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Client Alert

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AdvaMed Updates Code of Ethics on Interactions with U.S. Health Care Professionals

The Updated Code Includes Several New Topics and Additional Guidelines on Existing Topics

The Advanced Medical Technology Association (AdvaMed) published in late December 2018 an updated version of its widely-adopted Code of Ethics on Interactions with U.S. Health Care Professionals (the AdvaMed Code or the Code). The updated version of the AdvaMed Code will take effect January 1, 2020, and supersedes and replaces the current version of the Code that has been in effect since July 1, 2009.

A SIGNIFICANT DEVELOPMENT FOR MEDICAL DEVICE MANUFACTURERS

The AdvaMed Code is generally viewed by U.S. enforcement authorities as the baseline for ethical interactions between medical device manufacturers and U.S. health care professionals (HCPs). Although not law, the Code's principles are derived from and intended to help ensure compliance with a variety of U.S. laws and regulations (e.g., the federal Anti-Kickback Statute (AKS)), and enforcement authorities (such as the HHS Office of Inspector General (OIG)) view activities that are consistent with the Code as indicia of intent to comply with the AKS. In addition, several states like California, Connecticut, and Nevada have enacted laws that explicitly reference and, in some cases, mandate that manufacturers comply with industry codes for purposes of interactions with HCPs licensed in the state. Accordingly, many medical device manufacturers – even those who are not AdvaMed members – have adopted, or at least generally follow, the AdvaMed Code. The recent updates will require many manufacturers to make corresponding changes and/or updates to their policies, procedures, and practices involving interactions with U.S. HCPs before the updated Code takes effect January 1, 2020.

NEW TOPICS ADDRESSED IN THE UPDATED ADVAMED CODE

The updated Code includes several new topics that are not addressed by the current Code, including:

- **Partnering with HCPs to Conduct Joint Education/Marketing Programs**. This new section would apply to, for example, an educational program during which a manufacturer promotes its surgical implant and a surgeon highlights his/her ability to perform the implant procedure. The updated Code acknowledges the benefits of such jointly-conducted programs and provides principles that manufacturers should apply to these activities to help to ensure that a manufacturer's program support does not unduly benefit the participating HCP in a manner that might violate the AKS. Stated principles include, among others: that the manufacturer and HCP should serve as bona fide partners, and contributions and costs should be shared fairly and equitably between the parties; that there must be a bona fide, legitimate need for a manufacturer to engage in such programs for its own educational or marketing benefit; and that a manufacturer should establish controls to help ensure that decisions to engage in these arrangements are not made as unlawful inducements.
- **Manufacturer Communications about the Safe and Effective Use of Products.** The updated Code explicitly recognizes the value of ensuring that HCPs have access to truthful and non-misleading information about medical devices, including information on both on- and off-label uses. The updated Code provides that appropriate industry communications of such information can include, among other activities: proper dissemination of peer-reviewed scientific and medical journal articles, reference texts, and clinical practice guidelines; presentations at educational and medical meetings regarding clinical trial results or research and development data for an investigational use – excluding any claims regarding safety and effectiveness; and discussions with consultants and HCPs to obtain feedback on unmet patient needs, product research and development, and similar topics. The updated Code also encourages companies to develop policies and controls that govern the provision of information about unapproved or uncleared uses that incorporate applicable guidance (e.g., FDA guidance).
- **Manufacturer-representatives Providing Support in the Clinical Setting**. The updated Code recognizes the value that company representatives can provide in the clinical setting by providing technical support on the safe, effective, and appropriate use of medical technology and ensuring all necessary devices are present during a procedure. The updated Code sets out principles companies should follow when permitting representatives to enter a clinical setting, such as requiring that company representatives: only enter the clinical setting at an HCP's request; be transparent that they are providing technical support on behalf of the company (and not as a medical professional); refrain from interfering with HCPs' independent clinical decision-making; and comply with all hospital/facility policies and requirements. The updated Code also cautions that any technical support should not eliminate an overhead or other expense that HCPs should otherwise incur while providing patient care.
- **Consigned Products**. The updated Code expands the existing Code section addressing evaluation and demonstration products to address the placement of consignment product at an HCP's patient care setting. The updated Code provides that such consignment arrangements should be subject to an agreement that addresses the number of products, segregation requirements for consigned products, and storage space rental terms, as applicable. The updated Code encourages manufacturers to implement consignment product controls, including taking periodic inventory, reconciling discrepancies between company records and on-site inventory, and the return/removal of expired product.
- **Applicability of the Code**. The updated Code resolves several potential ambiguities regarding how the Code applies. For example, the updated Code clarifies that it will apply to interactions with U.S. HCPs, even when interactions take place outside the U.S. The updated Code also expressly clarifies that the Code applies to combination products that include a device, and that companies with different business lines (including some non-device business lines) should apply the Code to their device business lines. Finally, the updated Code expressly provides that it applies to a company's interactions with U.S. HCPs, even if an employee or agent pays for the interaction himself/herself (i.e., without being reimbursed by the company).

