AdvaMed Code Illustrative Best Practices

Medical Education & Technical Training Guidance

October 2024

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Advanced Medical Technology Association

1: INTRODUCTION

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Health care providers leverage medical technology at all levels of screening, diagnosis, and treatment of the world's worst diseases. Lung cancer, for example, has the highest mortality rate of all cancers worldwide, and providers cannot begin to address cancer without the benefit of medical technology. Recent developments in cancer laboratory screening testing, for example, can help detect the presence of cancer. Providers can discover actual lesions or suspicious thoracic lymph nodes using advanced imaging technology, like CT and PET scans. Biopsy confirmation of the cancer stage is required and leverages advanced medical technology such as Endobronchial Ultrasound-Transbronchial Needle Aspiration to sample thoracic lymph nodes. Finally, treatment options based on the cancer stage and tumor location and may include additional medical devices such as electro-surgery, injections, or other delivery mechanisms, and palliative care options such as stents or balloons. The provider's ability to deliver effective care – and the patient's chances of survival – depend extensively on the prevalence and availability of advanced medical technology solutions.

Patient diagnosis, treatment, and care have seen rapid transformation in recent years. From robotic surgery to AI-infused diagnostic testing, 3D-printed orthopedic implants, medical devices and remote monitoring equipment that interact with one another and provide real-time updates to providers, complex cardiovascular devices, among many others, the Medical Technology industry is at the forefront of this transformation. The Medical Technology industry has, for decades, led the way in developing the technological achievements in medicine that allow patients to live longer, healthier, and fuller lives.

AdvaMed's member companies undertake years of research, development, study, testing, data collection, and clinical trials to produce ground-breaking medical devices and diagnostic tests. This research yields not only new products and tests, but also new surgical procedures and modalities of delivering and deploying medical devices and diagnostics. Through all of this, our companies acquire the most extensive knowledge and expertise about our product's features, benefits, and risks. Sharing this information with physicians and other HCPs who use our products is vital to ensuring that these complex products are safely and effectively used.

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Each Medical Technology is unique. Each procedure in which Medical Technologies are used may be novel and complex. Multiple layers of training and education may be necessary to help ensure that a physician or other health care professional ("HCP") understands exactly how to safely and effectively use the product. For example, a physician may require an introductory didactic lecture on the science and mechanics of how a product functions. They may need to have a refresher course on the technical specifications of the product or the latest clinical trial data (consistent with product labeling). They may require, for example, multiple practice sessions in a synthetic tissue lab or cadaver lab to learn the precise surgical techniques required to deploy a product. And they may also need to learn directly from or observe a peer physician perform the procedure in the clinical setting to get it right.

Medical Technology companies play an important role in ensuring that HCPs receive high-quality training on the safe and effective use of the products that we make to improve, or even save, patients' lives. This includes training and education that is often mandated by the U.S. Food & Drug Administration as a requirement for our companies.
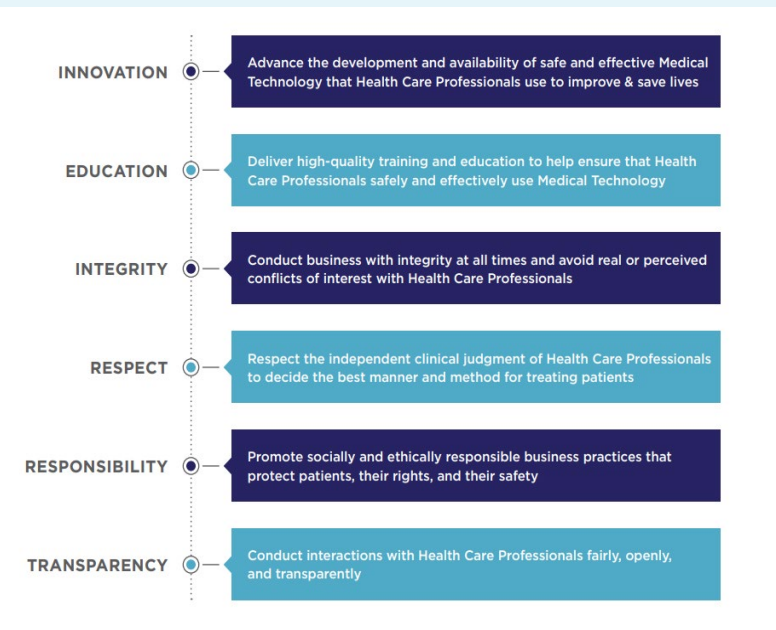
Medical Technology companies create educational programs that raise awareness about disease states and available treatments for patients. These programs – which are regularly focused on creating awareness among underserved people – benefit public health and help address health disparities among different populations.

