THE
NATIONAL LAW REVIEW

Revised Advamed Code Reflects An Evolving Industry

Monday, March 18, 2019

Article By Veleka Peeples-Dyer
Tony MaidaVernessa T. Pollard
Drew Elizabeth McCormickAnisa Mohanty
McDermott Will & EmeryOn the Subject

Health Law & Managed Care
Communications, Media & Internet
All Federal

OVERVIEW

In its first update in a decade and effective January 1, 2020, the revised Advanced Medical Technology Association (AdvaMed) Code of Ethics in Interactions with Health Care Professionals (Code) in the United States contains new provisions and revisions to existing language that touch on many common industry activities. Changes include express reference to digital health and software technologies as covered by the Code, clarifications on topics such as "legitimate need" for consulting services, development of fair market value methodologies, and guardrails around research grants and charitable donations. The revised AdvaMed Code also introduces sections discussing jointly conducted education and marketing programs by health care professionals and companies, provision of technical support in clinical settings, and principles for communicating about off-label uses. A detailed appendix to this article summarizes the changes and clarifications section-by-section.

IN DEPTH

Relationships between medical technology companies and health care professionals (HCPs) can help advance development of medical technologies, promote their safe and effective use, and foster medical research and education. These relationships can also create risk under state and federal laws, however, such as the federal Anti-Kickback Statute. The Advanced Medical Technology Association (AdvaMed), a medical technology trade association, originally developed a set of voluntary guidelines for its members to use in structuring their interactions with HCPs. The AdvaMed Code of Ethics in Interactions with Health Care Professionals in the United States (Code) was created in 1993 and revised in 2003 and 2009.

While the Code remains labeled a voluntary set of guidelines, AdvaMed requires its member companies to abide by the Code. Certain states, including California, Connecticut and Nevada, have made the Code's provisions mandatory. In addition, disclosure databases and reporting requirements have been created under the federal Sunshine Act and in California, Massachusetts and Vermont. And as the industry is well aware, alleged violations of the federal Anti-Kickback Statute may provide a basis for whistleblowers or the government to file cases alleging that Code non-compliance is evidence of improper conduct.

Effective January 1, 2020, the updated AdvaMed Code clarifies and refines its discussion of interactions between HCPs and representatives of AdvaMed member companies, which include medical device manufacturers and other medical technology companies. The updated Code adds new topics, incorporates related guidance previously issued by AdvaMed, and enhances guidelines on existing topics by bringing examples current, enhancing user-friendliness and clarity, and addressing the evolving nature of interactions with HCPs.

The updated AdvaMed Code notes that it does not replace any laws, regulations or codes that contain stricter requirements. It refers medical technology companies to government-issued guidance on effective compliance programs and specifically lists the US Federal Sentencing Guidelines and guidance materials from the US Department of Justice and the US Department of Health and Human Services Office of Inspector General.

AdvaMed Code: New Sections

The new AdvaMed Code introduces three new sections, discussed below.

Jointly Conducted Education and Marketing Programs

Companies may partner with HCPs to conduct joint education and marketing programs designed to highlight medical technology and to diagnose or treat medical conditions. The new Code provides the following guidelines for these programs:

- There should be a *bona fide*, legitimate need to engage in the activity for the company's own educational or marketing benefit.

- The company should establish controls to help ensure that decisions to engage in these arrangements are not undertaken as an unlawful inducement, and they should require HCPs to comply with company guidelines concerning to purchase and use the company's product
- Content should be balanced between promoting both the company and the HCP.
- The company and the HCP should serve as *bona fide* partners in the program and make equitable contributions toward the activity and cost.
- The arrangement should be documented in a written agreement that describes the purpose, roles, responsibilities and contributions of each party.

