

ADVAMED CODE OF ETHICS

On Interactions with U.S. Health Care Professionals

AdvaMed
Advanced Medical Technology Association

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The Advanced Medical Technology Association (AdvaMed) is a global trade association of Companies that develop, produce, manufacture, and market Medical Technologies. We are dedicated to advancing medical science; developing high quality, innovative Medical Technology; and improving patient care.

The Value of Interactions with Health Care Professionals

Health Care Professionals' first and highest duty is to act in the best interests of their patients. Medical Technology Companies help Health Care Professionals meet this duty through necessary, collaborative interactions.



Companies and Health Care Professionals advance medical care and clinical science through **research, product development, and product testing** that results in new or improved, innovative Medical Technology

Companies **instruct, educate, and train** Health Care Professionals on the safe and effective use of complex Medical Technology

Companies provide **product service and technical support** for Health Care Professionals to help ensure the safe and effective use of Medical Technology

Companies support Health Care Professionals' **scientific and medical research, as well as the enhancement of clinical skills and educational opportunities** to improve patient care

Companies promote **charitable giving and public awareness** of medical and health conditions through grants and donations in support of indigent care and patient education

FREQUENTLY ASKED QUESTIONS

1 Why does AdvaMed have a Code of Ethics that differs from codes that govern pharmaceutical or biologics companies?

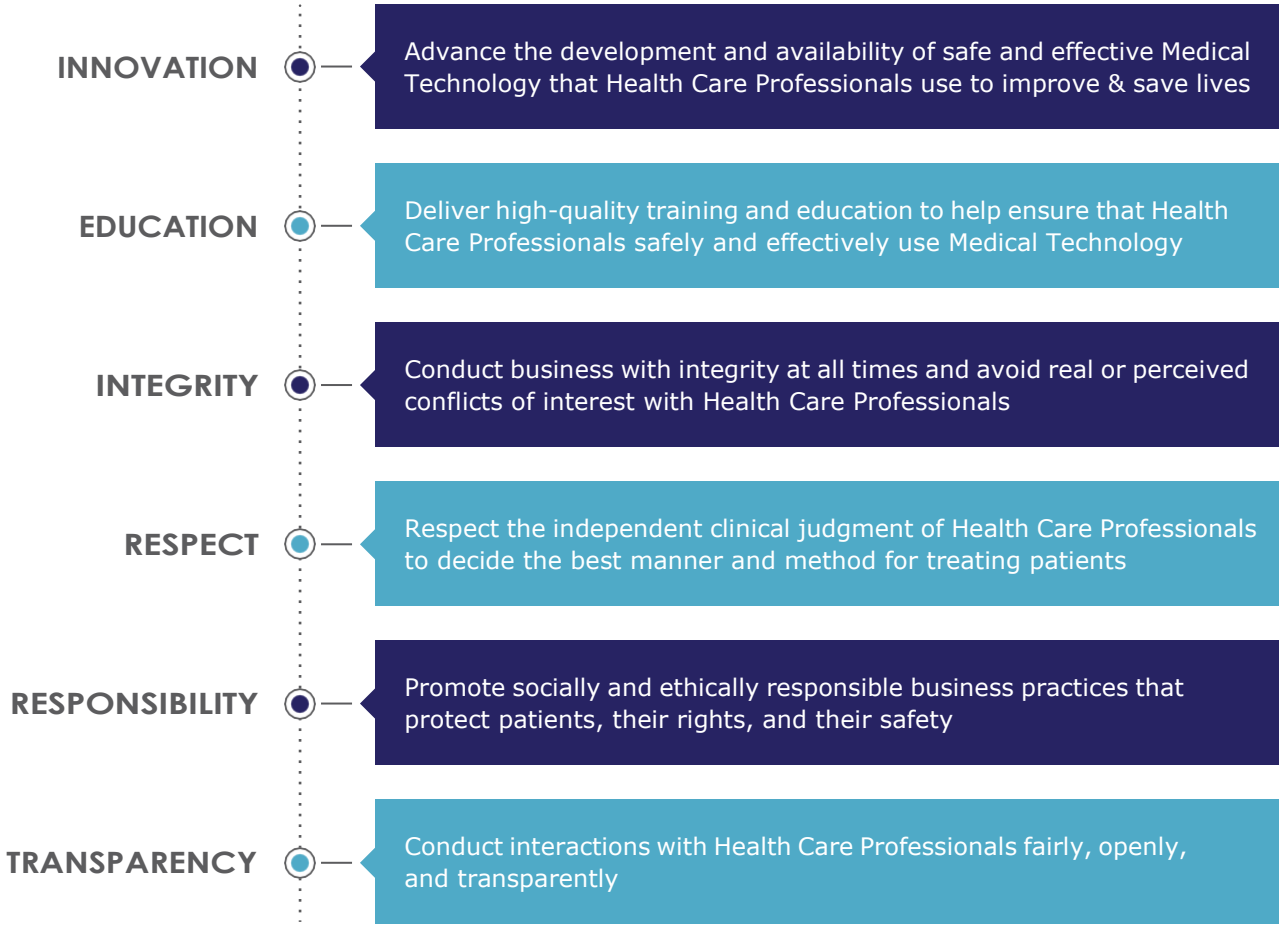
Drugs and biologics act on the human body by chemical means and can often be administered by the patient alone without the direct supervision of a Health Care Professional or the involvement of a Company representative to instruct on their safe and effective use. Medical Technology, on the other hand, often consists of complex tools, devices, and technology requiring highly dependent "hands on" interactions with Health Care Professionals from beginning to end. Health Care Professionals require training on and an understanding of how to use these products in a safe and effective way. We have developed the AdvaMed Code to address interactions with Health Care Professionals that are specific to the Medical Technology industry.

