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Client Alert

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AdvaMed Updates Code of Ethics on Interactions with HCPs: What's the Impact on MedTech?

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On March 18, 2022, the Advanced Medical Technology Association ("AdvaMed") announced revisions to its Code of Ethics on Interactions with Health Care Professionals ("Code"). The revised Code will take effect June 1, 2022.

According to AdvaMed's announcement, changes to the Code were intended "to address evolving compliance and legal standards, to account for innovative value-based care arrangements, and to incorporate additional provisions on risk areas specific to medical technology companies."[1]

Indeed, these changes come in the wake of the November 2020 U.S. Department of Health and Human Services Office of Inspector General ("OIG") Special Fraud Alert on speaker programs, in which OIG warned about potential fraud and abuse risks with company-sponsored speaker programs. The Code updates also follow OIG's December 2020 final rule revising the Anti-Kickback Statute ("AKS") safe harbor regulations to protect value-based care arrangements. In the final rule, OIG determined that most manufacturers of medical devices/supplies (and pharmaceutical manufacturers) are "ineligible to use this safe harbor for the exchange of remuneration pursuant to a value-based arrangement."[2]

Key revisions to the Code and the potential implications for medical device manufacturers are summarized below.

KEY REVISIONS TO THE CODE

Value-Based Care Arrangements. The revised Code includes new references to value-based care arrangements. "Value-Based Care" is defined, in part, as a "health care delivery model in which contributors to care are paid based on individual patient health outcomes, population health outcomes, increasing access to healthcare for underserved populations, managing costs, and/or improving efficiency."[3] Arrangements intended to advance value-based care strive to increase shared accountability among stakeholders for the quality of, access to, and/or the

total cost of care. The Code supports the role of data-driven devices and solutions in the health care industry and supports the idea that technology from medical device companies can further value-based care and improve health outcomes. Specifically, the Code recognizes the unique position of medical device companies because of their ability to leverage data and technology "to enable new insights, support health and wellness, improve patient interventions and outcomes, and enhance the quality and efficiency of health care delivery," noting that "a combination of technology and services [can be] designed to deliver a targeted outcome."[4]

The addition of these references to value-based care arrangements in the Code appears to be in response to the OIG December 2020 final rule that included new safe harbors for certain value-based care arrangements, but that specifically excluded most medical device manufacturers from using those safe harbors. The revised Code appears to acknowledge OIG's general exclusion of medical device manufacturers from these safe harbors, but clarifies that "even if no individual safe harbor may be fully applicable, a specific Value-Based Care arrangement may nevertheless be permissible under the Anti-Kickback Statute based on the particular facts and circumstances."[5] This point is further reiterated in a new FAQ that explains that "[n]ot having a safe harbor available (or not meeting all conditions of a safe harbor) for a particular interaction or arrangement does not necessarily mean the interaction would be a violation of the Anti-Kickback Statute."[6] Taken together, the collective updates to the Code regarding value-based care signal support for industry to continue moving forward with value-based care arrangements that present a low risk of violating the AKS, based on the specific facts and circumstances at issue.

Alcohol. The revised Code now specifically addresses alcohol in one FAQ—the only reference to alcohol throughout the Code. The new FAQ, which governs company-conducted programs and meetings with health care professionals ("HCPs"), does not appear to explicitly prohibit medical device companies from providing alcohol at company-conducted programs and meetings with HCPs. Rather, it provides the following:

> Companies also may consider adopting controls around the provision of alcohol at Company-Conducted Programs and Meetings. For example, considering government guidance, Companies may adopt per-person drink limits, per-drink spend limits, limitations on the types of alcohol permitted (e.g., beer and wine only), or disallow alcohol at certain events (such as the types of Company-Conducted Training and Education Programs described in Section IIIA of the Code).[7]

This statement, including the specific mention of "disallow[ing] alcohol at certain events (such as the types of Company-Conducted Training and Education Programs described in Section IIIA of the Code)" is likely in recognition of the November 2020 OIG Special Fraud Alert on speaker programs. The statement does not directly conflict with recent revisions to the PhRMA Code that more stringently prohibit pharmaceutical manufacturers from providing alcohol at speaker programs, but the revisions to the AdvaMed Code afford medical device manufacturers more discretion with respect to providing alcohol during certain interactions with HCPs. Nonetheless, the updated Code's statement that decisions to provide alcohol "must comply with the requirements of Section VII of the Code signals that whether the availability of alcohol would make an event location inconducive to the exchange of scientific, educational, or business information, or otherwise an "entertainment"-like event must be carefully considered.