Communicating Information for the Safe and Effective Use of Medical Technology

This new Code section contains principles for communicating information about unapproved or uncleared (off-label) uses for approved or cleared products. As stated in the Code, "[a]s recognized under U.S. law and by the FDA, off-label use of these Medical Technologies can be an important part of medical practice and may even constitute a medically recognized standard of care." Industry-appropriate communications of such information may 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 (taking care that no claims are made regarding safety and effectiveness)
- Discussions with consultants and HCPs to obtain advice or feedback relating to topics such as unmet patient needs or product research and development

Specifically, the Code provides the following guardrails around communications regarding off-label claims:

- They should only be made by authorized personnel.
- The claims must be truthful and non-misleading.
- The claims must be clearly identified as off-label.

The new Code also encourages companies to develop policies and controls that incorporate US Food and Drug Administration (FDA) guidance, judicial decisions and other relevant applicable authorities. The Code's off-label communication guidelines reflect recent judicial opinions affirming First Amendment protections for truthful and non-misleading off-label speech. Companies should evaluate and implement these guidelines in light of existing FDA laws and HHS/OIG guidance on off-label communications.

Company Representatives Providing Technical Support in the Clinical Setting

The final new section of the Code provides principles for company representatives providing technical support in the clinical setting—for example, directing or supervising an HCP to explain how a medical technology's settings and technical controls function, or assisting in clinical settings or the operating room to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when the medical technology involves multiple devices or accessories. Company representatives should:

- Only enter and be present in a clinical setting at the request and supervision of an HCP
- Be transparent that they are acting on behalf of the company in a technical support capacity
- Not interfere with an HCP's independent clinical decision-making
- Comply with applicable hospital or facility policies and requirements (*e.g.*, patient privacy or credentialing requirements)

Additionally, a company's technical support should not eliminate an overhead or other expense that the HCP should otherwise incur while providing patient care. Although expressly addressed in the Code, companies should also ensure that personnel have appropriate guidelines on managing off-label discussions, unsolicited requests or adverse events that may arise in the context of providing technical support in clinical settings.

AdvaMed Code: Consolidations and Clarifications

The new Code consolidates and clarifies content in the prior version. Key changes are summarized below.

Cornerstone Values

New cornerstone values, including innovation, education, integrity, respect, responsibility and transparency, are the basis for the updated Code. The Code directs medical technology companies to review all interactions with HCPs in light of these cornerstone values and to always avoid interactions designed to circumvent the Code.

Scope and Applicability

The updated Code applies to all interactions between medical technology companies and US HCPs, regardless of whether an interaction occurs outside the United States (such as at a conference or other event). The updated Code clarifies that for companies with multiple lines of business (*e.g.*, medical devices, pharmaceuticals, biologics, consumer items or research products), the Code only applies to the company's interactions linked to medical technology. The updated Code applies to all interactions with US HCPs related to combination products that include a medical technology component (*i.e.*, combination device/biologic and device/drug products).

Glossary

To make the Code more user friendly and provide additional clarification, the updated Code incorporates a glossary of terms. It also adds defined terms for "Commercial Sponsorship," "Educational Grant," "Satellite Symposium," "Third-Party Program" and "Third-Party Program Organizer," and enhances existing definitions of "Medical Technologies" and "HCP."

Consulting

Although the content regarding consulting remains mostly unchanged, the updated Code adds clarifying language regarding what constitutes a "legitimate need," and includes an explanation of how to develop a fair market value methodology. Specifically, the updated Code notes that a third party may assist in developing an approach to assess fair market value, and that a medical technology company's fair market value methodology should incorporate objective criteria in all circumstances. Medical technology companies are encouraged to document their methods for evaluating whether compensation reflects the fair market value of the services provided.

Marketing and Education Programs

Company Programs: The updated AdvaMed Code consolidates sections on industry-conducted training, education and other business meetings into a comprehensive section that provides parameters for all industry-conducted programs. This section largely tracks the previous Code language.

Third-Party Programs: The updated AdvaMed Code also consolidates sections regarding support for third-party education and charitable and research programs into one comprehensive section regarding grants, donations and commercial sponsorships. Among other changes, the updated Code focuses on meeting third-party organizer/accreditation standards; adds language to clarify that grant funds can, in turn, only be used by the organizer to provide items that are permissible under the Code (and not those that are impermissible); and includes checklists for use in evaluating requests. The updated Code also includes language that prohibits medical technology companies from passing along to HCPs benefits that the company receives in exchange for commercial sponsorship; further expands and clarifies the requirements for supporting independent research grant requests; and provides parameters for providing charitable donations.

