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AdvaMed Updates Code to Provide Guidance on Innovative Arrangements, Medical Technology, Interactions With HCPs

Article By:

Tony Maida

James A. Cannatti III

Vernessa T. Pollard

Anisa Mohanty

OVERVIEW

The Advanced Medical Technology Association (AdvaMed) announced its revised Code of Ethics on Interactions with Health Care Professionals (2022 Code) on March 18, 2022. Notable updates to the 2022 Code provide guidance on value-based care arrangements and address the integration of medical technology across products and services. Revisions also clarify requirements and best practices related to meetings, trainings, and communications with healthcare professionals (HCP). The revised 2022 Code will take effect on June 1, 2022.

IN DEPTH

The medical device industry has relied on the AdvaMed Code for decades to assist with navigating complex rules concerning compliance—particularly rules regarding fraud and abuse stemming from interactions with HCPs. AdvaMed's latest revisions provide additional guidance on technologically enhanced delivery models and novel arrangements, such as those involving value-based care. The medical device industry is working to adjust its compliance programs to deal with the fact that the US Department of Health and Human Services Office of Inspector General (HHS-OIG) precluded medical device companies from taking advantage of the new value-based safe harbors, except in limited circumstances involving digital health technology. Innovative arrangements, such as those that advance value-based care, are changing the way technology is used and how HCPs interact with industry. The complex and evolving regulatory environment necessitated revisiting AdvaMed's Code to provide additional guidance to industry. Other factors, including the integration of data analytics and an uptick in virtual events resulting from pandemic restrictions, add many layers of complexity to the already daunting task of establishing and maintaining a successful compliance program.

Below, we provide a high-level overview of relevant updates and revised Frequently Asked Questions

(FAQ) that are addressed in the 2022 Code.

2022 Code Revisions

Data-driven devices & solutions. AdvaMed added a new subsection to Section I in the 2022 Code to highlight the expanding role of data analytics and technology in the medical technology industry. The 2022 Code acknowledges that medical technology companies utilize data for many different purposes, including analyzing trends, delivering products and services, and improving quality of care and patient outcomes. This added subsection demonstrates that the 2022 Code contemplates integration of technological enhancements across products and services.

Company-conducted programs and meetings; education and training for value-based care arrangements. Section III of the 2022 Code emphasizes that companies have a "legitimate need" to educate and train HCPs on how to incorporate and use their Medical Technologies, as defined by the 2022 Code. With the appropriate safeguards in place, meetings with HCPs to discuss value-based solutions, services or other arrangements may be permissible. Further, arrangements that "advance value-based care" may include product trainings and education activities presented by a particular company. Such trainings and educational activities may be associated with medical device(s) and related offerings (*e.g.*, services, software, equipment or other similar offerings) that are, for example, designed to measure outcomes, as applicable.

Consulting arrangements with HCPs. The 2022 Code expands on guidance relating to HCP consulting services to address HCPs assisting with the development, evaluation or implementation of value-based care arrangements. Consistent with the prior version of the 2022 Code, there should be a "legitimate need" for a consulting arrangement, it should be established in advance, and consultants should be selected carefully (*e.g.*, through a vetting process) and paid fair market value for their services.

Definitions: Updates and Additions

The 2022 Code also adds and expands certain defined terms, including "Medical Technology," "Value-Based Care," and "Virtual." These additions reflect the 2022 Code's general modernization. While certain definitions are similar to terminology used in the Anti-Kickback Statute (AKS) Value-Based Enterprise (VBE) safe harbor provisions concerning digital health (see, *e.g.*, 42 CFR § 1001.952(ee)(14)(ii), defining "Digital health technology"), the 2022 Code takes a broader approach. Because of this broader approach, it is important to remember that certain arrangements may still be permissible under a facts and circumstances analysis—even if criteria for a particular safe harbor are not met.

- AdvaMed expanded the definition of "Medical Technology" in the 2022 Code. The term is generally defined to mean "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. . . ."

- The 2022 Code adds a new example to the definition: "[d]igital technology and software platforms that assist in . . . coordinating patient care." This update is consistent with AdvaMed's consideration of innovative tools used in the delivery of products and services.

- The 2022 Code adds "Value-Based Care" as a defined term. The definition describes healthcare delivery models in which payment may be based on several factors, including

patient health outcomes, population health outcomes, increasing access to healthcare for underserved populations, managing costs, and improving efficiency. Arrangements to advance value-based care are outcomes driven and "often condition payment or modify pricing for health care items or services based upon clinical, economic, and/or patient-experience outcomes, and may include payor-driven reimbursement arrangements for providers, arrangements between providers, and arrangements between providers and manufacturers or other participants in the health care system."

- "Virtual" means "an environment generally enabled by digital technology . . ." This newly defined term is consistent with AdvaMed's effort to accommodate unique meeting formats in the 2022 Code revisions.

