



AdvaMed Code of Ethics

Effective January 1, 2020

Training Slides

Background & Introduction

<p>What is AdvaMed?</p>	<ul style="list-style-type: none">✓ Advanced Medical Technology Association – “AdvaMed” – is the world’s largest trade association of medical technology and diagnostics manufacturers
<p>What is the AdvaMed Code?</p>	<ul style="list-style-type: none">✓ AdvaMed Code of Ethics on Interactions with Health Care Professionals in the United States – the “AdvaMed U.S. Code” – provides medical technology and diagnostics makers with baseline compliance principles
<p>Why does it matter?</p>	<ul style="list-style-type: none">✓ AdvaMed U.S. Code addresses key legal risk areas, like the Federal Anti-Kickback Statute, the U.S. Physician Payments Sunshine Act, and other important laws governing our industry’s business activities✓ Original AdvaMed Code launched in 1993 and again in 2003✓ Revised and restated AdvaMed Code launched in 2009

Background & Introduction

Why did the medtech industry revise the AdvaMed U.S. Code?

- ✓ Incorporate lessons from new government guidance, settlements & enforcement actions
- ✓ Review and pull from other industry guidance on critical topics (transparency, inventory management, PODs)
- ✓ Address evolving legal standards and business models
- ✓ Harmonize principles shared with other medtech associations' (APACMed, MedTech Europe) codes
- ✓ Clarify existing Code language where needed
- ✓ Improve user-friendliness & readability

When does the updated Code become effective?

Jan. 1, 2020

Background & Introduction

What is the Federal Anti-Kickback Statute?

- ✓ Federal law that makes it illegal to offer, pay, solicit, or receive payments or items of value in exchange for the purchase, sale, or use of goods or services that the Federal government reimburses (for example, under Medicare)
- ✓ Simply put, it is illegal to pay kickbacks for business
- ✓ This means that interactions with HCPs must be carefully analyzed to prevent unlawful inducement

What is the U.S. Physician Payments Sunshine Act?

- ✓ Federal law designed to increase transparency of financial relationships in the health care industry and uncover potential conflicts of interest
- ✓ Requires manufactures of ,medical devices, drugs, biological, and medical supplies to publicly report to the Centers for Medicare & Medicaid Services all payments and transfers of value made to physicians and teaching hospitals in the United States
- ✓ This means that details about certain interactions with HCPs will become public