[Posted Dec. 7, 2018]

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The Purpose of the AdvaMed Code & Its Cornerstone Values

The AdvaMed Code provides Medical Technology Companies with guidance on ethical interactions and relationships with Health Care Professionals, based on the following cornerstone values:



Companies should review all interactions with Health Care Professionals in light of these values and should always avoid interactions designed to circumvent the Code. The Code may be silent on a specific interaction or may not address all aspects of an interaction with a Health Care Professional. The Code is intended to help Companies make reasonable and appropriate decisions that align with the Code's values.

Companies and their employees and agents should be mindful of their interactions and the perception of their interactions with Health Care Professionals.

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Fair Access For All Patients & Inclusion 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 Facilitating Patient Access to Appropriate Health Care to ensure access and awareness is not compromised by the perpetuation of health barriers. AdvaMed's commitment to these principles ensures the medical technology industry collectively is doing its part to mitigate the adverse impacts of health barriers.

AdvaMed is committed to fair access to our technology. Inclusion of all patients leads to innovation. We will continue to build supportive relationships with various external partners to broaden the reach and incorporation of all patients within the medical technology industry.

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.

As widespread adoption of new technologies is underway, AdvaMed continues to promote industry best practices and good governance to benefit patients, clinicians, and the overall healthcare system's safety, reliability, and efficiency. The medical technology industry has a longstanding commitment to protecting the rights and privacy of individuals, advancing systems and processes to safeguard cybersecurity, and delivering trustworthy medical technologies to patients, clinicians, partners and collaborators.



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Scope & Applicability of the Code

Legal Principles	The Code does not provide legal advice or create legal rights or obligations.
Geographic Reach	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).
Interactions with Health Care Professionals	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.
Representatives	A Company adopting the Code is required to communicate the Code's provisions to its employees, agents, dealers, and distributors, with the expectation that they will adhere to the Code.
Multiple Business Lines	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 linked to Medical Technology.
Combination Products	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.

FREQUENTLY ASKED QUESTIONS

2 To which Company employees, agents, dealers, or distributors does the AdvaMed Code apply?

The AdvaMed Code is intended to apply to all bona fide employees and agents of a Company when acting on the Company's behalf, regardless of the individual's job function or position. The AdvaMed Code is also intended to apply to all dealers, distributors, and resellers – including sub-dealers and sub-distributors – that provide sales and marketing support for the Company and that interact with U.S. Health Care Professionals (as defined in the Glossary) on the Company's behalf.

[Posted June 14, 2019]

ADDITIONAL INSIGHTS

No Unlawful Inducements

Throughout, the Code refers to the concept of an **"unlawful inducement"** to reflect the prohibitions found in the U.S. Federal Anti-Kickback Statute. The Anti-Kickback Statute prohibits the knowing and willful payment (or offer to pay) or receipt (or solicitation to receive) of anything of value to induce or reward referrals or the generation of business that is payable under a Federal health care program, such as Medicare.

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FREQUENTLY ASKED QUESTIONS

3 What if a proposed interaction with a Health Care Professional does not fit into an existing safe harbor* to the Anti-Kickback Statute?

Not having a safe harbor available (or not meeting all conditions of a safe harbor) for a particular interaction or arrangement does not necessarily mean the interaction would be a violation of the Anti-Kickback Statute. The interaction or arrangement should instead be analyzed for compliance with the Anti-Kickback Statute based on the specific facts and circumstances, including the intentions of both the Company representative and the Health Care Professional behind the interaction or arrangement.