Virtual Meetings. In response to the global pandemic and restrictions on in-person interactions over the past two years, the Code was also revised to address the possibility of virtual meetings. The Code now explicitly contemplates that meals and refreshments may be provided to facilitate virtual meetings. There are also related changes throughout the Code that acknowledge that virtual settings may be appropriate for some types of interactions with HCPs. The Code also defines a "virtual" interaction as an "interaction that involves attendees participating in a virtual environment that is generally enabled by digital technology rather than meeting in a physical location."[8]

The revisions include a new FAQ related to the provision of meals for virtual interactions, which follows the COVID compliance guidance that AdvaMed issued in May 2020 at the outset of the global pandemic. The revised Code now provides that to "properly consider and manage the provision of meals to Health Care Professionals during Company-Conducted Meetings that are held virtually, Companies may create a process to control ordering and delivery, track attendance to ensure that only appropriate participants in the meeting receive the meals/refreshments, and/or prohibit home delivery."[9]

As it relates to travel and lodging, the revised Code also provides "[a]s an alternative to in-person programs, companies may wish to consider whether the legitimate need could be met via a virtually-conducted program."[10] This appears to signal to companies that they should thoughtfully scrutinize whether there is a "legitimate need" for travel and lodging for programming, likely in response to the growing use of virtual programming during the global pandemic and skepticism from federal regulators around the "legitimate need" for in-person activities.[11]

Compliance Certification. The Code has previously included a certification provision that strongly encourages companies that adopt the Code to submit a certification to AdvaMed stating that the company has adopted the Code and has implemented an effective compliance program. Those provisions were revised to remove the reference to "annual certification." The revised Code still strongly encourages manufacturers to submit a "certification," but does not include any specific cadence or timing for such certification.

TAKEAWAYS AND IMPLICATIONS

In the coming months, in advance of the June 1 effective date for the revised Code, companies should consider whether they should update their policies and procedures to address changes to the Code. Many of the changes, however, should have a limited tactical impact on most companies, and some companies may decide that no specific changes to their policies are needed. Companies should also assess any potential impact these updates might have on their efforts to comply with state laws that require adoption of the AdvaMed Code, such as laws in California and Connecticut. (Nevada law also references compliance with the AdvaMed Code, but does not require it.)

More broadly, the revisions to the Code reflect a shift in how device manufacturers and HCPs interact. The global pandemic fundamentally changed the way that medical device companies do business, as well as the way government enforcement authorities view these activities. The revised Code recognizes those shifts. Consequently, companies should closely review their existing policies and procedures to ensure that they reflect the current enhanced sensitivities around certain interactions. For example, manufacturers would be wise to scrutinize the legitimate need for travel and lodging expenses related to in-person meetings.

The revisions to the Code also should be encouraging to medical device manufacturers who are contemplating options for value-based arrangements. There is little doubt that AdvaMed and its members are hoping to further stoke interest in pursuing those arrangements, as a general matter, especially when they are deemed to present low risk under the AKS.

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[1] AdvaMed, Press Release, "AdvaMed Continues to Lead the Way in Compliance and Ethics with Revised Code of Ethics," (March 18, 2022), https://www.advamed.org/industry-updates/news/advamed-continues-to-lead-the-way-in-compliance-and-ethics-with-revised-code-of-ethics/.
[2] OIG, "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," 85 Fed. Reg. 77,684, 77,775 (Dec. 2, 2020).
[3] AdvaMed, Code of Ethics on Interactions with U.S. Health Care Professionals (June 1, 2022), at 8, https://www.advamed.org/wp-content/uploads/2022/03/2022-AdvaMed-Code-of-Ethics-Digital.pdf.
[4] *Id.* at 3.
[5] *Id.* at 8.
[6] *Id.* at 5.
[7] *Id.* at 12.
[8] *Id.* at 7.
[9] *Id.* at 27.
[10] *Id.* at 24.
[11] *See, e.g.,* OIG, "Special Fraud Alert: Speaker Programs" (Nov. 16, 2020), at 3-4 (expressing skepticism about in-person speaker programs because there are many other ways for HCPs to obtain information that does not involve remuneration to HCPs, specifically citing HCPs' ability to obtain the information using various online resources and other sources).