Key Updates to Frequently Asked Questions

Permissible Arrangements Under the Anti-Kickback Statute

AdvaMed added a new FAQ to Section I (renumbered as FAQ #3) to address proposed arrangements that do not fit squarely within the AKS safe harbors (see 42 CFR § 1001.952). While certain arrangements may not meet all of the conditions of a potentially applicable AKS safe harbor, the 2022 Code emphasizes that a particular arrangement may still be permissible under a facts and circumstances analysis, which considers factors such as whether the arrangement would adversely impact access to care, whether clinical decision-making is compromised, and whether the arrangement would affect patient safety or quality of care. The intentions of those involved in an arrangement will also be considered as part of the facts and circumstances analysis.

Interactions with HCPs Related to Value- or Outcomes-Based Care Arrangements

AdvaMed added a new FAQ to Section I (renumbered as FAQ #4) to clarify that the 2022 Code applies to interactions with HCPs under arrangements that promote value- or outcomes-based care. The 2022 Code reiterates that certain value-based care arrangements may be permissible even if no safe harbor applies, consistent with OIG's efforts to support "a broad range of participation and business structures."

Provision of Alcohol at Company-Conducted Programs and Meetings

AdvaMed added a new FAQ to Section III (renumbered as FAQ #9) to provide guidance on the provision of alcohol at company-conducted meetings and programs. The guidance identifies potential controls to consider related the provision of alcohol, such as per-person drink limits, per-drink spending limitations, and restrictions on the type of alcohol served at the event (*e.g.*, only beer and wine). The 2022 Code also highlights AdvaMed's periodic benchmarking surveys (*e.g.*, on best practices around providing modest meals and refreshments), which are available through its website for members.

In HHS-OIG's November 16, 2020 Special Fraud Alert addressing speaker programs, HHS-OIG considered the provision of alcohol a "suspect characteristic." In the 2022 Code, AdvaMed seeks assist industry with developing safeguards to ensure offerings are less likely to raise concerns. AdvaMed's approach is less stringent than the revised PhRMA Code's guidance, which advises against the provision of alcohol altogether (see our prior discussion of the revised PhRMA Code here).

Provision of Modest Meals or Refreshments to HCPs

AdvaMed's 2022 Code outlines best practices concerning the provision of modest meals to HCPs in Section VII. Generally, companies may provide HCPs with meals and refreshments, but they must be modest and "subordinate in time and in focus" to the purpose of the meeting. The 2022 Code includes further clarification through the addition of two new FAQs:

- A new FAQ in Section III (renumbered as FAQ #10) underscores that companies should consider factors set forth in Section VI when determining an appropriate venue for holding a company-conducted meeting at a restaurant. Factors include determining whether there is a legitimate need or reason for holding a meeting at a particular venue and if the location is appropriate for the exchange of information, among other considerations. Certain practices, such as paying for guests to attend, are not permitted.

- A new FAQ in Section VII (renumbered as FAQ #29) provides clarification concerning the provision of meals and refreshments when programs are held virtually. The 2022 Code recommends establishing controls and processes to ensure proper ordering and delivery. Procedures should involve tracking attendance to ensure that the intended recipients (*i.e.*, attendees) receive meals or refreshments. Generally, home delivery is not permitted.

Communication of Economic Efficiency Information Relating to Medical Technology

A new FAQ was added to Section XI (renumbered as FAQ #34) to clarify that it is permissible to provide certain accurate and objective information about the economically efficient use of Medical Technology as long as the information sharing does not result in unlawful inducement or impact an HCP's clinical decision-making. While consistent with prior AdvaMed guidance, this updated FAQ clarifies that a company may provide coverage, reimbursement, and health economics information to an HCP for the purpose of developing or negotiating a value- or outcomes-based contract.

Key Takeaways

Medical technology companies and HCPs should consider whether the 2022 Code warrants changes to their compliance policies and procedures. The delayed effective date allows industry time to review current practices and align with relevant updates. The 2022 Code provides helpful guideposts but does not override laws, regulations, or other governing codes that may be in effect. Stakeholders should keep this in mind as they consider their particular arrangements in light of the recent 2022 Code revisions.

Code Section	AvaMed Code 2009	AvaMed Code 2020	AvaMed Code 2022
Section I – Introduction	I. Preamble: Goal and Scope of AdvaMed Code and II. Code of Ethics Compliance Definitions: • **Medical**	Consolidates former sections I and II into a new **Section I – Introduction** section. New "Cornerstone Values": Innovation, Education, Integrity,	New "Data-Driven Devices & Solutions" information: acknowledges the role that technology and data-driven solutions play in industry, as well as the potential for improved outcomes and quality of care.