*The "safe harbor" regulations (42 C.F.R. § 1001.952) describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute. The safe harbor regulations, in their entirety, can be found here

[Posted March 15, 2022]

ADDITIONAL INSIGHTS

"Appropriately tailored" means that each Company's implementation of an effective compliance program differs depending on a variety of factors (such as size, resources, work force, and business line, among others). Given the wide diversity within the Medical Technology industry, there is no single best compliance program. Companies should develop and implement compliance controls that address the specific types of risks that apply to their operations.



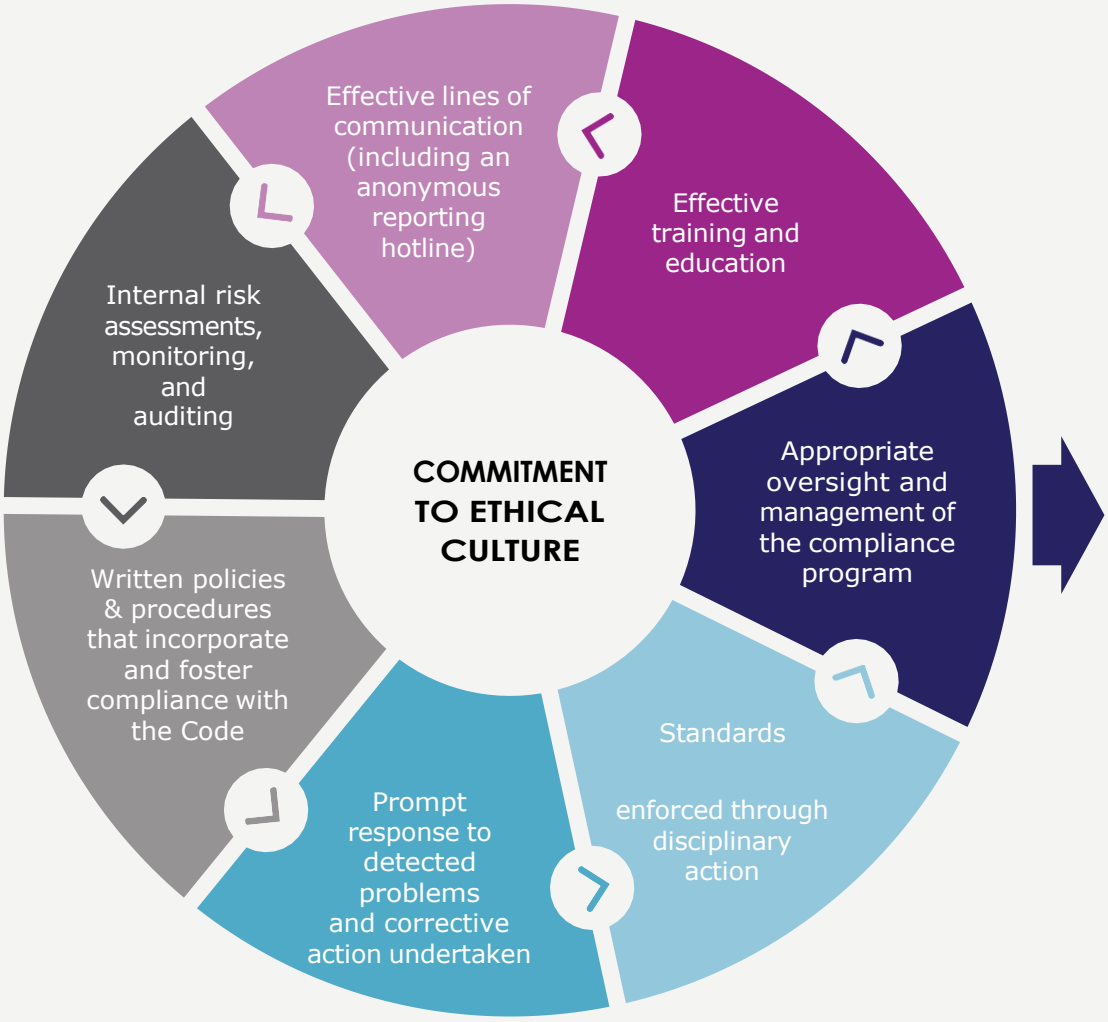
Complying with the AdvaMed Code

The AdvaMed Code does not replace any laws, regulations, or codes that may contain stricter requirements (for example, government ethics rules or state marketing laws). The AdvaMed Code requires Companies to comply with all applicable laws, regulations, and codes. 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.