This document is designed to provide the Medical Technology industry with direction on implementing training and education programs that strengthen HCPs' access to effective, meaningful, and sometimes complex training and education that can benefit patients and enable better quality care.
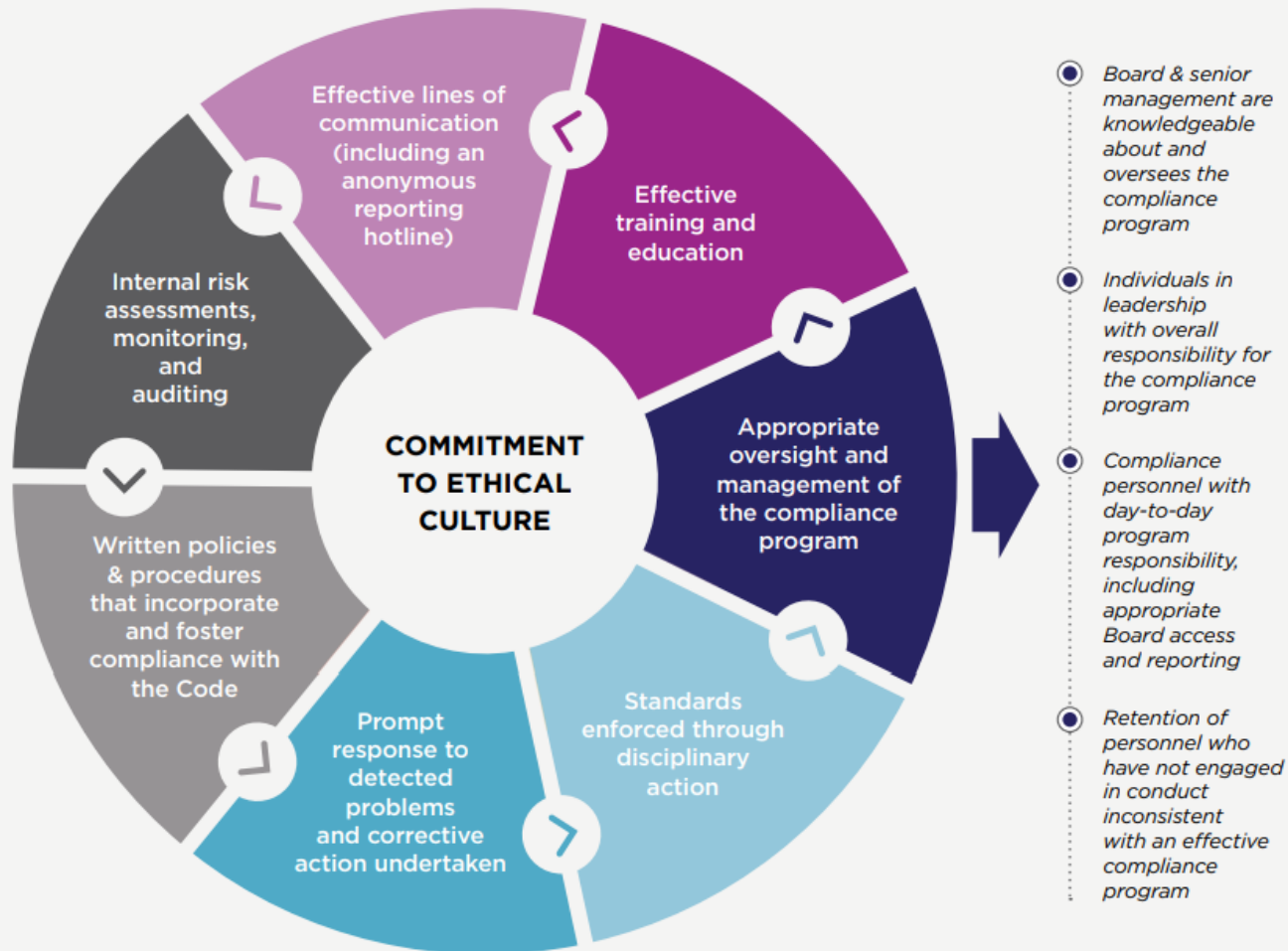
This document takes a holistic approach to addressing training and education programs and provides a roadmap. We have designed this document to allow our members to make informed choices when building training and education programs on the *safe and effective use* of our members' products, often as mandated by the FDA. No single factor or attribute of a training or education program is more important than another; and this document encourages companies to design their programs thoughtfully.

