

Training Presentations Included:

1. Overview of the 2022 Code Updates
2. Summary of the Current AdvaMed Code
3. Guidelines for Ethical Meetings



ReedSmith

AdvaMed Code:
2022 Update Overview

April, 2022



AdvaMed

Advanced Medical Technology Association

Intro – Overview of 2022 Update

The AdvaMed Code of Ethics has been revised, effective June 1, 2022.

Updates relate to:

- HHS OIG’s Special Fraud Alert on Speaker Programs – Noting special risks in presentations by health care professionals (“HCPs”) at company-sponsored events.
- HHS OIG’s Value-Based Arrangement Regulation – Safe harbor protection for certain value-based arrangements, including limited patient engagement technology safe-harbor.

Related changes to the AdvaMed Code may impact your meetings with clinicians, compensation of speakers, and collaboration with clinicians.

Update: Purposes of Medical Technology

AdvaMed, Sec. I

Data-Driven Devices & Solutions

- Medical Technology Companies leverage health care data and technology innovation to enable new insights, support health and wellness, improve patient interventions and outcomes, and enhance the quality and efficiency of health care delivery. Data-driven devices can also work independently or as part of a larger ecosystem to enable data collection, aggregation, and analysis. Uniquely positioned with data hub and analytics capabilities, clinical solutions to improve health outcomes, and business solutions to improve efficiency, Medical Technology Companies can also provide solutions: a combination of technology and services designed to deliver a targeted outcome.
- Digital technology and software platforms that assist in monitoring, diagnosing, and treating patients or in coordinating patient care.

Key Takeaways

- Medical Technology Companies improve patient care and ensure innovative and cost-effective care with data-driven solutions, beyond traditional interventions.
- Care coordination is an important and legitimate goal of medical device development.

Update: Meeting Guidelines

AdvaMed, Sec. III

Virtual Contexts Recognized

- There must be objective, legitimate reasons that support the need for out-of-town travel, as outlined in Sections III (A) and (B). As an alternative to in-person programs, Companies may wish to consider whether the legitimate need for travel could be met via a virtually-conducted program.

Use Discretion in Provision of Alcohol

- Decisions to provide alcohol must comply with the requirements of Section VII of the Code. Companies may consider adopting controls around the provision of alcohol at Company-Conducted Programs and Meetings. For example, considering government guidance, Companies may adopt per-person drink limits, per-drink spend limits, limitations on the types of alcohol permitted, or disallow alcohol at certain events. Companies may wish to review AdvaMed's periodic benchmarking surveys on best practices around providing modest meals and refreshments, which are available on its website.

Key Takeaways

- Consider Virtual Contexts When Determining “Legitimate Need.”
- Provision of alcoholic beverages must comply with rules applicable to modest meals and refreshments; companies may consider establishing internal policies to provide guardrails consistent with Section VII.

Update: Consulting & Entertainment

AdvaMed, Sec. II & IX

Appropriate Documentation

- A Company should maintain appropriate documentation which may include documentation regarding the process for determining legitimate need, fair market value compensation, and other relevant factors.

Prohibition on Entertainment / Recreation

- Entertainment and recreational activities are inconsistent with the appropriate business purpose of a Company's interactions with Health Care Professionals.

Key Takeaways

- Document reasoning and relevant considerations related to consulting arrangements with HCPs (e.g., need, qualifications, fair market value).
- Avoid ***even the appearance*** of engaging with HCPs for entertainment or recreational purposes.

Update: Value-Based Frameworks

AdvaMed, Sec. I, II, III, IX

Value-Based Care

- 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.

Purpose

- Value based care increases shared accountability among stakeholders for quality, access, and costs 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 among providers and other participants in the health care system.

Participation

- AdvaMed members may assist in the development, evaluation, or implementation of an arrangement to advance value-based care. May include Company-conducted product training and education. Where an arrangement to advance value-based care involves both medical devices and services designed to facilitate or measure given outcomes, training and education may relate to both the medical devices and the related offerings.