- **Cornerstone Values**. The updated Code sets-out "cornerstone values" that are intended to help guide decision-making, especially for activities that the Code does not expressly address. The "cornerstone values" include dedication to innovation, education, integrity, respect, responsibility, and transparency.

NOTABLE ADDITIONAL GUIDELINES ON EXISTING TOPICS

The updated Code also includes notable additional guidelines on topics addressed in the existing Code.

- **Consulting Arrangements with HCPs**. The principles for consulting arrangements set forth in the existing Code are maintained in the updated Code; however, the updated Code provides additional detail with respect to establishing a legitimate need for services, noting that a legitimate need arises when a company requires the services of an HCP to achieve a specific objective. The updated Code further states that rewarding an HCP for business or referrals is not a legitimate need for a consulting arrangement. The updated Code also notably provides an explanation for how manufacturers can establish fair market value compensation rates for consulting services.
- **Supporting Third Party Programs and Activities via Grants, Donations, and Sponsorships**. The principles for providing grants, sponsorships and donations remain largely unchanged, but AdvaMed helpfully consolidated its principles on those funding arrangements into one section. The updated Code also includes a checklist for reviewing educational grant requests and expands and clarifies requirements for providing independent research grants and charitable donations. There are also new principles that address satellite symposia (i.e., company-organized and funded programs that are appended to third party conference agendas, but that the conference organizers do not control).
- **Travel and Lodging**. The updated Code consolidates into one section the guidelines regarding covering HCPs' travel and lodging expenses. The updated Code provides clearer guidelines on when travel and lodging expenses are permitted (e.g., consulting services, company-conducted product training, speaking on the company's behalf, plant tours and product demonstrations) and when they are prohibited (e.g., general educational program, company meeting without an objective, to attend a third-party educational program). The updated Code also provides principles for evaluating appropriate venues for meetings (e.g., centrally located and easily accessible, avoid top category or luxury hotels, avoid selecting setting because of its entertainment or recreation facilities).
- **Meals**. The updated Code consolidates into one section the guidelines regarding providing meals to HCPs. The updated Code notably encourages companies to establish meal policies and expressly contemplates that such a policy may allow for variation to account for geographic areas that are generally more expensive (e.g., New York City).

Finally, the following topics were left largely unchanged in the updated Code: company-conducted programs, including device training and education programs and business meetings; providing educational and patient benefit items; prohibition of gifts; prohibition on entertainment and recreation; and provision of health economics and reimbursement information. AdvaMed, however, did consolidate its guidance on these topics into more cohesive sections (e.g., addressing both company-conducted device training programs and business meetings in one section, as compared to multiple disparate sections).

PRACTICAL IMPLICATIONS

The AdvaMed Code is intended to help clarify and distinguish appropriate activities between HCPs and medical device manufacturers, and is generally viewed by government enforcement authorities as setting the baseline for ethical and compliant relationships between industry and HCPs. Considering its role and importance, any updates to the Code are notable.

Medical device manufacturers would be wise to carefully review the updated Code and assess its potential impact on their existing policies and procedures. In particular, the Code's new sections – including those on joint marketing/educational programs between HCPs and manufacturers, representatives providing technical support in clinical settings, and consignment products – will likely require many companies to make updates to existing policies or adopt new ones. In addition, the appreciably enhanced guidance and principles governing grant funding and donation arrangements will increase expectations around the compliance infrastructure and processes that manufacturers utilize around those arrangements. The updates to the Code are also likely to impact obligations on medical device manufacturers under state laws in California, Connecticut, and Nevada that require manufacturers to adopt a code of conduct and/or comprehensive compliance program consistent with industry standards.

King & Spalding's fraud and abuse experts have extensive experience working with the AdvaMed Code and helping medical device manufacturers implement the principles of the Code through policies, procedures, and guidance. We have the practical perspective to help our medical device manufacturer clients understand how the updated Code will impact their activities and operations. We can also offer creative and workable solutions to update existing control documents as necessary to comply with the new expectations while minimizing disruption to the business and ongoing operations.