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AdvaMed Releases Updated Code of Ethics

The Advanced Medical Technology Association ("AdvaMed") has updated its Code of Ethics on Interactions with U.S. Health Care Professionals (the "Code"). The update—the first since 2009—is effective January 1, 2020. The Code sets standards for appropriate interactions between, on the one hand, manufacturers of medical devices and products, technologies, digital and software platforms, and related services, solutions, and therapies (collectively, "Medical Technologies"), and, on the other, health care professionals ("HCPs"). While the Code is voluntary, the Medical Technology industry follows it widely.

Key updates include (1) consolidated provisions on consulting arrangements, including new provisions addressing conflicts of interest; (2) expanded provisions on third-party support, including support for independent third-party research; (3) new provisions on jointly conducted marketing and education programs; (4) additional detail regarding standards for travel and meals; (5) new provisions on communication for the safe and effective use of Medical Technologies; and (6) new provisions on providing technical support in the clinical setting.

We describe these key updates immediately below and link here to a side-by-side comparison of provisions in the existing Code with those of the revised Code that takes effect in 2020.

Consulting Arrangements and Conflicts of Interest

The updated Code provides additional examples of permissible arrangements for consulting services, and states that companies should engage only as many consultants as are necessary to fulfill their requirements for *bona fide* services. The update also clarifies how companies might approach designing a methodology to assess fair market value for goods and services rendered by HCPs (*e.g.*, incorporating objective criteria, such as the HCP's specialty, experience, geographic location, and type of service performed, into fair market value calculation methodologies).

The updated version also explains that HCPs may have conflicts of interest that companies need to address, such as by recusing HCPs from decisions that implicate potential conflicts. The Code provides as examples of potential conflicts of interest physicians who hold leadership roles in medical societies, serve as conference planning chairs, or act as medical journal editors.

Third-Party Support

The updated Code expands the provisions regarding companies' support of third-party programs, and includes a checklist of factors that companies should consider when reviewing requests for support of third-party educational programs. The updated Code also now expressly prohibits companies from passing along to HCPs any benefits that they receive in exchange for commercial sponsorships. The updated version also provides additional guidance on company-sponsored satellite symposia, stating that a company must be transparent in promoting the events as company-conducted, and that it may not pay for the travel, lodging, or registration expenses of HCPs unless the HCPs serve as *bona fide* faculty members at the symposium.

With regard to support of third-party research, the updated Code continues to allow companies to support third-party research programs and to partner with HCPs for research purposes through in-kind or monetary grants. The updated Code identifies some recommended safeguards, including that companies limit in-kind or monetary support to legitimate expenses or services, provide reasonable quantities of products at no charge, ensure that the recipients of support retain independent control over the research, establish an internal review process for reviewing and awarding research grants, and limit the involvement of sales personnel in the decision of which third-party researchers receive support.

Jointly Conducted Marketing and Educational Programs

The updated Code has a new section on jointly conducted marketing and educational programs. The section requires companies to ensure application of various principles when conducting marketing and education jointly with HCPs.

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These include (1) that the company has a legitimate need to participate in the joint program for its own educational or marketing benefit; (2) that the company establishes controls to ensure that the joint programs are not conducted as an unlawful inducement to HCPs; (3) that the joint program contains balanced content between promotion of the company as well as the HCP; (4) that the company and HCPs are *bona fide* partners and make equitable contributions to the program; and (5) that the arrangement is reflected in a written agreement that specifies the purpose of the arrangement, the roles and responsibilities of each party, and the contributions of each party, including payment of costs.

Travel and Meals

The updated Code elaborates on circumstances in which a company may or may not cover the costs of HCPs' travel. For example, the Code permits reimbursement for travel to facilitate consulting, training, and speaking on a company's behalf, whereas it prohibits reimbursement for travel for general education, attendance at a third-party program, and when no legitimate need exists. The guidance also provides considerations that companies should use when choosing a setting for company-conducted programs, including whether the company has offices nearby, whether the program is intended for HCPs local to the area, and whether the company is hosting the meeting in conjunction with a third party. The updated version also strongly encourages companies to develop meal policies that include controls such as limits on spending and geographical location.

Communications Regarding Medical Technologies

The updated Code has a new section on communications regarding the safe and effective use of Medical Technology. The section describes examples of industry-appropriate communications (*e.g.*, peer-reviewed journal articles, presentations at educational and medical meetings), and requires companies to adhere to a set of principles in communicating medical and scientific information. These include (1) that company responses containing information on unapproved or uncleared uses should be provided by authorized personnel; (2) that communications must be truthful and non-misleading; and (3) that information related to unapproved or uncleared uses should be identified.

Technical Support in the Clinical Setting

Addressing an important function served by Medical Technology companies, which distinguishes the needs of Medical Technology companies from pharmaceutical companies, the updated Code adds a new section with guidelines on providing technical support in the clinical setting. The section includes a list of standards that companies should apply, such as requiring company representatives to be present in the clinical setting only when requested and supervised by an HCP, and prohibiting companies' technical support from eliminating overhead or other expenses that HCPs would otherwise incur.

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The Code has long been a bedrock of operations for Medical Technology companies, and an important guide for HCPs who interact with them. Many companies have publicly certified their election to comply with the Code; many others have incorporated much, if not all, of the Code into their compliance programs; and some have pointed to the Code when defending practices that have fallen under scrutiny. For companies in each category, assessment of the changes, and how to incorporate the changes into operations, will be an important activity in 2019. Our side-by-side comparison of the 2009 and 2020 Code provisions is linked here.

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