Key Takeaways

- Medical Technology Companies may participate in arrangements to advance value-based care.
- Typical role is to provide technology facilitating value-based care, and care coordination.
- The Code applies to interactions relating to such arrangements in the same way it applies to any other interactions with HCPs.
- Certain arrangements to advance value-based care involving Medical Technology Companies may not fit within available OIG safe harbors; nonetheless, the arrangement may be permissible based on the specific facts and circumstances.

ReedSmith

AdvaMed Code Overview:

What the Code Says & What it Means for You



AdvaMed

Advanced Medical Technology Association

Code Compliance

AdvaMed, Sec. I

- Companies “strongly encouraged” to adopt the Code and to implement an effective compliance program.
- Companies “strongly encouraged” to submit an annual certification of compliance, signed by the CEO and Chief Compliance Officer.
- Companies should refer to government-issued or other industry guidance, including seven core elements of an effective compliance program as outlined by the OIG.
- AdvaMed has published on its website companies that submit annual certification and companies’ compliance program contact information.
- Goal: solve issues intra-industry.

Key Concepts

- The AdvaMed Code applies to all interactions with health care professionals (“HCPs”).
- Compliance with the Code ensures ethical interactions and relationships with HCPs, consistent with “Safe Harbors” under the Anti-Kickback statute and similar state laws.
- The Code may not address all interactions; Companies should make reasonable decisions that align with the Code values.

Consulting Arrangements with HCPs

AdvaMed. Sec. II

- Provides standards for consulting agreements:
 - Company must have a legitimate need for the arrangement;
 - Consultants must be qualified to meet the identified need;
 - Pursuant to a written agreement;
 - Compensation must be fair market value for services actually provided, and may include reasonable expenses (e.g., travel, lodging, meals).
- Sales personnel may provide input but cannot control or unduly influence the decision of whether to engage a consultant.
- Royalty payments to HCPs may be appropriate.
- Suggested exclusion for self-referrals involving royalties.

Key Concepts

- Companies rely on HCP expertise for training, research, and development, among other activities to promote safe and effective treatment for patients.
- Companies should engage HCPs through written contracts that specify fair market value compensation for legitimate needs.
- Companies should maintain appropriate documentation, which may include records regarding legitimate need, fair market value, other factors.

Company-Conducted Training, Education, and Business Meetings

AdvaMed, Sec. III

- Companies can conduct various meetings with HCPs, often near place of HCP business.
- Setting should be conducive to effective transmission of information.
 - Selection of a resort location may give rise to an appearance of impropriety.
- Faculty should be qualified and attendees must have legitimate need to attend.
- Can pay for reasonable travel when necessary (plant tours, demos of non-portable equipment).
- Modest meals, subordinate in time and focus to a proper purpose, may be provided.
- No guests.

Key Concepts

- Companies have a legitimate need to provide training and education to HCPs on the safe, effective, efficient use of Medical Technology.
- Other business meetings may also be justified by legitimate needs, including tours of manufacturing facilities, product development, and sales meetings to discuss terms.
- All programs and meetings with HCPs should be conducive to accomplish the legitimate need.
- Consider whether “legitimate need” can be met by virtually-conducted programs.

Supporting Third-Party Education Conferences, Research, & Education Grants

AdvaMed, Sec. IV

- Permissible for companies to provide educational grants directly to third-party program organizers to support educational programs. Such funding may be used by the organizer to:
 - Defray/reduce costs of conducting the program;
 - Allow HCPs-in-training to attend (but company cannot select);
 - Cover reasonable travel, lodging, and meals of HCPs serving as faculty;
 - Provide attendees modest meals, refreshments, and educational items.
- Sales personnel should not control or unduly influence funding decisions, although they may offer input.
- Company cannot directly pay for travel, lodging, or registration fees for HCPs to attend third-party program, including satellite symposia.

