20th Anniversary Pharmaceutical Compliance Congress

Chief Compliance Officer Roundtable

ADVAMED UPDATE

November 6, 2019

Christopher L. White, Esq.
COO & General Counsel
Advanced Medical Technology Association (AdvaMed)

OVERVIEW OF PRESENTATION

- AdvaMed
- AdvaMed Legal Reform Agenda
- AdvaMed Code of Ethics
- Value-Based Arrangements
- Civil Justice
- Global Compliance

ADVAMED

ADVAMED FACTS

- World's largest medical technology association
- More than 70 percent of member companies have 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

ADVAMED LEGAL REFORM AGENDA

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Driving an even and predictable legal environment that rewards innovation and facilitates patient access to the best medical technology and health outcomes for them

VALUE-BASED COLLABORATIONS

- Modernize Anti-Kickback Statute deterrents to Value-Based Care
- Establish New Legal & Compliance Guidance to Support Innovative Value-Based Collaborations

CIVIL JUSTICE & LITIGATION REFORM

- 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

LEVEL THE GLOBAL PLAYING FIELD

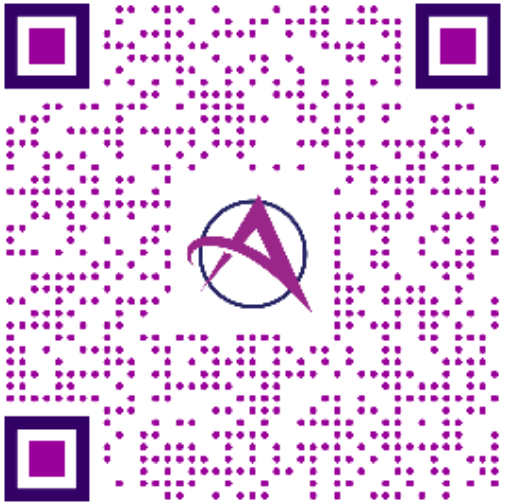
- Establish common global standards for anti-corruption and business integrity
- Attain industry-wide adoption of AdvaMed 2020 code and launch training and support programs to ensure its effectiveness
- Secure positive procurement, regulatory and enforcement incentives to support compliance

AdvaMed
Advanced Medical Technology Association

ADVAMED CODE OF ETHICS

ADVAMED
CODE OF ETHICS
REVISED FOR 2020

www.advamed.org/ethics



ADVAMED CODE REVISIONS

Background/Timeline

- Original AdvaMed Code launched in Sept. 2003 (formerly HIMA Code, eff. Jan. 1993)
- Revised & Restated AdvaMed Code launched in July 2009
- In the intervening 10 years:
  - New government guidance; informative settlements & enforcement actions
  - AdvaMed has issued additional guidance on critical topics (transparency, inventory management, PODs, etc.)
  - Other life sciences associations (MTANZ, MedTech Europe, and others) have launched and revised their own codes
  - AdvaMed launched AdvaMed Code in China, eff. Jan. 1, 2016

Project Goals

- Update language to address challenges under existing Code, reflect evolving standards & business models
- Integrate existing AdvaMed guidance, where appropriate
- Bring FAQs & examples current
- Improve readability & user friendliness in mobile environment

ADVAMED CODE REVISIONS (CONT'D)

Process

- Formed working group of 55+ attorneys and compliance officers to draft updates
- Collected feedback from stakeholders (physicians, medical societies, medical colleges/hospitals, supply chain organizations, sales organizations, former prosecutors)
- November/December 2018 – internal AdvaMed governance process to vet, review, and approve revisions to Code
- December 2018/January 2019 – communication plan to share revisions (and offer individualized training sessions to) provider groups, specialty societies, other life sciences associations, and relevant government agencies
- Approval & public notification – December 7, 2018

Effective date of revised Code – January 1, 2020

2019 Efforts

- Creating new FAQs & updated resources
- Evaluating Code certification program
- Developing small company resources
- Addressing Code enforcement or adjudication
- Launching Code training program
- Issuing additional communications

Features of the AdvaMed U.S. Code

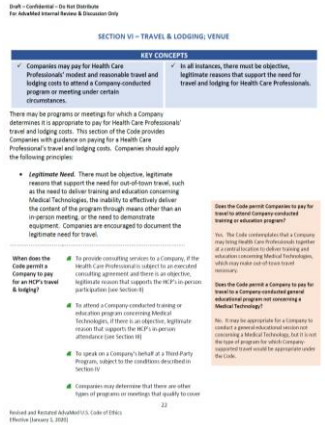
Cornerstone Values

INNOVATION	Advance the development and availability of safe and effective Medical Technology that Health Care Professionals use to improve & save lives
EDUCATION	Deliver high-quality training and education to help ensure that Health Care Professionals safely and effectively use Medical Technology
INTEGRITY	Conduct business with integrity at all times and avoid real or perceived conflicts of interest with Health Care Professionals
RESPECT	Respect the independent clinical judgment of Health Care Professionals to decide the best manner and method for treating patients
RESPONSIBILITY	Promote socially and ethically responsible business practices that protect patients, their rights, and their safety
TRANSPARENCY	Conduct interactions with Health Care Professionals fairly, openly, and transparently

