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Advertising and Marketing

AdvaMed's Updated Code of Ethics And Its Impact on the Medical Devices Industry

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The Board of Directors of the Advanced Medical Technology Association (''AdvaMed''), an association that represents companies that develop, manufacture, and market medical products, technologies, and related services, recently approved a revised and updated Code of Ethics on Interactions with Health Care Professionals (the ''Revised Code'') (3 MELR 19, 1/14/09). The Revised Code provides compliance recommendations for relationships between AdvaMed member companies and health care professionals (''HCPs'').

Effective as of July 1, 2009, the Revised Code includes several significant revisions to the AdvaMed Code that was adopted in 2005 (the ''Current Code''). These revisions generally provide guidance to device manufacturers to aid in compliance with the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)). The Anti-Kickback Statute forbids payment or remuneration of any sort intended to induce the referral of items or services reimbursable by Medicare, Medicaid, or other federal funds. The statute ascribes liability to parties on both sides of an impermissible ''kickback'' transaction. Federal courts have held that an arrangement violates the Anti-Kickback Statute if any one purpose of remuneration is to induce the referral of patients covered by the Medicare or Medicaid programs, even if there are other, lawful reasons for the agreement between the parties.

Violation of the Anti-Kickback Statute is a felony and may result in a fine of up to $25,000, imprisonment for up to five years, or both. In addition, the Office of Inspector General of the United States Department of Health and Human Services (the ''OIG'') may suspend or exclude a provider or other entity, including a medical device company, from participation in the Medicare or Medicaid programs if such provider or entity is convicted of violating the Anti-Kickback Statute. Compliance with the Revised Code and its restrictions on actions which may be considered ''unlawful inducement'' promotes compliance with the Anti-Kickback Statute.

Compliance with the Revised Code (particularly the Revised Code's guidance regarding reimbursement consulting) also promotes compliance with the federal False Claims Act (31 U.S.C. § 3729). The False Claims Act provides that any person who presents or causes to be presented false or fraudulent claims for payment or

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approval to the U.S. government or knowingly makes, uses or causes to be made or used, false records and statements to induce the government to pay or approve false and fraudulent claims, is liable for a civil penalty of between $5,500 and $11,000 per claim, plus three times the amount of the damages sustained by the federal government.

False Claims Act violations arising from medical device company's reimbursement consulting can have a serious impact on a company's operations. For example, in 2008, a subsidiary of Medtronic Inc. settled a qui tam suit alleging violations of the False Claims Act (2 MELR 379, 6/4/08). The initial cause of action was originally filed against Medtronic's recently acquired subsidiary, Kyphon Inc., alleging that Kyphon improperly promoted Kyphoplasty as an inpatient procedure and promoted a variety of schemes to maximize government reimbursement paid to hospitals and physicians for procedures using Kyphon products. The qui tam complaint alleged that Kyphon's activities resulted in false claims submitted to the Medicare and Medicaid programs. Under the terms of the settlement, Medtronic will pay damages totaling $75 million plus interest and enter into a five-year Corporate Integrity Agreement with the OIG.

Compliance with the Revised Code is not mandatory, but AdvaMed strongly encourages companies to adopt and adhere to the Revised Code. Those companies that choose to adopt the Revised Code are encouraged to submit an annual certification to AdvaMed that they have adopted the Revised Code and implemented an effective compliance program. AdvaMed will publish a list of companies that have submitted this certification on its Web site. All companies that are AdvaMed members, regardless of whether they certify that they have adopted the Revised Code, must provide AdvaMed with contact information regarding their compliance department or an anonymous hotline in order for individuals to report violations of the Revised Code.

AdvaMed members and other medical device manufacturers and distributors who desire to follow the Revised Code's guidelines should be aware of the following key revisions:

1. **Definitions.** AdvaMed broadened the definition of HCPs and included a new term, ''Medical Technologies'', in the Revised Code. HCPs now include not only those individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of or prescribe a medical technology product in the United States, but also all of those involved in the provision of health care services and/or items to patients in the United States. Thus, HCPs include both medical providers and non-providers who are involved in the decision-making regarding the purchase, lease or use of Medical Technologies. Medical Technologies include medical products, technologies and related services and therapies to diagnose, treat, monitor or manage patient conditions.
2. **Out-of-town Travel.** The Revised Code limits situations where companies may pay for out-of-town travel. The need for out-of-town travel to attend company-conducted product training and education sessions must be supported by objective reasons in order for companies to pay for HCPs reasonable travel and modest lodging costs. The Revised Code includes definitions of ''training'' and ''education,'' terms that are not defined in the Current Code.
3. **Consulting Relationships.** The section of the Revised Code which discusses consulting agreements with HCPs was substantially revised and includes a new subsection related to royalty payments. The following are the key revisions to this section.
   a. Companies may pay HCPs for consulting services only if such payments are fair market value for the services provided, are not based upon the consultant's past, present or anticipated business with the company, and are not an unlawful inducement.
   b. Sales personnel may not control the decision to retain an HCP as a consultant, but may provide input into such a decision.
   c. Royalty payments made to HCPs for novel, significant or innovative contributions to the development of a product, technology process or method must be appropriately documented and based on factors that preserve the objectivity of medical decision making by the HCP.
4. **Entertainment.** The Revised Code prohibits companies from paying for or providing any entertainment or recreational events for non-employee HCPs, regardless of the value or the entertainment or recreational events or whether the individual is a speaker or consultant for the company. These types of payments are not allowed even when the recreation or entertainment is secondary to an educational purpose.
5. **Meals.** The Revised Code states that companies may provide modest meals and refreshments to HCPs in connection with interactions that involve the presentation of scientific, educational or business information. The meal must be provided in a setting that is conducive to business or educational discussions and must not have the purpose of merely creating goodwill or developing business prospects. Finally, such meals should only be provided to those who actually attend the educational event and no meals shall be provided to HCPs in a carry-out fashion.
6. **Promotional Gifts.** The Revised Code entirely prohibits the provision of non-educational, branded promotional items, such as pens or notepads, which contain a company name or logo. This prohibition extends to items of minimal value, those related to the HCPs work, and those that benefit patients. The Revised Code, however, allows a company to provide to an HCP an item with a fair market value of $100 or less to be used for educational purposes, such as an anatomical model or a textbook.
7. **Reimbursement Consulting.** The Revised Code allows for companies to collaborate with HCPs to achieve commercial payor coverage decisions, guidelines, and policies that allow patients to access medical technologies. However, the Revised Code states that companies may not, in any case, interfere with an HCP's independent clinical decision making, promote billing for services that are not medically necessary or suggest a method for the HCP to engage in fraudulent billing practices.
8. **Samples.** The Revised Code contains a new section entitled Evaluation and Demonstration Prod-

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ucts, allowing for companies to provide HCPs with a reasonable number of their products for evaluation purposes. The HCP uses these demonstration products to analyze their functionality and to determine whether the HCP will, in the future, use, purchase, or recommend the products. These products are not to be considered gifts. An HCP should only be allowed to use a product for the length of time reasonably necessary to evaluate the product and the provision of products for evaluation purposes should be documented. Adhering to these restrictions will minimize the risk that medical device manufacturers will be accused of allowing HCPs to use free products to induce product purchases or recommendations in violation of the Anti-Kickback Statute.