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

Features of the AdvaMed U.S. Code

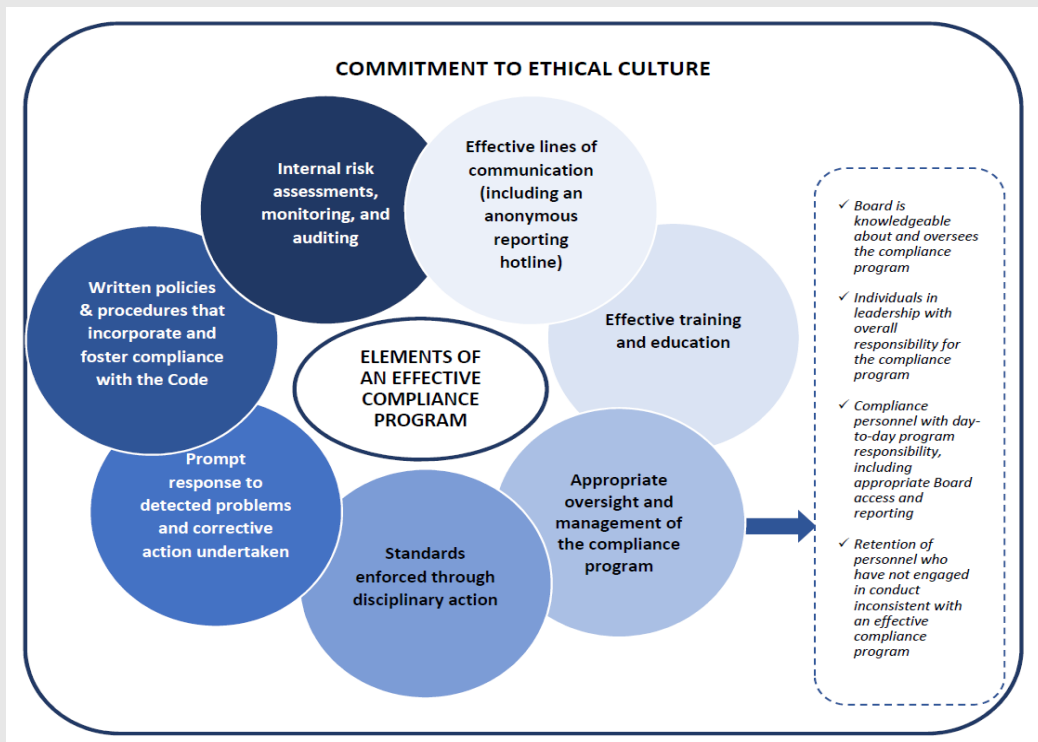
Interpretive Principles

- Be aware of the following:
 - ✓ Applies to all interactions with U.S. HCPs – **doesn't matter if you interact inside or outside the United States**
 - ✓ Applies to interactions with U.S. HCPs, **even if an employee or agent of a Company pays out of pocket himself/herself**
 - ✓ Applies to **all interactions linked to medical technology**

<i>Legal Principles</i>	The Code does not provide legal advice or create legal rights or obligations.
<i>Geographic Reach</i>	The Code applies to all Company interactions with U.S. Health Care Professionals, whether occurring inside or outside the United States (such as at a conference or other event).
<i>Personal Interactions with Health Care Professionals</i>	The Code applies to a Company's interactions and a Company's employees' and agents' interactions with U.S. Health Care Professionals, even if an employee or agent pays for the interaction himself/herself.
<i>Representatives</i>	A Company adopting the Code is required to communicate the Code's provisions to its employees and agents acting on the Company's behalf, with the expectation that they will adhere to the Code.
<i>Multiple Business Lines</i>	Companies with different business lines (for example, medical devices, pharmaceuticals, biologics, consumer items, and/or research-only products) may have other industry codes that apply to their businesses. The AdvaMed Code applies to Companies' interactions with U.S. Health Care Professionals linked to Medical Technology.
<i>Combination Products</i>	The Code applies to all interactions with U.S. Health Care Professionals related to combination products that include a Medical Technology component (for example, those that are both biologics and devices or drugs and devices), which may also be subject to other trade association codes.

Features of the AdvaMed U.S. Code

Compliance Program Infographic



- Snapshot of the **complexity** of an effective medtech compliance program
- **Everyone plays an important role in compliance!**
- If you don't know if a business activity is appropriate, ask your **manager**, your **manager's manager**, or your Company **compliance officer**

Features of the AdvaMed U.S. Code

Glossary

Health Care Professional:

A Health Care Professional is any person or entity:

- (a) Authorized or licensed in the U.S. 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 U.S.

The 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).

The term does not include Health Care Professionals who are bona fide employees of a Company, while acting in that capacity.

Glossary

Commercial Sponsorship	A payment or in-kind support provided to a third party in exchange for advertising or promotional opportunities for the Company (for example, a Company exhibit at a Third-Party Program).
Company	A company that develops, produces, manufactures, and markets Medical Technology, including its employees and agents.
Educational Grant	A payment or in-kind support to a third-party entity (for example, a Third-Party Program Organizer or a training institution) to reduce the costs of providing education. An Educational Grant is not offered for Commercial Sponsorship opportunities.
Health Care Professionals or HCPS	A Health Care Professional is 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 directly 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). This term does not include Health Care Professionals who are bona fide employees of a Company, while acting in that capacity.
Medical Technology	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 diagnose, treat, monitor, manage, and alleviate health conditions and disabilities. Some examples include: <ul style="list-style-type: none">• Implantable medical devices that are placed in or on the human body to replace, repair, or strengthen a body part;• Surgical devices used to perform procedures;• Digital technology and software platforms that assist in monitoring, diagnosing, and treating patients; and• Non-invasive reagents, instrumentation, and/or software to aid in the diagnosis and treatment of patients; among other technology.
Modest	Moderate value, but may differ depending on regional differences
Occasional	An interaction is considered occasional if it occurs infrequently and not on a routine basis
Third-Party Program	A bona fide, independent health care-related educational, scientific, business, and/or policymaking conference, meeting, or event put on by a third party other than a Company. This term includes programs that are accredited to provide continuing education credits and programs that are not accredited.
Third-Party Program Organizer	A third-party entity that organizes and/or oversees the development of the Third-Party Program, including the selection of presenters, attendees, topics, materials, and methods. A Third-Party Program Organizer could include, for example, a health care professional society, institution, and association, medical trust fund, continuing medical education provider, or hospital or other health care entity.