Finally, this document expands on existing concepts enshrined in our longstanding and foundational AdvaMed Code of Ethics on Interactions with Health Care Professionals. The language of this document is intended to align with the AdvaMed Code, and it should be read in connection with the Code.

We also encourage our companies to build their HCP interactions and related practices based on the **AdvaMed Code's 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

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ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

Effective lines of communication (including an anonymous reporting hotline)

Effective training and education

Internal risk assessments, monitoring, and auditing

COMMITMENT TO ETHICAL CULTURE

Written policies & procedures that incorporate and foster compliance with the Code

Appropriate oversight and management of the compliance program

Prompt response to detected problems and corrective action undertaken

Standards enforced through disciplinary action

- Board & senior management are knowledgeable about and oversees the compliance program

- Individuals in leadership with overall responsibility for the compliance program

- Compliance personnel with day-to-day program responsibility, including appropriate Board access and reporting

- Retention of personnel who have not engaged in conduct inconsistent with an effective compliance program

In addition, we have designed this document with an eye towards the elements of an effective compliance program, as detailed in the AdvaMed Code. We have sought to identify considerations, key questions, auditing and monitoring techniques, and other concepts to assist our companies in implementing the Code and in making sure that their technical training and education programs meet the standards of the AdvaMed Code and their own internal corporate expectations.

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Throughout this guidance we refer to "Company-Conducted Training & Education." This term refers to technical training and medical education programs that Medical Technology companies develop and execute and as described in section III-A of the AdvaMed Code. In general, we refer to two broad categories of programs, which can typically be distinguished based on the type of content:

(1) **Technical Training Programs:** The primary purpose of a company-conducted technical training program is for HCP attendees to receive training on the technical features of a product and/or how to safely and effectively use or deploy a specific product in accordance with its approved indications for use. These programs teach HCPs the skills needed to perform new procedures proficiently. Examples include cadaver labs, other practice wet labs, hands-on simulator practice, case proctoring or preceptorships and "in service" presentations.

(2) **Education Programs:** The primary purpose of a company-conducted education program is to offer HCPs information on a multitude of topics, such as disease states and treatment options, patient selection criteria, published clinical evidence, clinical treatment standards and outcomes, care pathways, clinical protocols, health economics, and how Medical Technologies benefit certain patient populations. Examples include didactic programs and lectures on disease states and treatment options, office in-service demonstrations and lectures, patient selection criteria, clinical treatment standards and outcomes, care pathways, clinical protocols, health economics, and how Medical Technologies benefit certain patient populations.

There may be some programs that are not clearly a technical training or an education program and may instead consist of a mix of both. All programs, regardless of whether they would be considered a technical training or an education program should be accompanied by an agenda outlining the topics and objectives of the program and a presentation or other educational content (as applicable).

2: ASSESSING NEEDS; ENGAGING HCP FACULTY & TRAINERS

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PROACTIVE COMPLIANCE QUESTIONS

Is there a legitimate business need to provide training or education that has been identified and documented in advance? (For example, in an annual needs assessment or strategic planning document)

Consider establishing a process to identify training and educational needs for the upcoming time period. This could include assessing the need for different types of programs (hands-on, cadaver labs, proctorships, lectures, in-service programs, etc.). Think about the following questions:

- ❑ What information do HCPs have a need to understand in order to safely and effectively deploy the product?
- ❑ Is there a new product or a new indication that requires the Company to provide technical training and education to HCPs?
- ❑ Are there HCPs (for example, new specialists emerging from a residency program) that require training on an existing product, indication, disease state, or diagnosis guidelines, etc.?
- ❑ Are there new product features or technical settings that would require hands-on training on how to use or deploy a product?
- ❑ Does the product or indication require education on the underlying disease state?
- ❑ Are there new health economics or reimbursement concepts that HCPs need to know in order to better serve patients
- ❑ Has there been a government mandate for new training or education?
- ❑ What types of programs would best deliver the training or educational content?
- ❑ What criteria are required of HCPs to deliver the training or educational content?

