



24th Annual Pharmaceutical
and Medical Device Ethics and Compliance Congress

AdvaMed Update

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Ida Nassar (inassar@advamed.org)
VP, Assistant General Counsel, Ethics & Compliance
AdvaMed

AGENDA

- ❖ Who is AdvaMed?
- ❖ AdvaMed Legal / Compliance Policy Agenda
- ❖ The AdvaMed Code of Ethics
- ❖ APEC 2024 Ethics Meetings

Who is AdvaMed?

- ❖ World's largest medical technology association.
- ❖ More than 70 percent of member companies are small companies with less than \$100 million annual U.S. revenue.
- ❖ Global CEO Level Board of Directors representing the diverse nature of our industry.
- ❖ Recognized by foreign governments and international organizations, Congress and the Administration, CMS, FDA, DOJ, and Commerce/USTR as the organization speaking for the medical technology industry.

Who is AdvaMed?

AdvaMed advocates globally for the highest ethical standards and patient access to safe, effective and innovative medical technologies that save and improve lives.

2023-2027 Legal / Compliance Policy Agenda

Improve Transparency and Fairness in Litigation

- Defend supremacy of FDA decision making on safety and effectiveness.
- Address deceptive/misleading nature of attorney advertising targeting medtech.
- Enhance transparency of third-party litigation funding.

Ensure Patient Access to Medtech Worldwide / Leveling the Global Playing Field

- Establish common global standards for anti-corruption and business integrity.
- Ensure AdvaMed Code of Ethics is up to date and applicable to current operating environments.
- Secure procurement, regulatory, and enforcement incentives that reward compliance.

Modernize AKS deterrents to Value-Based Care

- Advance Anti-Kickback Statute regulatory safe harbors and statutory exceptions that enable medtech engagement in more comprehensive, patient-centric VBAs, in a simpler, less time consuming, and less costly fashion.

Secure Patient-Centered Framework for Medtech Health Data

- Distinguish medtech data collection, uses, transfers & stewardship in emerging legislation & regulation to ensure that this data can continue to be utilized to provide the highest levels of care and advance healthcare & innovation.
- Harmonize with other regulations governing medtech.

The AdvaMed Code of Ethics

This year marks the AdvaMed Code of Ethics' 30th Anniversary. The AdvaMed Code is the foundation, supporting AdvaMed's mission to promote patient access to safe, effective, and innovative medical technologies that save and improve lives. The AdvaMed Code's history spans several decades. The Code originally appeared as the Health Industry Manufacturers Association (HIMA) Code in 1993. It was later updated and relaunched as the AdvaMed Code in 2003.

- ❖ To ensure collaborative relationships between medtech companies and health care professionals meet the highest ethical standards, the AdvaMed Code of Ethics provides companies with guidance on ethical interactions/relationships with health care professionals, based on the cornerstone values of innovation, education, integrity, respect, responsibility, and transparency.
- ❖ Companies are strongly encouraged to adopt an effective ethics and compliance program aimed at (1) promoting an organizational culture that encourages ethical practices and a commitment to comply with the law and (2) preventing and detecting inappropriate conduct. Programs should be appropriately tailored for each Company.