AdvaMed U.S. Code Topics

- Consulting Arrangements with U.S. Health Care Professionals
- Company-Conducted Training & Educational Programs
- Company-Conducted Business Meetings
- Supporting Third-Party Educational Grants, Research Grants, Charitable Donations, and Commercial Sponsorships
- Jointly-Conducted Education & Marketing Programs
- Business Courtesies for Health Care Professionals (Travel, Lodging, Meals, Educational Items)
- Prohibition on Gifts, Entertainment, and Recreation
- Communicating for the Safe & Effective Use of Medical Technology
- Providing Health Economics & Reimbursement Information
- Demonstration, Evaluation, and Consignment Product
- Representatives Providing Technical Support in the Clinical Setting

AdvaMed U.S. Code Training - Consulting Arrangements (II)

Q: What does the AdvaMed U.S. Code mean by “consulting arrangements”?

Any time a medtech manufacturer hires an HCP to provide services, this is considered a consulting arrangement. Examples:

- ✓ Providing education & training services
- ✓ Speaking on behalf of the Company
- ✓ Conducting proctorships or preceptorships
- ✓ Serving on advisory boards
- ✓ Working on product research and development
- ✓ Acting as a clinical trial site or investigator

Q: What does the Code require for consulting arrangements with HCPs?

<input type="checkbox"/> Company must have a legitimate need for the services	<input type="checkbox"/> Compensation must be consistent with the fair market value of the services in an arm’s length transaction
<input type="checkbox"/> Consultants selected based on qualifications to meet the need (for example: specialty, years of experience; location; practice setting; speaking & publication experience; clinical research experience; podium presence, etc.)	<input type="checkbox"/> Written agreement describing all of the services and all of the compensation to be provided
<input type="checkbox"/> Cannot select consultants based on past, present, or anticipated product use, referrals, or purchases	
<input type="checkbox"/> Engage only as many consultants as needed to meet the needs	<input type="checkbox"/> Sales personnel cannot control or unduly influence the decision to engage an HCP to provide consulting services

AdvaMed U.S. Code Training - Consulting Arrangements (II)

- Additional clarity in Code:
 - ✓ Description of “legitimate need”
 - ✓ Guidance on developing an objective, consistent “fair market value” (FMV)
 - *Valuation methods vary, but in all instances, a Company should use objective criteria (e.g., specialty, experience, practice setting, etc.) and document evaluation*
 - ✓ Explanation of **limits on sales involvement** in consulting selection
 - *Avoids the perception that HCP was engaged to secure or reward for purchasing, using, or recommending products*
 - ✓ Mitigating HCPs’ **conflicts of interest**
 - *Conflicts of interest may arise for HCPs, and steps may need to be taken to address them*

Key reminders:

- Certain consulting arrangements – including amount of compensation – are publicly disclosed under the Sunshine Act
- Important to meet baseline Code requirements to minimize risk under Federal Anti-Kickback Statute

AdvaMed U.S. Code Training - Company Training/Education & Other Meetings (III)

Q: What requirements does the AdvaMed U.S. Code place on Company-conducted training or educational programs?

Examples:

- ✓ Company-organized technical training session, like a cadaver lab or a preceptorship or proctorship
- ✓ Company-organized didactic lecture or in-service program on a medical topic relevant to the product

Setting must be **conducive to the effective transmission of information** – ex: clinical, educational, or conference settings; hotels, other commercially available space; HCP’s location

Hands-on technical training should be held at training facilities, medical institutions, labs, or other facilities

Engage **faculty with proper qualifications and expertise** – can include HCPs and employees with technical expertise

HCPs must have **legitimate need to attend** a Company-conducted training or education program

Q: What requirements does the AdvaMed U.S. Code place on Company sales, promotional, or other business meetings?

