignment products for use in HCP clinical settings. The Code calls for consignment arrangements to be subject to a written agreement that specifies the terms of consignment, the number of products consigned, segregation requirements and rental space terms. Controls should also include taking periodic inventory of consigned products and reconciling discrepancies in inventory. This section also includes additional guidance on evaluation devices. Of particular note, the updated Code acknowledges that the length of time necessary for an HCP to evaluate a product can vary and encourages companies to assess the extent to which federal and state transparency laws require reporting the value of the evaluation products provided to HCPs.

6. Consulting Arrangements (Section II)

The updated Code maintains a detailed section on HCP consulting arrangements but adds new provisions that require companies to ensure HCP consultants are duly vetted and have the qualifications necessary to meet the specific objective of their consultancy. The revised Code also reinforces the need for consultant compensation to be based on fair market value (FMV), which is determined based on objective criteria and not on an HCP's past, present or anticipated business. The revised Code provides examples of how FMV can be determined, such as through use of third-party vendors or other experts, and encourages documentation of FMV analyses.[1]

7. Grants, Donations and Sponsorships (Section IV)

AdvaMed has made the updated Code more "user friendly" by consolidating guidance on grants, charitable donations and sponsorships into a single section. New language provides both a definition for commercial sponsorships, and guidance on when and how to ensure such sponsorships are appropriate. An expanded section on research grants makes

[1] As discussed below, the prior provisions on reimbursement for consultant travel and meals have been moved to new, consolidated sections on travel and meals.

clear that such requests should be accompanied by clinical protocols that outline objectives and milestones; document the nature and scope of research activity, budget and duration of research; and provide for independent approvals. New language also defines and provides guidance for satellite symposia, which are company-organized and -funded programs appended to third-party programs (such as medical conferences) but that such third parties do not control.

8. **Company-Sponsored Training and Education Meetings (Section III)**

   The new Code consolidates prior sections on sales/promotional programs and company-conducted trainings into a single section. This section provides more specificity as to the type of meetings that are appropriate to conduct, including meetings that address product features, sales terms, health economics information or purchase contract arrangements; plant/facility tours; meetings to demonstrate equipment; and meetings to explore product development or clinical testing needs. HCPs in attendance at such meetings must have an objective, legitimate need to attend. This, by negative implication, means spouses, family and others without a legitimate need should not be permitted to attend.[2]

9. **Travel and Lodging (Section VI)**

   The updated Code clarifies when companies may provide HCPs with travel and lodging in connection with legitimate company-conducted programs. The Code specifies that there must be an objective, legitimate reason requiring the HCPs' out-of-town travel, such as the need to deliver training and education on a company's products, the inability to effectively deliver the content of the program through means other than an in-person meeting or the need to demonstrate equipment.

   The updated Code provides principles for evaluating appropriate venues, which should be centrally located, easily accessible and conducive to the exchange of information. Venue should not be the main or primary attraction for an HCP to attend a meeting, and luxury venues or those with associated recreational or entertainment attractions should be avoided.

10. **Meals (Section VII)**

    The updated Code simplifies and consolidates the previous section on meals. As in the prior Code, meals and refreshments should be provided only as part of a bona fide business discussion and in a setting that is conducive to bona fide scientific, educational or business discussion. The new Code provides that this can include, for instance, an HCP's place of business or an off-site space that is conducive to the discussion, such as a restaurant. Meals intended to build goodwill or for entertainment or recreational purposes remain prohibited. Companies are strongly encouraged to develop meal policies, including establishing a per meal spending limit, which may take into account geographic differences.

Implications for Medical Device and Technology Makers

While styled as voluntary industry guidelines, AdvaMed requires member companies to abide by the Code, and several states such as California, Connecticut and Nevada make the Code's provisions mandatory. Violations of a similar code for pharmaceutical manufacturers have been cited by prosecutors as evidence of a company's improper intent in cases alleging improper inducements to health care professionals.[3] As such, medical device companies should familiarize themselves with the updated Code and assess their ability to meet the Code's requirements before it becomes effective next January.

[2] As noted below, guidance on whether companies can provide or reimburse for meals, travel and/or lodging for such meetings is addressed in separate new sections on those activities.

[3] *See* Amended Compl. in Intervention at 22, *U.S. ex rel. Bilotta v. Novartis Pharms. Corp.*, 11-00071 (July 15, 2013).

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