Key Concepts

- Companies have an important role in educating HCPs and patients, providing charitable support, and supporting impactful research.
- Companies may support third-party education, charity, and research through monetary, in-kind, or other contributions.
- Companies should make objective decisions based on consistent guidelines and processes, to avoid unlawful inducements to HCPs.
- When a virtual context is available, consider whether there is truly legitimate need for a program.

Joint Education and Marketing Programs

AdvaMed Sec. V

- Companies must have a bona fide, legitimate need for engaging in joint education and marketing activities, i.e., a program must offer educational or marketing benefits to the company.
- Programs must be balanced and promote both the company and its products, as well as the HCP's services as they relate to relevant medical conditions.
- Companies should establish controls to help ensure that decisions to engage in these arrangements are not made as an unlawful inducement. Companies should also require participating HCPs to comply with Company guidelines on providing information related to a product's labeling, and guidelines for furnishing appropriate health economics information, among other controls.

Key Concepts

- Companies and HCPs can partner for appropriate joint education and marketing programs.
- The Company and the HCP should serve as bona fide partners, and contributions and costs should be shared fairly and equitably between the parties.

Travel & Lodging; Venue

AdvaMed, Sec. VI

Companies may pay for Health Care Professionals' modest and reasonable travel and lodging costs to attend **Company-conducted programs** and meetings, which have:

1. Legitimate Need for Attendance;
2. Modest and Reasonable Travel & Lodging;
3. No payment to unnecessary guests;
4. No personal travel or lodging included;
5. An appropriate setting conducive to exchange of information;
6. Appropriate compliance with other applicable law.

Companies **may not directly pay** for an HCP's travel or lodging associated with **third party programs**.

Key Concepts

- Companies may pay for HCPs' modest and reasonable travel and lodging costs to attend a Company-conducted program or meeting under certain circumstances.
- In all instances, there must be objective, legitimate reasons that support the need for travel and lodging for HCPs.

Providing Modest Meals and Refreshments to HCPs

AdvaMed, Sec. VII

- Meals can be provided to HCPs in conjunction with the presentation of scientific, educational or business information and in conjunction with consulting arrangements.
- Setting should be conducive to the exchange of information, which may be HCP site or off-site.
- Can be provided to only those HCPs who actually attend and have a bona fide purpose for attending meeting.
- Companies are encouraged to develop Meal Policies including per-meal spending limits, which may include geographic variation.
- Companies may consider adopting controls around the provision of alcohol at Company-Conducted Programs and Meetings.

Key Concepts

- Meals and refreshments provided to HCPs must be provided in a manner and setting conducive to the legitimate need for the presentation.
- Should be subordinate in time and focus to scientific, educational or business presentation.
- Alcohol is a refreshment, and provision of alcohol must comply with the rules in this section; Companies may develop more specific guidelines in compliance with the Code.

Educational Items: Prohibition on Gifts

AdvaMed, Sec. VIII

- Companies may provide modest, appropriate education items to HCPs that benefit patients or service an educational function.
 - Modest = \$100 or less, except medical text books or anatomical models.
- Prohibits items the HCP can use for non-educational or non-patient-related purposes (e.g., office supplies, laptop).
- Prohibits branded promotional items (pens, notepads, mugs).
- No cookies, wine, flowers, food baskets, etc.

Key Concepts

- Companies **may not** provide branded, promotional items or “gifts” to HCPs.
- Companies **may** provide modest, appropriate educational items or patient benefit items to HCPs.

Prohibition on Entertainment and Recreation

AdvaMed, Sec. VIII

- Strictly prohibits all entertainment and recreation.
- Includes theater tickets, sporting events, golf, skiing, hunting, sporting equipment, vacations and similar items.
- Applies regardless of the value of the activity, whether the HCP is a consultant, and whether it is secondary to an educational purpose.
- Entertainment and recreational activities are inconsistent with the appropriate business purpose of a Company's interactions with HCPs.