- 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

ADVAMED CODE REVISIONS

- Co-Conducted Education & Marketing:
  - New section on jointly-conducted education and marketing programs
  - Requires legitimate need for the program; appropriate company controls (including requiring HCP to meet company's off-label and content should be balanced between HCP and company; equitable contributions towards activity and cost; subject to written agreement)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SECTION VI – TRAVEL & LODGING; VENUE

KEY CONCEPTS

- Companies may pay for Health Care Professionals' 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 Health Care Professionals.

There may be programs or meetings for which a Company determines it is appropriate to pay for Health Care Professionals' travel and lodging costs. This section of the Code provides Companies with guidance on paying for a Health Care Professional's travel and lodging costs. Companies should apply the following principles:

- ***Legitimate Need.*** There must be objective, legitimate reasons that support the need for out-of-town travel, such as the need to deliver training and education concerning Medical Technologies, the inability to effectively deliver the content of the program through means other than an in-person meeting, or the need to demonstrate equipment. Companies are encouraged to document the legitimate need for travel.

When does the Code permit a Company to pay for an HCP's travel & lodging?

- To provide consulting services to a Company, if the Health Care Professional is subject to an executed consulting agreement and there is an objective, legitimate reason that supports the HCP's in-person participation (see Section II)
- To attend a Company-conducted training or education program concerning Medical Technologies, if there is an objective, legitimate reason that supports the HCP's in-person attendance (see Section III)
- To speak on a Company's behalf at a Third-Party Program, subject to the conditions described in Section IV
- Companies may determine that there are other types of programs or meetings that qualify to cover

Does the Code permit Companies to pay for travel to attend Company-conducted training or education program?

Yes. The Code contemplates that a Company may bring Health Care Professionals together at a central location to deliver training and education concerning Medical Technologies, which may make out-of-town travel necessary.

Does the Code permit a Company to pay for travel to a Company-conducted general educational program not concerning a Medical Technology?

No. It may be appropriate for a Company to conduct a general educational session not concerning a Medical Technology, but it is not the type of program for which Company-supported travel would be appropriate under the Code.

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Revised and Restated AdvaMed U.S. Code of Ethics
Effective [January 1, 2020]

- Travel:
  - New section that consolidates existing travel guidance, provides clarification on when travel is permitted (consulting, company training, legitimate need for meeting and HCP presence) and when travel is prohibited (general education; attending Third-Party Program; no legitimate need)
  - Includes additional information on evaluating appropriate venues for meetings (central location, conducive to exchange of information, no top category or luxury hotels)

- Meals – Consolidates all guidance on meals into one section, adds language encouraging companies to develop meal policies & to review benchmarking information for support

ADVAMED CODE REVISIONS (CONT'D)

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SECTION XIII – COMPANY REPRESENTATIVES PROVIDING TECHNICAL SUPPORT IN THE CLINICAL SETTING

KEY CONCEPTS

- ✓ Company representatives can play an important role in the clinical setting by providing technical support on Medical Technology.
- ✓ Companies are encouraged to apply the principles outlined in this section and develop related controls.

Company representatives may play an important role in the clinical setting by providing technical support on the safe and effective use of Medical Technology.

- Company representatives may need to explain how a Medical Technology's unique settings and technical controls function and may make recommendations.
- Company representatives may assist the clinical/operating room team to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when dealing with Medical Technology that involves multiple devices and/or accessories.

Companies should apply the following principles:

1. Company representatives should enter and be present in the clinical setting only at the request of and under the supervision of a Health Care Professional.
2. Company representatives should be transparent that they are acting on behalf of the Company in a technical support capacity.
3. Company representatives should not interfere with a Health Care Professional's independent clinical decision-making.
4. Company representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements.
5. A Company's technical support should not eliminate an overhead or other expense that the Health Care Professional should otherwise incur while providing patient care.

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Revised and Restated AdvaMed U.S. Code of Ethics
Effective [January 1, 2020]

- **Communications & Technical Support –** Two new sections on:
  - Describes principles for communicating information on unapproved or uncleared uses of products:
    - ✓ Company representative must have appropriate expertise
    - ✓ Communications must be truthful & non-misleading
    - ✓ Information on off-label uses should be identified as such
    - ✓ Includes note for Companies to reference existing guidance – including judicial decisions – in developing policies
  - Principles for company representatives providing technical support in the clinical setting
    - ✓ Must be present at the request & under supervision of HCP;
    - ✓ No medical decision-making;
    - ✓ Must comply with applicable patient privacy requirements;
    - ✓ Must comply with applicable hospital/facility policies; and
    - ✓ Cannot provide to eliminate an HCP's overhead expense)

VALUE-BASED ARRANGEMENTS

BACKGROUND: INDUSTRY & MODEL EVOLUTION

MedTech Industry Transformation to Delivering Solutions

- Medtech companies have evolved from primarily manufacturing devices to delivering solutions, a combination of technology and services to achieve a targeted outcome.
- We want to be partners in care to drive comprehensive solutions to detect, treat, and manage disease, and share accountability for achieving better outcomes as well as managing costs.