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For assistance in evaluating a compliance program's effectiveness, Companies may consider referring to government-issued or other industry guidance on what constitutes an effective compliance program (for example, the U.S. Federal Sentencing Guidelines and materials from the U.S. Department of Justice and the U.S. Department of Health and Human Services Office of Inspector General). Elements of an effective compliance program can include:

ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM



- *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*

A Company that adopts the Code is **strongly encouraged to submit to AdvaMed a certification** stating that the Company has adopted the Code and has implemented an effective compliance program.

AdvaMed member Companies must, and non-member Companies may, supply contact information for the Company's compliance program or an anonymous hotline to facilitate reporting of possible violations of the Code. AdvaMed will publish on its website the contact information supplied by each Company.

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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.
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 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: • 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 or in coordinating patient care; 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
Virtual	An interaction that involves attendees participating in a virtual environment that is generally enabled by digital technology rather than meeting in a physical location.

ADDITIONAL INSIGHTS

For purposes of the AdvaMed Code, a "Health Care Professional" is not necessarily limited to a licensed clinician. Whether an individual qualifies as a Health Care Professional may vary based on the facts and circumstances.

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Satellite Symposium	A Satellite Symposium is a Company-organized and funded program that is appended to a Third-Party Program agenda but that the Third-Party Organizer does not control. These programs often take place during meal breaks at the Third-Party Program and may address education and training topics that coincide with the Third-Party Program's focus. A Satellite Symposium does not include a Company-organized meeting, training, or educational session (such as an advisory board, consultant meeting, or product education session) that (a) may be held in close physical and temporal proximity to a Third-Party Program and (b) is not appended to or included in the Third-Party Program's official agenda.
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.
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. Arrangements to advance value-based care (also referred to as results-based, outcomes-based, or performance-based payment arrangements) are designed to increase shared accountability among stakeholders for quality of, access to, and/or the total cost 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 for providers, arrangements between providers, and arrangements between providers and manufacturers or other participants in the health care system.

FREQUENTLY ASKED QUESTIONS

4 How does the Code apply to interactions with Health Care Professionals relating to arrangements that advance value- or outcomes-based care?

The Code applies to interactions with Health Care Professionals relating to arrangements to advance Value-Based Care the same as it applies to any other interaction with Health Care Professionals. The safe harbors and related OIG guidance are designed to facilitate innovative approaches to Value-Based Care and to encourage a broad range of participation and business structures. Accordingly, even if no individual safe harbor may be fully applicable, a specific Value-Based Care arrangement may nevertheless be permissible under the Anti-Kickback Statute based on the particular facts and circumstances.

[Posted March 15, 2022]

The AdvaMed Code's history spans several decades. The Code originally appeared as the Health Industry Manufacturers Association Code in 1993. It was later updated and relaunched as the AdvaMed Code in 2003. The last revision and restatement of the Code became effective in 2009.

This version of the AdvaMed Code of Ethics on Interactions with Health Care Professionals in the United States, upon its effective date, supersedes and replaces all previous versions of the AdvaMed Code.

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KEY CONCEPTS

Companies rely on Health Care Professionals' expertise in a variety of important ways, such as training on the safe and effective use of Medical Technology, conducting research, and developing product advancements that lead to safer and more effective treatments for patients.

Based on legitimate need, Companies engage Health Care Professionals through written contracts that document the Health Care Professional's services and any fair market value compensation for those services.

A. Engaging a Health Care Professional to Provide Consulting Services

Companies engage Health Care Professionals to provide a wide-range of valuable, bona fide consulting services. Some examples include arrangements for a Health Care Professional to provide education and training, speaking services, proctoring and preceptorships, reference center or center of excellence services, participation on advisory boards or focus groups, medical technology development and research services arrangements (such as research and development, clinical studies, clinical investigator services, collaborative research, and post-market research), arrangements for the development or transfer of intellectual property and to assist in the development, evaluation, or implementation of an arrangement to advance value-based care.

Companies should apply the following principles to all consulting arrangements with Health Care Professionals:

- **Legitimate Need.** A Company should enter a consulting arrangement with a Health Care Professional only if it has identified a legitimate need for the Health Care Professional's services in advance.

- **Consultant Selection.** A Company should select only duly vetted Health Care Professionals to serve as consultants, based on the Health Care Professional's qualifications to meet the identified need. Some examples of these qualifications include the Health Care Professional's specialty, years of experience, location, practice setting, clinical research experience, podium presence, speaking and publication experience, or experience with, usage of, or familiarity with a specific Medical Technology, among other qualifications.