	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.	Respect, Responsibility & Transparency New Definitions: Commercial Sponsorship, Educational Grant, Satellite Symposium, Third-Party Program, Third-Party Program Organizer Revised Definitions: • **Medical Technologies**: medical devices and products, tec hnologies, **digital and software platforms**, and related service s, **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	Revises the recommendation to submit an *annual* certification to AdvaMed declaring compliance with the Code; "a certification" is now sufficient. New FAQ (FAQ #3 in 2022 Code): underscores that proposed interactions that do not fit within the AKS safe harbors may be permissible under a facts and circumstances analysis. New FAQ (FAQ #4 in 2022 Code): reiterates that the 2022 Code applies to communications with HCPs under arrangements that involve value- or outcomes-based care. Adds & revises definitions: • **Medical Technology (revised)**: "Medical Technology is a broad term that means medical devices and products, technologies, digital and software platforms, and related services, solutions, and therapies used to

			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**.	diagnose, treat, monitor, manage, and alleviate health conditions and disabilities. Some examples include: . . . Digital technology and software platforms that assist in monitoring, diagnosing, and treating patients **or in coordinating patient care** . . .” • **Virtual (added)**: “An interaction that involves attendees participating in a virtual environment that is generally enabled by digital technology rather than meeting in a physical location.” • **Value-Based Care (added)**: “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.” Arrangements to advance value-based care (also referred to as results-based, outcomes-based, or performance-based payment arrangements) are designed to increase shared accountability among stakeholders for quality of, access to, and/or the total cost of care. These arrangements often condition payment or modify pricing for health care items or services based upon clinical, economic, and/or patient-experience outcomes, and may include payor-driven reimbursement arrangements for providers, arrangements between providers, and arrangements between providers and manufacturers or other participants in the health care system.”
Section II – Consulting Arrangements with	VI. Consulting Arrangements with	Moves to **Section II – Consulting**	Revises “Key Concepts”: relating to

Health Care Professionals	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.”	**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	engaging an HCP for consulting services. The 2022 Code clarifies that engaging an HCP for consulting services may include “assisting in the development, evaluation, or implementation of an arrangement to advance value-based care.”

		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.	<u>Revisions clarify that</u>: • Companies have a responsibility to train HCPs on how medical technologies may improve value-

			based care arrangements. • Arrangements to “advance value-based care” may include product trainings and education activities presented by a company. Such training and education may be related to medical device(s) and equipment designed to measure outcomes, as applicable (*e.g.*, services, software, and other equipment or similar offerings). • Companies may meet with HCPs to discuss value-based solutions, services or arrangements. • Virtual meetings serve as an appropriate setting. New FAQ (FAQ #9 in 2022 Code): to provide additional clarity on the provision of alcohol at company meetings and programs; revisions present options to limit availability to attendees. New FAQ (FAQ #10 in 2022 Code): factors set forth in Section VI should be considered when determining an

			appropriate venue for holding a company-conducted meeting at a restaurant.
Section IV – Educational & Research Grants, Charitable Donations, and Commercial Sponsorships	IV. Supporting Third-Party Educational Conferences; XI. Research and Educational Grants and Charitable Donations 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." 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 bonafide charitable mission.	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	No notable substantive changes.

		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: 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. <u>Charitable Donations</u>: 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	No notable substantive changes.

		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**. <u>Travel</u>: 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	<u>Revisions clarify that</u>: • While companies may pay for modest and reasonable travel and lodging, there are limitations and guiderails. There must be a "legitimate need" for travel, and the revised 2022 Code encourages companies to consider whether a legitimate need may be met via a virtual program or meeting. • Certain principles apply to the chosen setting (*e.g.*, must be conducive to information exchange); however, the principles set out in the 2022 Code apply when the meeting is in person (as they

		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. <u>Venue</u>: 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	relate to physical settings).
Section VII – Providing Modest Meals and Refreshments to Health Care	III. Company-Conducted Product Training and Education; IV. Supporting Third-Party	Consolidates guidance on meals and replaces section VIII with new **Section VII –**	<u>New FAQ (FAQ #29 in 2022 Code)</u>: to provide guidance concerning the provision of meals or

Professionals	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	**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.	refreshments when programs are held virtually. The 2022 Code recommends establishing controls and processes to ensure proper ordering and delivery.
Section VIII – Educational & Patient Benefit Items; Prohibition on Gifts	IX. Educational Items; Prohibition on Gifts	No significant revisions.	No notable substantive changes.
Section IX – Prohibition on Entertainment & Recreation	VII. Prohibition on Entertainment and Recreation	Moved to **Section IX – Prohibition on Entertainment & Recreation**.	Revisions emphasize that "[e]ntertainment and recreational activities are inconsistent with the appropriate business purpose of a Company's interactions with Health Care Professionals."
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-	No notable substantive changes.

		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.	New FAQ (FAQ #34 in 2022 Code) and revisions to permissible activities: clarifies that it is permissible to provide certain accurate and objective information (*e.g.*, reimbursement, economic efficiency information) when a company negotiates with an HCP to develop or negotiate a value- or outcomes-based contract in accordance with the conditions set forth in the 2022 Code.
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.	No notable substantive changes.
Section XIII – Company Representatives Providing Technical Support in the Clinical Setting		New **Section XIII – Company Representatives Providing Technical Support in the Clinical Setting**.	AdvaMed offerings and descriptions of resources removed.

		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.	

National Law Review, Volume XII, Number 97