Travel, Lodging and Venue

In addition to consolidating guidance on travel, lodging and venue into a single section, the updated AdvaMed Code clarifies that travel is not permitted for general education programs. It also suggests that companies avoid selecting a setting because of its entertainment or recreational facilities (considering, for example, the season or time of year of the event).

Meals

In addition to consolidating guidance on meals into a single section, the updated AdvaMed Code adds language encouraging medical technology companies to develop meal policies and to review benchmarking information.

Demonstration and Evaluation Products

The updated AdvaMed Code clarifies existing language regarding provision of evaluation products, and provides guidance regarding evaluation agreement contents and transparency in operating the program. The updated Code also states that consignment arrangements should generally be subject to an agreement addressing the terms of the consignment, for example:

- Number of products
- Requirements to segregate consigned products that a company provides for the HCP's use and that the HCP stores at its location, even though the company retains the title to the product, from other products
- Space rental terms

Consistent with prior stand-alone guidance, the updated Code encourages medical technology companies to consider implementing controls, such as taking periodic inventory of consigned products and returning or removing expired product.

Next Steps

To reduce compliance risks, medical technology companies and HCPs should consider whether the updates to the AdvaMed Code warrant changes to their policies, procedures and practices regarding interactions with one another. The delayed effective date of the new Code is intended to provide time to conduct this review.

Appendix: Summary of Changes by Section

	ADVAMED CODE 2009	ADVAMED CODE 2020
Section I – Introduction	I. Preamble: Goal and Scope of AdvaMed Code and II. Code of Ethics Compliance	Consolidates former sections I and II into a new **Section I – Introduction** section. New "Cornerstone Values": Innovation, Education, Integrity, Respect, Responsibility & Transparency New Definitions: Commercial Sponsorship, Educational Grant, Satellite Symposium, Third-Party Program, Third-Party Program Organizer
	Definitions: • Medical Technologies: medical products, technologies, and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities • Health Care Professionals (HCPs): individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States.	Revised Definitions: • Medical Technologies: medical devices and products, technologies, **digital and software platforms**, and related services, **solutions** and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (*e.g.*, implantable medical devices; surgical devices; **digital technology and software platforms**; and non-invasive reagents, instrumentation or software). • HCPs: any person or entity (a) authorized or licensed in the United States to provide health care services or items to patients or (b) who is involved in the decision to purchase, prescribe, order or recommend a Medical Technology in the United States. This term includes **individual clinicians** (for example, physicians, nurses and pharmacists, among others), **provider entities** (for example, hospitals and ambulatory surgical centers) and **administrative personnel at provider entities** (for example, hospital purchasing agents). **Does not include** Health Care Professionals who are **bona fide employees of a Company, while acting in that capacity**.

Section II – Consulting Arrangements with Health Care Professionals	VI. Consulting Arrangements with Health Care Professionals "Consulting arrangements should be entered into only where a **legitimate need** for the services is identified in advance and documented." "Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business . . . There are different valuation methods that may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria. The method or methods used by a Company should be documented."	Moves to **Section II – Consulting Arrangements with Health Care Professionals**. Clarifies that a "**legitimate need** arises when a company requires the services of a HCP to achieve a specific objective, such as the need to train HCPs on the technical components of safely and effectively using a product; the need for clinical expertise in conducting product research and development; or the need for a physician's expert judgment on clinical issues associated with a product." Explains how to develop fair market value (FMV) methodology: many third-party vendors or other experts can assist a company in developing an approach to assessing FMV compensation. In all instances, a company should use a method that incorporates objective criteria (*e.g.*, an HCP's specialty, years and type of experience, geographic location, practice setting, the type of services performed). States that sales personnel must not control or unduly influence the decision to engage an HCP as a consultant, because separation is necessary to avoid the perception that a company has entered into a contract with an HCP to secure or reward the HCP for purchasing, using or recommending the company's medical technology or other sales considerations. Also notes that HCPs' interactions with companies may create potential conflicts of interests (COIs) (*e.g.*, through leadership roles in medical societies, conference planning, medical journal editorial staff). Companies should be aware of these potential COIs and mindful of steps that may be necessary to address conflicts, such as recusal from decisions that implicate conflict. In addition to entering into consulting arrangements for an HCP's services in advance, companies should confirm that services are performed in accordance with the agreement.

