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February 14, 2019

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HEALTH CARE

CHANGES TO THE ADVAMED CODE OFFER FLEXIBILITY TO HEALTH CARE PROVIDERS AND MEDICAL DEVICE COMPANIES

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The Advanced Medical Technology Association ("AdvaMed") recently announced the revision of its "Code of Ethics on Interactions with Health Care Professionals" (the "Code"), effective January 1, 2020. The new guidance addresses some of the most difficult issues faced by health care professionals in their interactions with medical device manufacturers.

Background

AdvaMed is a trade association that represents the interests of its member medical device manufacturers across the globe. The Code is intended to provide guidance to medical device companies on how to maintain ethical relationships with health care professionals ("HCPs"). The Code does not carry with it the force of law. However, federal and state regulators such as the Department of Health and Human Services Office of Inspector General generally take the position that arrangements between device companies and HCPs that are consistent with the Code do not run afoul of federal or state anti-kickback laws or civil monetary penalty laws prohibiting inducements offered to beneficiaries of federal health care programs.

Here, we focus on two new Code sections that address topics that hospitals and HCPs traditionally find challenging. Despite the frequent use of both of these arrangements, the Code now addresses them explicitly for the first time.

Jointly Conducted Patient Education and Marketing

Hospitals and HCPs often jointly hold educational events for patients. These events present, for example, opportunities for patients to learn more about the management of a particular disease or maybe a new procedure or technology in use at the hospital. They are also part of a hospital's patient marketing strategy. They usually feature a presentation by specialists employed by or affiliated with the hospital. A medical device company often helps to offset the cost of an event at which the company's technology will be discussed. These sessions can be highly beneficial to patients, but also present potential kickback issues because of the financial support offered by the medical device company.

When structuring these arrangements, the Code sets forth the following principles:

- There must be a bona fide, legitimate need for the device company to engage in the activity. These programs cannot simply be a means for the device company to subsidize the hospital's marketing efforts.
- Information provided by HCPs should be consistent with a product's labeling and with the device company's own internal policies and procedures.
- Information presented at the event should be balanced to promote both the hospital/HCP and the medical device company.

- The hospital/HCP should make equitable contributions to the content of the program and toward its costs.
- The hospital/HCP and the device company should enter into a written agreement that describes the purposes of the educational program and the responsibilities of each party (including the payment of the program's costs).

Patient Assistance with Payors

New, complex medical device technology comes on to the market at a blinding pace. Payors struggle to keep pace with these technologies through the issuance of involved coverage and reimbursement policies. To help patients and their providers navigate these coverage rules, the Code authorizes certain collaboration between medical technology companies, HCPs, and patients that would otherwise raise both kickback and beneficiary inducement concerns.

Under the revised Code, at the request of a HCP, a medical device company can facilitate the preparation and submission of requests for coverage determinations, payor pre-authorizations, and pre-certifications in connection with the company's technology. Device companies can even help with the appeals of denied claims. The Code adds that this type of assistance should not be provided as an "unlawful inducement" to the patient, but does not offer any guidance as to how to structure an arrangement that would not be construed as such an inducement.

While the Code now explicitly allows medical device manufacturers to become involved with insurance companies for the benefit of patients, it appears not to permit this same conduct when it is done on behalf of HCPs. The Code cautions against the provision of free services the cost of which a HCP would otherwise have to incur in the course of normal business operations. The Code would therefore appear to prohibit a no-cost arrangement in which a device company sought to obtain all of the surgical pre-authorizations that a HCP would otherwise have to procure for patients.

If you would like to discuss the impact of the revised Code, or fraud and abuse concerns generally, please contact any member of our Health Care Practice Group at 585.232.6500 or visit www.hselaw.com.

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