  A Company may not select or compensate consultants as a reward for past usage or as an unlawful inducement for future purchases. A Company should implement safeguards so that consultants are not selected based in whole or in part on sales considerations.

ADDITIONAL INSIGHTS

A legitimate need arises when a Company requires the services of a Health Care Professional to achieve a specific objective, such as the need to train Health Care Professionals on the technical components of safely and effectively using a product; the need for clinical expertise in conducting product research and development; or the need for a physician's expert judgment on clinical issues associated with a product. Designing or creating an arrangement to generate business or to reward referrals from the contracted Health Care Professional (or anyone affiliated with the Health Care Professional) are not legitimate needs for a consulting arrangement.

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- **Number of Consultants.** A Company should engage only as many consultants as are necessary to fulfill the Company's requirements for the bona fide services.

- **Fair Market Value Compensation.** A Company should compensate a consultant consistent with the fair market value in an arm's length transaction of the services provided. A Company should not base compensation on the volume or value of the consultant's past, present or anticipated business. A Company should confirm the services performed by the Health Care Professional in accordance with the agreement.

- **Expenses.** A Company may pay for documented, reasonable, and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, lodging, and modest meals. See Sections VI and VII of the Code for information on providing travel, lodging, and meals to Health Care Professionals.

- **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.

- **Written Agreement.** A Company should enter into written agreements that describe all consulting services to be provided and the compensation to be paid in exchange for the services. When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.

- **Sales Involvement.** Sales personnel cannot control or unduly influence the decision to engage a particular Health Care Professional as a consultant. A Company's sales personnel may provide input about the qualifications of a proposed consultant. A Company should consider implementing appropriate controls to promote compliance with this section.

FREQUENTLY ASKED QUESTIONS

5 Why does the AdvaMed Code restrict the involvement of sales in selecting consultants?

The Code requires this separation to avoid the perception that a Company has entered a contract with a Health Care Professional to secure or reward the Health Care Professional for purchasing, using, or recommending the Company's Medical Technology or other sales considerations.

[Posted Dec. 7, 2018]

6 When determining whether a Health Care Professional is qualified to serve as a consultant, is it appropriate to consider the Health Care Professional's subjective abilities, for example his or her recognition as an expert or thought leader on the specific topic?

Yes. There is no single appropriate method of evaluating a Health Care Professional's qualifications to serve as a consultant. A Company may take into account objective factors, such as number of years of practice, familiarity with the Company's products, educational and training background, or geographic location, among others. A Company may also take into account subjective factors, such as recognition as a thought leader or the ability to effectively deliver training content.

A Company may weigh these factors differently in making consultant selections, depending upon the type of consultant the Company needs and the type of services to be delivered. For example, a Company may consider educational background and clinical experience to be important factors when engaging an HCP to perform clinical research. Or, a Company may consider recognition as a thought leader as a critical factor for some types of HCP consulting services.

[Posted June 14, 2019]

7 How can a Company establish "fair market value" for goods or services?

There are different valuation methods that may be used to establish fair market value. For example, many third-party vendors or other experts can assist a Company in developing an approach to assessing fair market value compensation. In all instances, a Company should use a method that incorporates objective criteria – for example, a Health Care Professional's specialty, years and type of experience, geographic location, practice setting, the type of services performed, etc. A Company is encouraged to document its method(s) for evaluating whether compensation reflects the fair market value of the services provided.

[Posted Dec. 7, 2018]

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B. Royalties

Arrangements involving the payment of royalties to a Health Care Professional should meet the standards listed in this section of the Code.

Health Care Professionals often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property (for example, patents, trade secrets, or know-how), under a product or technology development or intellectual property licensing agreement.

A Company should enter a royalty arrangement with a Health Care Professional only if the Health Care Professional (individually or as part of a group) makes a novel, significant, or innovative contribution to the development of a product, technology, process, or method, subject to intellectual property protections. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

FREQUENTLY ASKED QUESTIONS

8 To which Company employees, agents, dealers, or distributors does the AdvaMed Code apply?

The AdvaMed Code is intended to apply to all bona fide employees and agents of a Company when acting on the Company's behalf, regardless of the individual's job function or position. The AdvaMed Code is also intended to apply to all dealers, distributors, and resellers – including sub-dealers and sub-distributors – that provide sales and marketing support for the Company and that interact with U.S. Health Care Professionals (as defined in the Glossary) on the Company's behalf.

[Posted June 14, 2019]

A Company should base the calculation of royalties payable to a Health Care Professional in exchange for Intellectual Property on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, a Company should not condition royalties paid in exchange for Intellectual Property on: (1) a requirement that the Health Care Professional purchase, order or recommend any product or Medical Technology of the Company or any product or technology produced as a result of the development project; or (2) a requirement to market the product or technology upon commercialization.

Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the Health Care Professional and/or members of the Health Care Professional's practice.

C. Clinical Studies & Research Arrangements

Arrangements that involve clinical research services by a Health Care Professional in return for compensation are also a type of consulting arrangement, subject to the principles in this section of the Code. The clinical program for which the services are being provided should fulfill a legitimate research purpose. A written services agreement should govern these arrangements, and Companies should base compensation on the fair market value of the services provided.

A clinical study agreement typically is entered between a Company and a Health Care Professional that is a facility, institution, or practice group, and compensation for the clinical research services is paid to that entity. An individual Health Care Professional may act as a study investigator but also provide related services in his or her individual capacity that is outside the scope of the services covered in the clinical study agreement (e.g., protocol development, delivering education and presentations on the Company's behalf, etc.). In that case, it may be appropriate to enter a separate consulting arrangement with that individual Health Care Professional.

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KEY CONCEPTS

Companies have a legitimate need to provide important training and education to Health Care Professionals about the safe, effective, and efficient use of Medical Technologies.

Companies may also have a legitimate need to conduct other business meetings with Health Care Professionals (for example, a manufacturing facility tour, a product development meeting, or meetings to discuss service offerings or sales terms).

All Company-conducted programs and meetings with Health Care Professionals should be conducted in a manner conducive to the exchange of information, and all attendees must have a legitimate need to attend the program or meeting.

Companies have a legitimate need to conduct training and education for Health Care Professionals and to hold other important business meetings with Health Care Professionals. This section of the Code provides Companies with guidelines for organizing and conducting these meetings and programs.

A. Company-Conducted Training & Education

Companies have a responsibility to train and educate Health Care Professionals on their Medical Technologies, the procedures in which these Medical Technologies are used, and related information:

- Medical Technology may involve complex equipment, devices, and/or sophisticated software platforms that require technical instruction.
- Procedures in which Medical Technologies are used be complex and require skilled clinical instruction.
- Health Care Professionals need training and education on disease states and treatment options, patient selection criteria, clinical treatment standards and outcomes, care pathways, how Medical Technologies benefit certain patient populations, and with respect to arrangements that advance value-based care, among other important topics.

All of this information contributes to the safe and effective use of Medical Technology. In fact, the U.S. Food and Drug Administration (FDA) often mandates this training and education.

ADDITIONAL INSIGHTS

This section of the Code applies to Company-conducted training, education, or other business meetings. For a discussion of programs or meetings conducted by a third party (for example, third-party educational conferences), see Section IV of the Code.

FREQUENTLY ASKED QUESTIONS

9 May Companies Provide Alcohol at Company-Conducted Programs & Meetings?

Decisions to provide modest refreshments, including alcohol, must comply with the requirements of Section VII of the Code. In furthering the Code's commitment to responsible business practices, Companies also 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 (e.g., beer and wine only), or disallow alcohol at certain events (such as the types of Company-Conducted Training and Education Programs described in Section IIIA of the Code). Companies may wish to review AdvaMed's periodic benchmarking surveys on best practices around providing modest meals and refreshments, among other topics, which are available on its website.

[Posted March 15, 2022]

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Companies should apply the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals:

- **Setting.** Companies should conduct live or virtual training and education programs in settings that are conducive to the effective transmission of information. In addition to virtual settings, appropriate in-person locations may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. It could also include the Health Care Professional's location.

  Programs providing hands-on technical training and instruction on Medical Technologies (for example, a cadaver lab) should be held at training facilities, medical institutions, laboratories, or other appropriate facilities.

- **Faculty.** Companies should only engage faculty that have the proper qualifications and expertise to conduct the training or education. This may include Health Care Professionals or qualified Company employees (including field sales staff) who have the technical expertise and experience necessary to perform the training.

- **Attendees.** Health Care Professionals must have a legitimate need to attend a Company-conducted training or education program (for example, the need to obtain technical instruction on how to use a new Medical Technology).

- **Travel & Lodging.** See Section VI of the Code for more information on providing travel and lodging to Health Care Professionals to attend a Company-conducted training or education program.

- **Meals & Refreshments.** See Section VII of the Code for information on providing meals and refreshments to Health Care Professionals attending a Company-conducted training or education program.

ADDITIONAL INSIGHTS

See Section II of the AdvaMed Code for guidelines on engaging Health Care Professionals to provide consulting services on behalf of a Company, such as **serving as faculty** at a Company-conducted training and education program.