Key Concepts

- Companies may not provide entertainment or recreation to HCPs **in any form.**

Communications About Use of Products

AdvaMed, Sec. X

- Communications for the safe and effective use of products must recognize both a company's responsibility to communicate truthful and non-misleading information about its products and an HCP's right to exercise his or her medical judgement in using products, both on- and off-label.
- Key principles:
 - Company responses that contain information regarding unapproved/uncleared uses should be provided by authorized personnel;
 - Communications must be truthful and non-misleading;
 - Information regarding unapproved/uncleared uses should be identified as such.

Key Concepts

- Access to truthful and non-misleading information relating to Medical Technologies is critical to HCP ability to exercise medical judgment and provide safe, high-quality care.
- Companies are encouraged to develop policies and controls on communications based on the Code.

Provision of Coverage, Reimbursement and Health Economics Information

AdvaMed, Sec. XI

- Identifies several permissible activities, including:
 - Providing information on clinical value of a company's product;
 - Collaborating with HCPs on joint advocacy for coverage, reimbursement and health economics concerns;
 - Providing accurate and objective coverage, coding and billing information;
 - Providing information/training on payor policies and procedures for obtaining prior authorization (includes providing sample letters and information on medical necessity and appeals of denied claims).
- Prohibits services that would interfere with clinical decision making, or eliminate an HCP's overhead or other expenses.

Key Concepts

- Companies may support patients in obtaining access to a Company's Medical Technology by providing HCPs with timely and complete coverage, reimbursement, and health economics information.
- Companies may not, however, interfere with a HCP's independent clinical decision making or provide coverage, reimbursement and health economics support as an unlawful inducement.

Evaluation and Demonstration Products

AdvaMed, Sec. XII

- Specific guidelines are included for single-use products (consumable or disposable items), multiple-use products (capital equipment), demonstration or unsterilized products.
- Includes standards for determining:
 - Duration of a demonstration and evaluation period;
 - Appropriate amount of product that should be provided to customers (reasonable amount for adequate evaluation).
- Companies should provide documentation to HCPs of the no charge status of evaluation and demonstration products, as well as appropriate terms and documentation for consigned products.

Key Concepts

- Companies can provide reasonable quantities of products to HCPs for evaluation and demonstration purposes at no charge to permit HCPs to evaluate and assess whether to purchase the product.
- Companies may also provide HCPs with non-sterile demonstration units to use in educating patients about the product and its use.

Technical Support in the Clinical Setting

AdvaMed, Sec. XIII

- Company representatives may play an important role in the clinical setting by providing technical support on products. Representatives should:
 - Only enter and be present in the clinical setting *at the request and under HCP supervision*;
 - Be *transparent* about the fact that they are acting on behalf of the company in a technical support capacity;
 - Not *interfere* with the HCP's independent clinical decision-making;
 - Comply with all applicable *facility policies and requirements*.
- A company's technical support should not eliminate an overhead or other expense that the HCP should otherwise incur while providing patient care.

Key Concepts

- Access to truthful and non-misleading information relating to Medical Technologies is critical to a HCP's ability to exercise medical judgment, to provide high-quality care, and to safely use available Medical Technology.
- Companies are encouraged to apply the principles outlined in this section and develop related controls.

ReedSmith

Interacting with Clinicians with Integrity: Ethical Guidelines for Meetings



AdvaMed

Advanced Medical Technology Association

Agenda – Ethical Guidelines for Meetings

This training provides guidelines for meetings involving health care providers (“HCPs”), including:

1. Purposes of a Meeting;
2. Meals and Refreshments (including Alcohol);
3. Choice of Venue;
4. Travel & Lodging;
5. Restrictions on Entertainment; and
6. Documentation for Consultants.

The AdvaMed Code governs various types of meetings, including Company business, Company training, and third-party-run events.

Valid Meeting Purposes

Principles for Conduct of Meetings and Programs with HCPs include:

1. Legitimate Need for conducting the meeting;
2. Setting conducive to discussion of relevant information;
3. Attendees with an objective, legitimate need to attend the business meeting; and
4. Compliance with generally applicable travel, lodging, meal, and refreshment standards.