Examples:

- ✓ Meetings to discuss product features, sales terms, Company service offerings, product line offerings, health economics information, purchase contract arrangements, etc.
- ✓ Plant or facility tours; product demonstrations

Company must have a **legitimate need** to conduct the meeting

Setting must be **conducive to the effective transmission of information** – ex: meetings at or close to HCP’s place of business; centralized location; Company facility

HCPs must have **legitimate need to attend** a Company-conducted training or education program

AdvaMed U.S. Code Training - Educational & Research Grants; Charitable Donations (IV)

Q: What does the AdvaMed mean by “Third-Party Program”?

- ✓ Bona fide, independent health care-related educational, scientific, business, and/or policymaking conference, meeting, or event put on by a third party other than a Company
- ✓ Companies can support through **Educational Grants** and/or **Commercial Sponsorship**, provided such support is not unlawful inducement of business

Educational Grant:

Payment or in-kind support to a third-party entity (for example, a Third-Party Program Organizer or a training institution) to **reduce the costs of providing education**

Commercial Sponsorship:

Payment or in-kind support provided to a third party **in exchange for advertising or promotional opportunities** for the Company (for example, a Company exhibit)

Q: What requirements does the AdvaMed Code place on Educational Grants?

- ✓ OK to provide Educational Grants:
 - (a) to **reduce the costs of conducting the educational** component of the program;
 - (b) to **allow HCPs-in-training** to attend;
 - (c) to cover the **reasonable compensation, travel or lodging of HCP faculty**; and
 - (d) to provide attendees with **appropriate items of value** under the Code

Q: Are there additional parameters for supporting Third-Party Programs?

- ✓ Cannot pay directly for individual HCP’s registration fees, travel, or lodging to attend a Third-Party Program
- ✓ Must adhere to Third-Party Program Organizer’s conference standards & accreditation standards
- ✓ If Company receives benefits as a result of sponsorship (ex: additional entry badges, golf foursome, etc.), the Company cannot pass these items along to HCPs
- ✓ OK to host Satellite Symposia, including meals/refreshments

AdvaMed U.S. Code Training - Educational & Research Grants; Charitable Donations (IV)

Q: Can companies support other types of third-party educational programs?

- Yes. Companies can provide Educational Grants to training institutions (such as medical schools and teaching hospitals) to support **legitimate educational and training programs**.
- Examples:
 - ✓ **Fellowship programs** for physicians
 - ✓ **Training for health care and medical personnel** (ex: physicians; medical students; residents; fellows, or other Health Care Professionals-in-training)
 - ✓ Educational programs for **patients and the public** about important health care topics

Sales personnel may provide input, but should not control or unduly influence decisions re grants or donations

Q: May companies support third-party research programs?

Yes. Companies may provide in-kind or monetary support to advance **independent research with scientific merit**.

- Requests for research grants should include **clinical protocols** that outline defined goals, objectives, and milestones
- Document** the nature and scope of the research activity, budget, and approximate duration of research
- Grants may be used for **legitimate, study-related, documented expenses or services** and/or reasonable quantities of **no-charge product**
- Recipient should retain **independent control** over research

Q: May companies make charitable donations?

Yes. Companies may provide in-kind or monetary charitable donations, such as for indigent care or education.

- Only for **bona fide** charitable purposes/organizations
- Funds must be used **only for charitable purposes**

AdvaMed U.S. Code Training - Jointly Conducted Education & Marketing Programs (V)

Q: What do Companies need to know about joint education & marketing programs?

Yes. Companies may partner with HCPs to conduct joint education and marketing programs (commonly referred to as “co-marketing arrangements”) subject to the following guidelines:

- ✓ **Bona fide, legitimate need** for the arrangement
- ✓ **Independent controls** to help ensure arrangements are not made as unlawful inducements
- ✓ Requirement to **follow Company policies** (off-label; HE&R)
- ✓ **Fair and equitable contributions** towards the activity and payment of costs
- ✓ **Written documentation** of arrangement

What are Jointly Conducted Education & Marketing Programs?