Arrangements 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, software, equipment, or other similar offerings that are designed to facilitate or measure given outcomes, training and education may relate to both the medical devices and the related offerings.



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B. Company Business Meetings

Companies may identify a legitimate need to conduct other types of business meetings with Health Care Professionals to discuss, for example, Medical Technology features, sales terms, Company service offerings and their impact on health care delivery, product line offerings, health economics information, or purchase contract arrangements. Other examples could include plant or facility tours, meetings to demonstrate equipment, meetings to explore product development or clinical testing needs, or meetings to discuss value-based solutions, services, or arrangements.

FREQUENTLY ASKED QUESTIONS

10 When is it appropriate to hold a Company-Conducted Meeting in a restaurant?

Companies should consider the factors outlined in Section VI of the Code when evaluating and selecting a venue.

[Posted March 15, 2022]

Companies should apply the following principles when organizing and conducting business meetings:

- **Legitimate Need.** Companies must have a legitimate need to conduct the meeting. For example, a company may identify a need to show Health Care Professionals how they make Medical Technologies, their quality control systems, or other aspects of their manufacturing processes through a plant tour.
- **Setting.** Companies may hold meetings at or close to a Health Care Professional's place of business or facility; another centralized location; at a Company's own facility; or virtually. In all instances, the setting for a Company-conducted program or meeting must be conducive to the discussion of relevant information.
- **Attendees.** Each Health Care Professional in attendance must have an objective, legitimate need to attend a Company's business meeting.
- **Travel & Lodging.** See Section VI of the Code for information on providing travel and lodging to Health Care Professionals attending a Company's business meeting.
- **Meals & Refreshments.** See Section VII of the Code for information on providing meals and refreshments to Health Care Professionals attending a Company's business meeting.



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KEY CONCEPTS

Medical Technology Companies – together with other organizations – play an important role in educating Health Care Professionals and patients, providing charitable support to the community, and supporting life-changing research.

Medical Technology Companies may support third-party educational, charitable, and research programs through monetary, in-kind, and other contributions.

Medical Technology Companies should establish processes and guidelines so that decisions to support Third-Party Programs are made objectively and not used as unlawful inducements to Health Care Professionals.

Companies provide monetary, in-kind, and other contributions to third parties in support of their educational, charitable, and research programs.

Companies can support these programs for many valid reasons, such as advancing medical education and training for Health Care Professionals, raising patient and public awareness on important health care topics, helping underserved or indigent populations through bona fide charitable programs, or funding independent scientific or clinical research.

A. Supporting Third-Party Programs Through Educational Grants and Commercial Sponsorship

Third-Party Programs allow Companies to support Health Care Professional- and patient-related training and education; to participate in clinical, research and scientific exchanges related to their Medical Technologies; and to advertise and promote their products and services.

Companies should apply the following principles when supporting Third-Party Programs through Educational Grants and/or Commercial Sponsorship:



ADDITIONAL INSIGHTS

Documentation.
A Company should document grants, donations, and sponsorships in writing as appropriate based on the program and type of support provided. This could include, for example, a written agreement.

Funding Requests.
Companies may receive requests to support Third-Party Programs that include requests for both Educational Grants and Commercial Sponsorship. Sometimes these requests can be co-mingled.

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Supporting Third-Party Programs Through EDUCATIONAL GRANTS

A Company may provide an Educational Grant in support of a Third-Party Program directly to the Third-Party Program Organizer or, in some instances, to a training institution or other entity designated by the Third-Party Program Organizer.

A Third-Party Program Organizer (or training institution or designee) may use an Educational Grant:

- To defray or reduce the costs of conducting the educational components of a Third-Party Program
- To allow Health Care Professionals-in-training (for example, medical and nursing students, residents, and fellows) to attend the Third-Party Program, provided that the Company does not select or control the selection of the specific Health Care Professionals-in-training who will benefit
- To cover the reasonable compensation, travel, lodging, and modest meals of Health Care Professionals who serve as bona fide faculty at the Third-Party Program
- To provide Health Care Professionals attending the Third-Party Program with items of value permissible under the Code, such as modest meals, refreshments, and educational items.

Sales personnel should not control or unduly influence the decision of whether a particular entity will receive an Educational Grant or the amount of the grant. A Company's sales personnel may provide input about the proposed Educational Grant recipient or program.

Supporting Third-Party Programs Through COMMERCIAL SPONSORSHIPS

When Companies provide Commercial Sponsorship in support of a Third-Party Program, the level of Commercial Sponsorship should reflect a commercially reasonable fee in exchange for the marketing and promotional benefits received by the Company, such as advertising, signage, display/exhibit space, or other promotional opportunities.