The needs assessment might also identify how the content shared during the program might benefit patients, identify the types and anticipated numbers of HCPs that require the training or education and why, assess how many trainers and faculty would be required to deliver the training or education and their relevant qualifications, and anticipated numbers of programs required across different regions of the country (if available), among other topics.

A needs assessment is typically developed on an annual basis in connection with the budget cycle where needs are translated into budgetary considerations for engaging HCPs.

Has the HCP been evaluated against faculty/trainer criteria that have been laid out in advance?

Examples of criteria for HCPs to serve as faculty or trainers at a Medical Technology training or educational program:

- ❑ Relevant specialty?
- ❑ Appropriate licensure?
- ❑ Years of experience?
- ❑ Publication in peer-reviewed journals?
- ❑ Podium presence and ability to deliver educational content?
- ❑ Is medical affairs, clinical affairs, or the Company's educational function involved in faculty/trainer selection and validation?
- ❑ Experience and expertise with the product or in performing the procedure?

Note: With respect to measuring an HCP's experience and expertise with the specific product or procedure, Companies should be mindful that this assessment should not be based on the volume or value of past, present, or anticipated future uses of the product. Avoid undertaking a return on investment or "ROI" analysis in connection with engaging faculty or trainers.

Has the selection of this HCP to serve as faculty or trainer been unduly influenced by sales?

Think about the following:

- ❑ Has sales exercised significant influence beyond providing a simple recommendation for an HCP to serve as faculty/trainer?
- ❑ Does sales have any role in the contracting process (e.g., FMV compensation evaluation, contract execution, etc.)?
- ❑ Does sales have the final decision over who is selected to serve as faculty/trainer?

Does the proposed compensation paid to the HCP reflect the fair market value of the training and educational services provided?

Has the HCP been screened against government exclusion & debarment sites?

Is there a written contract in place that describes the services to be provided and the related compensation for providing those services?

🟩	*Answer should be "yes"*
🟧	*Answer can be "yes" or "no" – depends on program*
🟥	*Answer should be "no"*

COMPLIANCE MONITORING / AUDITING CONSIDERATIONS

After a Company has implemented a training or education program for HCPs, the Company may consider undertaking compliance monitoring or auditing to ensure that the Company's internal policies and procedures were followed.

For example, companies may want to consider questions or concepts like the following:

- ❑ Was there a contract in place with the HCP prior to the delivery of services?

- ❑ How many times has the Company engaged a particular HCP to serve as faculty or a trainer in a year? Does that usage correspond with the actual training/education needs within that year and align with the terms of the contract?

- ❑ Were the number of hours delivered in alignment with the contract? If more than contemplated under the contract, consider whether number of hours associated with the training or education engagement was reasonable. How were any additional hours approved?

- ❑ Is the Company paying for the faculty or trainer's preparation time and/or travel time? If so, has the HCP presented on the same topic or the same material previously?

- ❑ Were there any expenses submitted by the faculty or trainer? If so, do they comply with Company policy? Are they reasonable and supported by receipts (where appropriate)?

- ❑ Was the faculty or trainer paid the correct amount as described in the contract?

- ❑ Was payment provided only after delivery of the services?

- ❑ Is there evidence available that the materials used by the faculty or trainer were reviewed by appropriate internal corporate functions?

- ❑ Does the Company have the appropriate documentation on file to support its decision to select and engage the HCP to provide training or faculty services?

- ❑ Did the faculty/trainer adhere to the pre-approved / company-prepared slides and agenda?