Providing Food & Alcohol

A Company may occasionally provide HCPs with modest meals and refreshments if the meal is provided with an appropriate:

1. Purpose, so that the meal is subordinate to discussion or presentation of medical technology development or improvement, pricing and contract negotiation, or an educational session;
2. Setting & Location, which is conducive to the bona fide purpose, including an office or restaurant;
3. Participant, specifically HCPs with a bona fide purpose for attendance.

It is inappropriate to provide food:

1. For an entire office staff unless all attend the meeting;
2. If a Company representative is not present (e.g. a 'dine & dash' program);
3. For guests of the HCPs without a bona fide professional interest in the information shared during the meeting.

Providing Food & Alcohol (cont.)

Companies are “strongly encouraged to develop policies on providing modest and occasional meals to HCPs.” This policy may include an overall cap on expenses, and varying expenses by geographic region.

Modest refreshments may include alcohol, and Companies may consider adopting controls including per-drink, drink type, and spending limits. Companies may inform their policies by reference to AdvaMed benchmarking surveys on best practices for meals and refreshments.

Modest meals and refreshments may be provided for Company-conducted meetings that are held virtually.

Venue: Company Meetings & Trainings

Companies should use settings “conducive to effective transmission of information” including consideration of virtual meetings which might reduce the need for travel.

Company Meetings & Trainings: The setting for a Company-conducted program or meeting of HCPs should always be conducive to the exchange of information and should not be the main attraction of the event. If the event is in person, Companies should consider the following principles when choosing a setting:

1. The setting should be centrally located and easily accessible (for example, considering proximity to airports and highways) in relation to the place of origin of the invited participants.
2. Companies should not select a setting because of its entertainment or recreational facilities (considering, for example, the season or time of year of the event).
3. Companies should avoid top category or luxury hotels or resort facilities without an appropriate justification.

Venue: Third-Party Programs

The venue and setting of a third-party program should be conducive to the exchange of educational information.

When considering whether to sponsor an educational program, at a luxury/resort/getaway location, a Company “may want to consider other factors about the program to determine if, on the whole, the program is appropriate” including:

1. Robust agenda, and intention of any gaps or breaks;
2. Associated entertainment or recreational activities;
3. Promotion of entertainment purposes in a venue’s advertising materials;
4. Adequacy of conference facilities; and
5. Audience composition.

Travel & Lodging

Companies may pay for HCPs modest and reasonable travel and lodging costs under certain circumstances, in order to:

1. Provide consulting services subject to an executed consulting agreement, with an objective and legitimate reason for in-person participation;
2. Attend a company-conducted training, or educational program, or meeting, with an objective and legitimate reason for in-person attendance;
3. To speak on a company's behalf at a third-party program;
4. For other purposes including plant tours, demonstrations, and similar activities, provided there is a legitimate, objective reason for in-person attendance.

Principles relevant to the reasonableness of travel arrangements include:

1. Legitimate need for attendance;
2. Modest accommodations;
3. Controls on timing and location;
4. Avoidance of personal travel;
5. Proper setting;
6. Compliance with federal and state law.

It is *inappropriate* arrange for travel or lodging for a HCP to attend a third-party program.

Entertainment Guidelines

- Entertainment and recreation are “inconsistent with the appropriate business purpose of a Company’s interactions with Health Care Professionals.”
- A Company “may not provide or pay for any entertainment or recreational event for a Health Care Professional.”
- Prohibition applies regardless of the (1) value, (2) consultant arrangement, (3) presence of educational purpose.

Documentation for Clinician Consultants

Companies may engage HCPs to conduct training and education, as long as they have the proper qualifications and expertise, subject to Code provisions on consulting arrangements with HCPs.

Specific documentation of consulting arrangements with HCPs, should include:

1. Process to determine legitimate need;
2. Fair Market Compensation;
3. Written agreements describing services provided and compensation paid;
and
4. Written research protocol for any clinical studies.