- Programs designed to highlight both a product and an HCP’s ability to diagnose or treat medical conditions
- Ex: A Company shares information about a product to an audience of patients and an HCP speaks about the medical conditions the product is intended to treat and the HCP’s ability to use procedures that use the product

AdvaMed U.S. Code Training - Travel & Lodging (VI)

Q: May Companies pay for travel and lodging for HCPs?

Yes, subject to the following guidelines:

- ✓ Must be an “**objective, legitimate reason**” to support the need for out-of-town travel
Ex: Need to deliver training/education content; need to demonstrate equipment; etc.
- ✓ All travel and lodging must be **modest and reasonable**
- ✓ Comply with **Company controls** on timing & location of HCP travel/lodging
- ✓ **Cannot pay for HCP’s guests** or spouse; cannot pay for **personal travel** for HCPs

OK to Pay for HCP Travel under the Code:

- ✓ If HCP provides consulting services to the Company (subject to executed agreement)
- ✓ To attend a Company-conducted technical training
- ✓ To speak on a Company’s behalf at a third-party program

Not OK to Pay for HCP Travel under the Code:

- ✓ To attend any Company meeting without an objective, legitimate reason that supports the need for travel
- ✓ To attend a general education program
- ✓ To attend a third-party program

AdvaMed U.S. Code Training - Meals (VII)

Q: May Companies provide meals and refreshments to HCPs?

Companies may **occasionally** provide **modest** meals and refreshments, subject to these principles:

- Meals/refreshments should be **subordinate in time and in focus** to the **bona fide** educational/business purpose
- Setting** should be conducive to discussion (ex: HCP's location; restaurant)
- Company may only provide to HCPs/staff who actually attend the meeting and have a **bona fide** purpose for attending
- HCPs must have **legitimate need to attend** a Company-conducted training or education program
- Companies are **encouraged** to develop policies on meals, including a spending cap; may vary by location; consider AdvaMed benchmarking data

Transparency Impact:

- Meals = high-visibility aspect of annual Sunshine / Transparency disclosures
- Focus of several recent enforcement actions

Not OK to Pay for under the Code:

- ✓ An entire office staff where everyone does not attend
- ✓ If a Company representative is not present (i.e., "dine and dash")
- ✓ Guests of HCPs or for any other person who does not have a bona fide professional interest in the information

AdvaMed U.S. Code Training - Educational & Patient Benefit Items; No Gifts (VIII)

Q: What kinds of restrictions on educational and patient benefit items and gifts does the Code provide?

OK to Provide to HCPs under the Code:

- ✓ Modest, appropriate educational items to HCPs
 - Should have a **fair market value of less than \$100** (other than medical textbooks or anatomical models)
- ✓ Benefit patients or serve a genuine educational function

Not OK to Provide to HCPs or staff under the Code:

- ✓ Gifts
 - Ex: Cookies; wine; flowers; chocolates; gift baskets
 - Including gifts for **life events**, such as a wedding, birth, or anniversary
- ✓ Items that a HCP (or his/her family members, office staff, or friends) can use for **non-educational or non-patient-related purposes**
 - Ex: office supplies; scrubs; tablets; phones; laptops
- ✓ **Branded, non-educational promotional items**, even if of minimal value, related to HCP's work
 - Ex: pens; notepads; mugs; and other items with logos
- ✓ Companies **may not raffle** an item that it could not otherwise give to a HCP

AdvaMed U.S. Code Training - No entertainment or recreation (IX)

Q: May Companies provide entertainment and recreation to HCPs?

No. Ex: theater; sporting events; golf; skiing; vacations; etc. Applies regardless of:

1. Value of the activity;
2. Whether the Company engages the HCP as a **consultant**; or
3. Whether the entertainment or recreation is **secondary** to an educational purpose

AdvaMed U.S. Code Training - Communications for the Safe & Effective Use of Medical Technology (X)

- HCPs may use a product for any use that they determine is in the best medical interests of their patients
- This includes uses that are contained in the Medical Technology's labeling or consistent with labeling
- It also includes uses that are not approved or cleared (*i.e.* "off-label" uses)

Industry-appropriate communications of off-label information include:

- ✓ 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 investigational use

No claims re safety and effectiveness

- ✓ Discussions with consultants and HCPs **to obtain advice or feedback** relating to topics such as unmet patient needs, product research and development

Q: What principles apply?