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3: SELECTING HCP ATTENDEES; ATTENDEE EXPENSES

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SELECTING HCP ATTENDEES; ATTENDEE EXPENSES

PROACTIVE COMPLIANCE QUESTIONS

Consider documenting how attendees are selected; consider keeping track of HCP attendees and incorporating limits on the number of times that an HCP can attend the same program. Incorporate other controls associated with attendance at a training or education program.

Has the Company documented the types of HCPs who should attend the program and how they are selected?	**Does the Company keep track of HCP attendees and/or limit the number of programs that an HCP can attend in a given period of time?**	**Are sales personnel permitted to attend the program?**	**Are HCPs' guests, family, or spouses permitted to attend the program?**

Not every HCP is required to attend all educational or technical training programs. Companies should consider establishing clear criteria for HCP attendees, including specialty types or training needs.

Consider the following questions:

❑ What is the primary audience for the training or education program?

❑ Who identifies and selects the attendees for the program?

❑ Who is responsible for inviting attendees to the program?

There may be a legitimate need or reason for an HCP to attend a training or education program more than once. For example, for technical training, an HCP may require attending the same program a few times in order to demonstrate dexterity and competence with respect to a specific procedure. In these instances, consider documenting how the Company measures an HCP's skill pre- and post-program, the complexity of the type of procedure at issue and whether it might merit multiple training sessions, and whether a skills assessment or other documentation should be required in order to attend repeat training.

For some programs, on the other hand, an HCP may not require attending the same program multiple times. In these instances, Companies can document steps taken to ensure that one session is sufficient – for example, making enduring materials available or access to a recording to allow an HCP to refresh knowledge on demand.

Companies should also be mindful of the need to track data on HCP attendees of training and education programs in the event that any items of value are provided that require disclosure under any applicable transparency laws (*e.g.*, the Sunshine Act).

Companies should also be mindful that some in-person training programs may require an HCP's full attendance during all portions of the agenda.

Companies should be mindful that the extent and scope of sales personnel attendance at a training or educational program might detract from the legitimate purpose of the event.

Consider the following questions:

❑ What is their purpose or role in attending the program? (For example, serving as faculty for an in-service? Require training? Setting up program equipment?)

❑ To the extent sales personnel are permitted to attend the program, what instructions are they given regarding their participation?

❑ Is the primary focus of the program education and training or does the program allow significant one-on-one time with sales personnel, networking with referral sources, or other promotional opportunities?

Guests, family, or spouses of HCPs should not attend a training or educational program unless they have a legitimate need to attend (for example, they are also an HCP that meets the qualifications for attendance that the Company has established).

Do HCPs receive any compensation to attend the program?

HCPs should not be compensated to attend an education or training program. Depending upon the type of program and the controls in place, an HCP may receive modest meals or refreshments, educational items, and travel and lodging to attend the program.

🟩	*Answer should be "yes"*
🟧	*Answer can be "yes" or "no" – depends on program*
🟥	*Answer should be "no"*

HCP ATTENDEE SELECTION AND EXPENSE CONSIDERATIONS

After a Company has implemented a training or education program for HCPs, the Company may consider undertaking compliance monitoring or auditing to ensure that the Company's internal policies and procedures were followed.

For example, companies may want to consider questions or concepts like the following:

- ❑ Have the program organizers recorded HCP attendance?

- ❑ How has attendance been recorded (*e.g.,* virtual sign-in? Physical sign-in sheets?)

- ❑ What information has been recorded? Is the information sufficient to submit reports required under applicable transparency obligations (*e.g.,* Open Payments)?

- ❑ Have HCP attendees been provided with travel or lodging in order to attend the program?

- ❑ How many programs has an HCP attended in a given time frame? Does this comply with Company policy? Is there an appropriate reason for attending multiple programs?

- ❑ Has the Company established a method of tracking and monitoring repeat HCP attendance at programs to facilitate auditing and monitoring? For example, adding a unique program ID tag to the existing collection of transparency-related data.

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4: SELECTING VENUE & LOCATION

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SELECTING VENUE AND LOCATION

The content of the training or education program will dictate the appropriate venue for the program. In all instances, a training or education program should be held in a venue that is conducive to the exchange of information and should not be held in a setting that detracts from the ability to effectively communicate about the relevant topics.