Section III – Company-Conducted Programs & Meetings with Health Care Professionals	III. Company-Conducted Product Training and Education; V. Sales, Promotion, and Other Business Meetings	Consolidates former sections III and V into a new **Section III – Company-Conducted Programs & Meetings with Health Care Professionals** to cover all company-conducted programs.
Section IV – Educational & Research Grants, Charitable Donations, and Commercial Sponsorships	IV. Supporting Third-Party Educational Conferences; XI. Research and Educational Grants and Charitable Donations	Consolidates former sections IV and XI into a new **Section IV – Educational & Research Grants, Charitable Donations, and Commercial Sponsorships**. Educational Grants: Focuses definition on payment or in-kind support to a **third-party entity** (*e.g.*, Third-Party Program Organizer or training institution) and clarifies that these programs may or may not be accredited to provide continuing education credits. Also clarifies that third parties may only use grant funds to provide items permissible under the Code. Adds a checklist for grant "Review Processes" for use in evaluating grant requests. Commercial Sponsorship: Clarifies that company sponsors may not pass along any benefits they receive from the third-party organizer (*e.g.*, complimentary conference registrations) to an HCP. Satellite Symposia: Companies may cover expenses for an HCP to serve as a bona fide faculty member, including at a Satellite Symposium (limited, as appropriate, to the time necessary to speak at the Satellite Symposium). Companies may not cover expenses if the HCP is merely attending the Symposium.

	Research Grants: "Company may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies."	Research Grants: Clarifies requirements for supporting independent research grant requests: • Objectives & Milestones: defined goals, objectives and milestones; accompanied by clinical protocols; document the nature and scope of the research activity, the budget, the approximate duration of research, and requirements for independent authorizations or approvals (*e.g.*, FDA approval). • Limitation: in-kind or monetary support for legitimate, study-related, documented expenses or services, or reasonable quantities of no-charge product for limited duration of research. • Company Involvement: recipient should retain independent control over research. • Company Review Process: company should establish controls for reviewing requests for research grants. • Sales Involvement: sales personnel should not control or unduly influence the decision of who will receive support or the amount of support.

	Charitable Donations: Donations should be motivated by bona fide charitable purposes and should be made only to bona fide charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission.	Charitable Donations: Clarifies requirements for providing charitable donations: • Charitable or Philanthropic Mission: for bona fide charitable purposes and only to charitable organizations and non-profits with bona fide charitable or philanthropic purposes. Companies should consider the entity's tax status, corporate status under state law, and whether the organization has a charitable mission or purpose, among other factors. • Use of Funds: company must require donations be used only toward charitable or philanthropic purposes. • Indigent Care Donations: company may make donations of product for indigent patients, but these donations must serve exclusively to the benefit of patients and be otherwise permitted under applicable laws (*e.g.*, state law). Companies should consider including a provision that no third parties will be billed for the donated product in a formal agreement with a hospital. • Charitable Events: companies may not pay for HCPs to attend charitable events. • Sales Involvement: sales personnel should not control or unduly influence the decision whether a particular entity will receive support or the amount of support.

Section V – Jointly Conducted Education and Marketing Programs		New **Section V – Jointly Conducted Education and Marketing Programs** Companies may partner with HCPs to conduct joint education and marketing programs designed to highlight Medical Technology and an HCP's ability to diagnose or treat medical conditions if: • There is a bona fide, legitimate need to engage in the activity for its own educational or marketing benefit. • The company establishes controls to help ensure decisions to engage in these arrangements are not made as an unlawful inducement. • Content is balanced between the company and the HCP. • The company and the HCP make equitable contributions toward the activity and cost. • The arrangement is documented in a written agreement that describes the purpose, roles, responsibilities and contributions of each party.