- Information must be **truthful and non-misleading**
- Responses to requests that contain information regarding **unapproved** or **uncleared** uses should be provided by **authorized** personnel
- Information regarding **unapproved** or **uncleared** uses should be **identified** as such

AdvaMed U.S. Code Training- Health Economics & Reimbursement Information (XI)

Q: What restrictions does the Code place on provision of health economics and reimbursement information (HE&R) to HCPs?

Permissible activities include:

- ✓ Collaborating with HCPs, patients, and organizations to achieve government and commercial payor coverage decisions, guidelines, policies, and **adequate reimbursement**
- ✓ **Identifying clinical value** of products and services and procedures in which they are used
- ✓ Conducting **joint advocacy** on coverage, reimbursement, and health economics issues
- ✓ Developing **materials** with coverage and reimbursement information
- ✓ Identifying **codes and billing** options
- ✓ Facilitating access by providing information on payor policies for **prior authorization**

Information must be **accurate** and **objective**

May not **interfere with HCP's independent clinical decision making**

Should not be provided with the intent to **relieve a HCP or his/her staff or institution of their responsibility for performing these functions** (unlawful inducement)

AdvaMed U.S. Code Training - Demonstration, Evaluation, and Consigned Products (XII)

Q: What restrictions does the Code place on provision of products for evaluation, demonstration, and consignment?

Evaluation Equipment

OK to provide reasonable quantities of products at no charge to allow HCPs to assess appropriate use and functionality and to determine whether to use, order, purchase, or recommend the product in the future

Single Use/Consumable/Disposables

- Amount should not exceed amount reasonably necessary for the adequate evaluation

Multiple Use/Capital

- Reasonable period of time under the circumstances (may vary by frequency of anticipated use, duration of required training, number of HCPs who need to evaluate, etc.)
- Terms of an evaluation should be set out in writing in advance
- Companies should retain title and have a process for tracking and removing
- Transparency requirements may obligate companies to track value after 90 days

Demonstration Units: OK to provide unsterilized single use products or mock-ups at no charge to aid in HCP and patient awareness and education on the product

- ✓ Not expected to be used in patient care
- ✓ Unsterilized single use products or mock-ups
- ✓ Identified with “Sample” or “Not for Human Use” or similar

Consignment:

- For use in and storage at HCP’s patient care setting and Company retains titles **until product is used**
- Arrangement** should provide for terms, such as number of products, requirements to separate consigned for others, and storage space rental terms (if applicable)
- Companies are encouraged to consider **implementing appropriate controls** (ex: periodic inventory; reconciling discrepancies; removal of expired product; etc.)

AdvaMed U.S. Code Training - Company Representatives

Providing Technical Support in the Clinical Setting (XIII)

Q: What restrictions does the Code place on Company representatives providing technical support in the clinical setting?

Company representatives may need to be in the clinical setting during a procedure in order to:

- ✓ Explain how a medical technology's unique **settings and technical controls function**
- ✓ Make **recommendations** regarding a medical technology's unique features
- ✓ Assist the clinical/operating room team to ensure that the appropriate **range of devices** are available during a procedure

Governing Principles:

- Enter and be present only **at the request of and under the supervision** of an HCP
- Should be **transparent** that rep is acting on behalf of the Company in a technical support capacity
- Should **not interfere** with a HCP's independent clinical decision making
- Should comply with **applicable facility policies** or procedures, including patient privacy and credentialing
- Should **not eliminate overhead** or other expense that the HCP would otherwise incur

An abstract graphic on the left side of the slide, featuring several white geometric shapes. A large, light-colored triangle points downwards from the top center. To its left, a curved white shape, possibly a stylized letter 'A' or a similar symbol, is partially visible. The background is a solid teal color.

Thank you!