The AdvaMed Code – A Roadmap

Introduction

Consulting Arrangements with Health Care Professionals

Company-Conducted Programs & Meetings with Health Care Professionals

Educational & Research Grants, Charitable Donations, and Commercial Sponsorships

Jointly-Conducted Education & Marketing Programs

Travel & Lodging; Venue

Providing Modest Meals and Refreshments to Health Care Professionals

Educational & Patient Benefit Items; Prohibition on Gifts

Prohibition on Entertainment & Recreation

Communicating for the Safe & Effective Use of Medical Technology

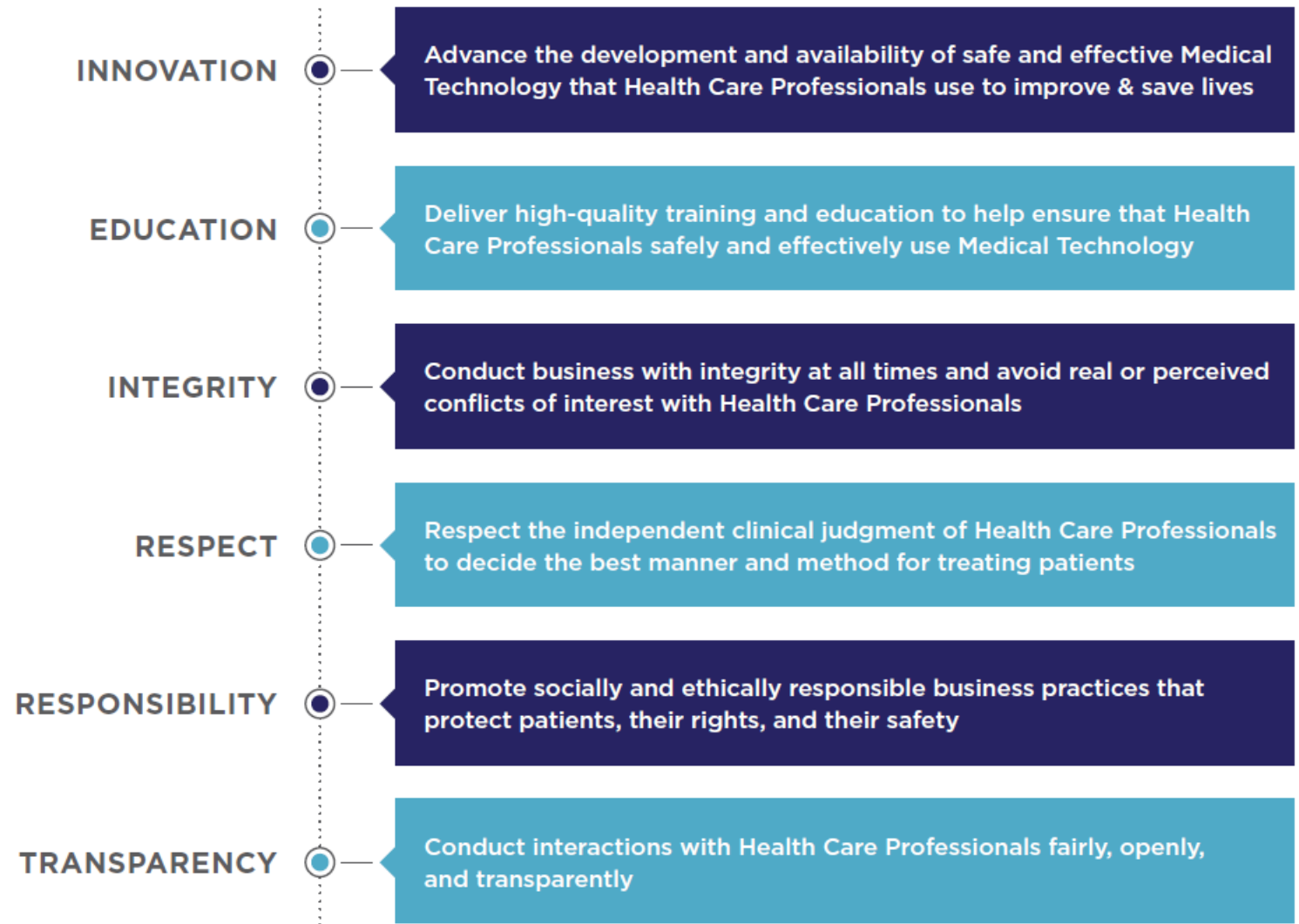
Provision of Health Economics & Reimbursement Information

Demonstration, Evaluation, and Consigned Products

Company Representatives Providing Technical Support in the Clinical Setting

The Purpose of the AdvaMed Code & Its Cornerstone Values

- ❖ Consult the Cornerstone Values to help analyze arrangements not addressed under the Code.
- ❖ Values guide day-to-day business decisions and remind us about the industry's patient-centric focus.



2023 Update – Values of the AdvaMed Code

EQUITABLE ACCESS FOR ALL PATIENTS & DIVERSITY IN THE MEDICAL TECHNOLOGY INDUSTRY

AdvaMed advocates globally for patient access to safe, effective and innovative medical technologies that save and improve lives. We developed Principles on Health Equity to ensure access and awareness is not compromised by the perpetuation of health disparities. AdvaMed's commitment to these principles ensures the medical technology industry collectively is doing its part to mitigate the adverse impacts of health disparities.

AdvaMed is committed to equitable access to our technology. Diversity leads to innovation. We will continue to build supportive relationships with external diversity partners to broaden the reach and incorporation of diversity within the medical technology industry.

Effective June 1, 2023 (page 4).

The AdvaMed Code - Overview of 2022 Update

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

These 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 company meetings with clinicians, compensation of speakers, and collaboration with clinicians.

2022 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.

2022 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.

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.

2022 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.*

2022 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.

APEC 2023 Ethics Meetings

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Implementing Government Strategies to Encourage Ethical Business Conduct, particularly regarding Enterprise Integrity in Public Procurement.

- ❖ Public procurement represents a substantive portion of government spending and is a significant driver of innovation and development, including in the health care sector.
- ❖ At the same time, public procurement is vulnerable to unethical behavior and corruption.
- ❖ Unethical conduct in public procurement can result in the wasting of resources and erosion of trust by the public.
- ❖ Partnership between industry and governments can be particularly effective in building integrity into the procurement process.

References

- [AdvaMed Code of Ethics](#)
- [AdvaMed China Code of Ethics \(English\)](#)
- [AdvaMed China Code of Ethics \(Chinese\)](#)
- [AdvaMed India Code of Ethics](#)
- [The MedTech Conference | The Leading Global MedTech Event \(Oct. 15-17, 2024\)](#)