Section VI – Travel & Lodging; Venue	III. Company-Conducted Product Training and Education; IV. Supporting Third-Party Educational Conferences; V. Sales, Promotional, and Other Business Meetings; VI. Consulting Arrangements with Health Care Professionals	Consolidates existing travel and venue guidance into new **Section VI – Travel & Lodging; Venue**. Travel: Permitted: • To provide consulting services to a company, if the HCP is subject to an executed consulting agreement and there is an objective, legitimate reason to support in-person participation • To attend company-conducted training or education program concerning Medical Technologies and there is an objective, legitimate reason to support in-person attendance • To speak on the company's behalf at Third-Party Program • Other programs or meetings if there is an objective, legitimate reason that supports in-person attendance Not permitted for general education programs. Venue: Provides additional guidance on evaluating appropriate venues for meetings, including: • Central location and ease of accessibility (such as proximity to airports or highways) • Not selected because of entertainment or recreational facilities (*e.g.*, season or time of year) • Avoid top category or luxury hotels or resort facilities without appropriate justification

Section VII – Providing Modest Meals and Refreshments to Health Care Professionals	III. Company-Conducted Product Training and Education; IV. Supporting Third-Party Educational Conferences; V. Sales, Promotional, and Other Business Meetings; VI. Consulting Arrangements with Health Care Professionals; VIII. Modest Meals Associated with Health Care Professional Business Interactions	Consolidates guidance on meals and replaces section VIII with new **Section VII – Providing Modest Meals and Refreshments to Health Care Professionals**. Strongly encourages companies to develop policies on providing modest and occasional meals to HCPs, including establishing a per-meal spending limit and with consideration for geographic variances.
Section VIII – Educational & Patient Benefit Items; Prohibition on Gifts	IX. Educational Items; Prohibition on Gifts	No significant revisions.
Section IX – Prohibition on Entertainment & Recreation	VII. Prohibition on Entertainment and Recreation	Moved to **Section IX – Prohibition on Entertainment & Recreation**.
Section X – Communicating for the Safe & Effective Use of Medical Technology		New **Section X – Communicating for the Safe & Effective Use of Medical Technology**. Contains principles for communicating unapproved or uncleared (off-label) uses: • Only by authorized personnel (*e.g.*, in response to unsolicited requests and by medical affairs) • Truthful and non-misleading • Identified as off-label Companies are encouraged to develop policies and controls that incorporate FDA guidance, judicial decisions and other relevant applicable authorities.

Section XI – Provision of Health Economics & Reimbursement Information	X. Provision of Coverage, Reimbursement and Health Economics Information	Moved to **Section XI – Provision of Health Economics & Reimbursement Information**. No significant revisions.
Section XII – Demonstration, Evaluation, and Consigned Products	XII. Demonstration & Evaluation Products	Enhances existing language with clarity on when it is acceptable to provide evaluation products and contents of evaluation agreement; adds language that companies should be mindful of transparency requirements; adds language on consignment products and recommendations for controls.

Section XIII – Company Representatives Providing Technical Support in the Clinical Setting		New **Section XIII – Company Representatives Providing Technical Support in the Clinical Setting**. Provides principles for company representatives providing technical support in the clinical setting, for example: • Direction/supervision of HCP to explain how a Medical Technology's settings and technical controls function • Assisting in clinical/operating room to ensure the appropriate range of necessary devices and accessories are available during a procedure, especially when the Medical Technology involves multiple devices or accessories Company personnel: • Should only enter and be present in clinical setting at request and supervision of HCP • Should be transparent that they are acting on behalf of the company in a technical support capacity • Should not interfere with an HCP's independent clinical decision-making • Should comply with applicable hospital or facility policies and requirements (*e.g.*, patient privacy, credentialing requirements). • A company's technical support should not eliminate an overhead or other expense that the HCP should otherwise incur while providing patient care.