Does the Company have control over the venue?	**Is the venue conducive to the communication of medical, scientific, educational, or other training topics?**	**Is the venue for a technical training program an appropriate specialized facility?**	**Is the venue a luxury or resort hotel? Is the venue known for its entertainment or recreational offerings?**

Companies may not always have control over the venue for their training and educational programs. For example, if a Company hosts a Satellite Symposium, the third-party educational program organizer may be solely responsible for selecting the venue and location of the primary event.

In these circumstances, for example during a satellite symposium at a third-party educational program, a company should continue to enforce all relevant controls and should maintain responsibility for setting the agenda, assessing need and engaging HCPs to serve as faculty or trainers, selecting and inviting HCP attendees, and providing meals, refreshments, and educational items to attendees.

Any venue selected for a Company training or education program – for example, a private room in a restaurant, a location at the HCP's place of business, a conference room in a hotel – should be selected only if it permits the faculty or trainer to effectively deliver the training and educational content.

Typically, these programs should be conducted in the clinical setting or in a setting designed to simulate the clinical setting. This could include, for example, a cadaver lab held in a converted hotel conference room, or a hands-on proctorship held in a hospital.

Consider the following:

- ☐ Is there a contract in place with the training facility?
- ☐ Is there a fee paid for the use of the facility? If so, does the fee reflect the fair market value of the use of the facility?
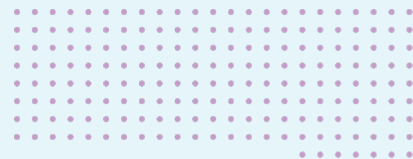
Companies should generally avoid holding training and education programs at venues that are viewed as luxury or resort destinations or that are known for their entertainment and recreational value.

There may be instances in which a Company does not have control over the venue selection (for example, when a Company hosts a Satellite Symposium).

Should this program be held virtually?

- ☐ Companies should continue evaluating whether programs could be held in a virtual format and should consider documenting the decision-making process regarding when a program is held virtually, including whether the information can be delivered effectively and meaningfully in a virtual format.

- ☐ Companies should consider identifying which programs – for example, technical hands-on training programs – require an in-person setting.

🟩	*Answer should be "yes"*
🟧	*Answer can be "yes" or "no" – depends on program*
🟥	*Answer should be "no"*

SELECTING VENUE AND LOCATION

After a Company has implemented a training or education program for HCPs, the Company may consider undertaking compliance monitoring or auditing to ensure that the Company's internal policies and procedures were followed.

For example, companies may want to consider questions or concepts like the following:

❑ Consider conducting periodic monitoring & auditing of training and educational programs to review venue selection and other criteria for establishing programs.

❑ There are special considerations for satellite symposia held in connection with third-party educational events. Consider establishing internal controls to separate the review and approval of satellite symposia from educational grants or other types of conference sponsorship. Consider establishing internal controls to validate and ensure that the expense for the meeting space or relevant venue meets Company policies or expectations.

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5: MEALS, REFRESHMENTS, TRAVEL & LODGING

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MEALS, REFRESHMENTS, TRAVEL, AND LODGING

Does the Company plan to provide attendees at a technical training or educational program with meals and refreshments?

- ❑ Follow the guidelines found in the AdvaMed Code for the provision of meals and refreshments to HCPs
- ❑ Meals must be modest and reasonable in nature; and they cannot detract from the delivery of educational or training content
- ❑ This includes considering establishing controls around alcohol in connection with any Company program
- ❑ Meals should also comply with internal company policies on spending limits (for example, per person meal limits) and/or other controls (for example, tracking attendance to ensure transparency data is collected)

Does the Company plan to provide attendees with educational items or patient benefit items?

- ❑ Follow the guidelines found in Section VIII of the AdvaMed Code

Has the Company paid for HCP attendees' travel & lodging expenses?

- ❑ Follow the guidelines found in Section VI of the Code
- ❑ Consider controls regarding HCPs' extending travel for personal or other reasons

Does the Company intend to provide attendees with branded promotional items that are not intended for patient benefit?

- ❑ Follow the restrictions on branded promotional items found in Section VIII of the AdvaMed Code
- ❑ The AdvaMed Code prohibits the provision of branded, promotional items and any "gift" or "hospitality" other than modest meals and refreshments and educational items

Does the Company intend to provide attendees with entertainment or recreation?