Value Model in Evolving Landscape

- Early in the evolution
- Customers are changing - consolidation, new demands for data, seek partners that can share in accountability

ADVAMED PROPOSALS

www.AdvaMed.org/VBHC

- Integrates Industry Evolution to Provide Solutions – a combination of products and services to achieve a targeted outcome
- Broad Participation Eligibility - Allow for arrangements involving Manufacturers, Providers, Payors, & Beneficiaries
- Directly Address Purchase Arrangements for Bundled Reimbursable Items & Services
- Three New Value-Based AKS Safe Harbors for:
  (1) Value-Based Pricing Arrangements (VBPA) - Pricing adjustments based on whether Bundled Items and Value-Based Services (VBS) achieve Clinical/Cost Outcome Targets

  (2) Value-Based Warranties (VBW) - Clinical/economic outcome warranty on Bundled Items and Services and providing a warranty remedy that includes providing items and services, including alternative & supplementary services

  (3) Value-Based Risk-Sharing Arrangements (VBRSA) – standalone services to improve clinical outcomes/reduce costs on risk-sharing payment terms.
- Proposed Preamble text to address One-Purpose Test

AKS PROPOSED RULE - BACKGROUND

- AKS and Stark Proposed Rules published on 10/17 (Comment Deadline: 12/31)
  - AKS: 84 Fed. Reg. 55694
  - Stark: 84. Fed. Reg. 55766
- Focused on Provider-Provider / Provider-Payor Arrangements
- Manufacturers, Distributor, and Suppliers of DMEPOS, Laboratories, and Pharmaceutical manufacturers – Excluded from most proposed Safe Harbor protections
  - Originally All Devices Excluded
- Considering Excluding All "Device Manufacturers" based on Historical Enforcement Risk; not able to envision how many devices would contribute to Care Coordination/Management/ VBC.
- Purchase/Sale Arrangements for covered Items Not addressed -OIG is Considering:
  - Future NPRM for Discount SH Modifications and Additional Modifications to Warranties SH; and
  - Future Device-Specific Rulemaking.

CIVIL JUSTICE

ADVAMED CIVIL JUSTICE POLICY

Specific Issues/Areas of Interest:

- Attorney Advertising
  - Regulatory Environment (who is regulating?)
  - Problematic Practices
- Financing of Litigation
  - Aggregates
  - Transparency of third-party litigation funding arrangements
- Defend FDA Decision Making Authority

GLOBAL COMPLIANCE

GLOBAL COMPLIANCE UPDATES

Continued Progress Toward Global Code of Ethics Harmonization

Asia-Pacific: APEC Forum (21 Countries): 29 Harmonized Codes

- Worked with U.S. Department of Commerce in 2010 to create code of ethics work stream for the healthcare industry in the Asia-Pacific Economic Cooperation Forum (APEC)
- Developed high-level principles of business ethics based on AdvaMed's code(the "Kuala Lumpur Principles," approved in 2011), worked with industry associations to develop/upgrade codes to align to a high standard
- Organized with Commerce and industry mentor team annual business ethics forum meetings, most recently this past July in Tokyo, which was the largest yet, with over 230 participants from public, private and civil society organizations, including 24 AdvaMed member companies
- The result are 29 high-standard codes of ethics, covering more than 13,000 enterprises (10,000+ SMEs)
- Last year, APEC endorsed Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector, and this year AdvaMed developed an implementing tool kit for distributors
- This year, governments agreed to develop a "government enablers compendium" to support and reward company compliance programs
- Next Meeting: 2020 China (summer or fall)

www.advamed.org www.klprinciples.org www.bogotaprinciples.org

From September 23–25, 2019, more than 3,300 of the world's top medtech executives gathered in Boston, MA, for the leading event in our industry — The MedTech Conference.
Join us again as we take Toronto, October 5–7, 2020!

Featuring world-class plenary speakers, cross-cutting educational programming, valuable networking and business development opportunities, The MedTech Conference is a must-attend event for the industry's prominent and most promising companies.

https://themedtechconference.com/

THANK YOU!

Christopher White
cwhite@advamed.org

Advanced Medical Technology Association - AdvaMed
701 Pennsylvania Avenue, NW, Suite 800
Washington, DC 20004

@ChrisMedTech

@CwhiteAdvaMed