- ❑ Follow the prohibition on entertainment and recreation found in Section IX of the AdvaMed Code

After a Company has implemented a training or education program for HCPs, the Company may consider undertaking compliance monitoring or auditing to ensure that the Company's internal policies and procedures were followed. For example, companies may want to consider questions or concepts like the following:

- ❑ Conduct field monitoring to verify meals / refreshments are modest, reasonable, and secondary to the educational purpose of the program
- ❑ Review itemized receipts and related program invoices to determine whether any prohibited items were furnished
- ❑ Were meals and refreshments (including alcohol) provided in accordance with company policy, the approved program description/agenda, and/or approved needs assessment?
- ❑ Were travel & lodging provided to HCP attendees? If so, does this align with company policy?

🟩	*Answer should be "yes"*
🟧	*Answer can be "yes" or "no" – depends on program*
🟥	*Answer should be "no"*

6: Provision of Accredited Programs

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PROACTIVE COMPLIANCE QUESTIONS

When providing accredited programs, companies should apply the guidance and restrictions provided in the AdvaMed Code as well as the best practices of this Guidance provided in Sections 1-5 above.

Has the company met all the requirements of the accrediting body?	Is the accredited program being offered free of charge or will a fee be charged?	Does the program promote the medical services of a particular provider or highlight a particular physician group and their services?
Accrediting bodies have their own set of standards that determine how Continuing Education (CE) is allowed to be conducted. This includes guidelines for meals and refreshments that may be offered and type of venue. Accreditation requirements may depend on the accrediting body, the state, and the type of HCP.	Fair market value for a CE program should be considered for any CE program being offered, which may require evaluation of the circumstances specific to the CE program at issue. OIG has issued an Advisory Opinion (22-14) analyzing CE programs and stated that the CE programs are something of value.	No individual HCPs or HCP groups should be favored, in terms of attendance, fees, and content. Programs discussed herein are distinct from Jointly Conducted Education and Marketing Programs discussed in Section V of the AdvaMed Code. In addition, invitations should be broadly distributed to avoid pulling in only referring HCPs and there should be no requirement that attendees refer patients to the company as a condition of attendance.

COMPLIANCE MONITORING / AUDITING CONSIDERATIONS

Consider the following questions:

❑ What topic(s) will the program address? Is this consistent with the Company's identified legitimate business needs? Will the content be substantive in nature?

❑ What is the primary audience for the program? Who identifies and selects the attendees? What are the criteria used to select attendees/those to be invited?

❑ Who is responsible for inviting attendees to the program?

❑ Is a fee being charged for the program or is the program being provided free of charge to the attendees? Has the fair market value (FMV) of the program been considered, including any CE credit, meals, travel or other benefits provided as part of the program? In determining whether to charge a fee, the circumstances and FMV of a particular program should be considered. For example: Is the program part of a third-party conference for which the attendees paid a registration fee that covers the CE program/credit? Consider the company's role in obtaining accreditation and credit for the program (including paying the fee for accreditation) and/or the company's role in acquiring CE credits on behalf of individual attendees (e.g., by submitting information to their state licensing authority). For certain types of HCPs, other free CE programs may be readily available from non-industry entities.

❑ Does the program comply with Company policy related to venues, meals, entertainment, etc.? Consider if the program will be held in an appropriate venue, if alcohol will be provided/available, and if there will be entertainment or recreational activities associated with the program.

❑ Are HCP faculty qualified and compensated at FMV?

❑ The Company must ensure that it is following the accrediting body's rules and requirements, including those related to content and selection of faculty and attendees.

❑ The Company should maintain appropriate documentation related to the program, which may include documentation regarding the process for determining legitimate need, FMV of the program, and other relevant factors.

❑ Consider conducting a post-program budget reconciliation.

❑ If working with a third party, consider entering into an agreement or other written confirmation of the respective roles and responsibilities, and requirements for the program.

❑ The Company should consider auditing and monitoring programs, including those that are provided free of charge.

🟩	Answer should be "yes"
🟧	Answer can be "yes" or "no" – depends on program
🟥	Answer should be "no"

Thank you

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