A Company may provide Commercial Sponsorship, even if the Company determines not to provide the Third-Party Program Organizer with an Educational Grant.

FREQUENTLY ASKED QUESTIONS

11 Review Processes

Companies are encouraged to adopt controls for reviewing requests to support Third-Party Programs. Companies should consider the following questions when reviewing such requests:

- ✔ Is the request for funding reasonable and reflective of the educational purpose of the program?
- ✔ Do the topics, faculty, attendees, and educational materials reflect an objective, legitimate, educational purpose?
- ✔ Are the venue and setting conducive to the exchange of educational information?
- ✔ Does the agenda reflect the legitimate educational, medical, scientific, or policymaking purpose of the meeting?
- ✔ Do any of the meals or refreshments, recreational activities, or free time provided detract from the primary purpose of the Third-Party Program?
- ✔ Does the Third-Party Program appear to primarily promote the medical services of a specific provider (for example, a program focused on highlighting a particular physician practice group's medical services vs. appropriate educational topics)?

[Posted Dec. 7, 2018]

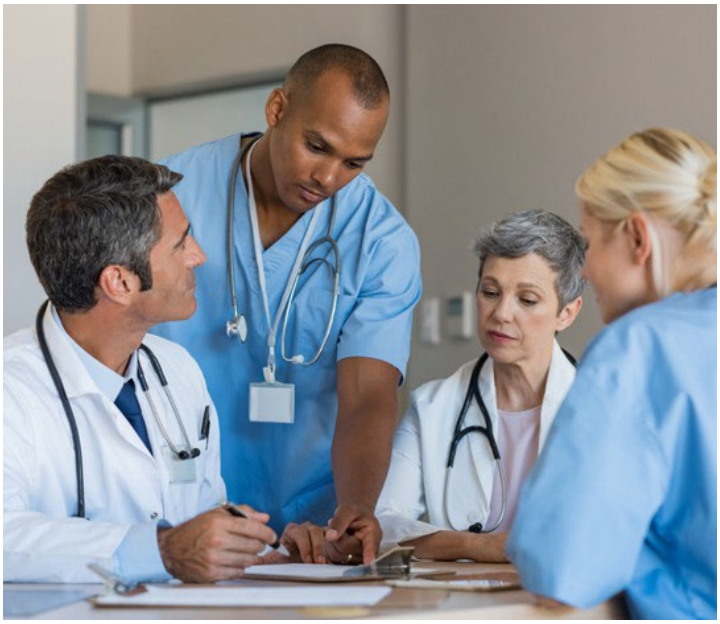
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- **No Support to Individuals.** A Company may not provide any contribution (whether monetary or in-kind) directly to an individual Health Care Professional or pay directly for an individual Health Care Professional's registration, fees, or travel or lodging expenses to attend a Third-Party Program.

- **Adherence to Program Standards.** Companies should adhere to all standards established by the Third-Party Program Organizer or the body accrediting the Third-Party Program, as applicable.

If permitted by applicable standards, a Company can (a) recommend a knowledgeable faculty or appropriate categories of attendees; or (b) select and send faculty to the Third-Party Program to speak on the Company's behalf, provided that the Company contracts with the faculty subject to the provisions of Section II of the Code and an appropriate disclosure is made to the Program attendees that the faculty is presenting on behalf of and paid by the Company.

Each Third-Party Program may vary in terms of the accreditation standards that apply (for example, ACCME standards) and the Third-Party Program Organizer's own internal rules and requirements.



FREQUENTLY ASKED QUESTIONS

12 As part of my Company's financial support of a third party's program, the organizer has offered several sponsorship benefits, including a golf foursome and several additional badges to secure entry into the conference. Can my Company invite a Health Care Professional to join the golf foursome? Can we give one of the badges to a Health Care Professional?

No. A Company should not pass along to a Health Care Professional any benefits that the Company receives in exchange for its financial support, including for educational and charitable programs.

[Posted Dec. 7, 2018]

13 Does the Code permit my Company to host a Satellite Symposium?

Yes. The opportunity to host a Satellite Symposium may be offered to Companies who provide a Commercial Sponsorship in support of a Third-Party Program. Although the Company is responsible for the content of the Satellite Symposium, these programs may be subject to the Third-Party Organizer's application and approval process. While Satellite Symposia are generally included on the Third-Party Program's agenda and promotional materials, these are Company-conducted events. Companies should be transparent in promoting these as such.

[Posted Dec. 7, 2018]

14 Can a Company offer meals and refreshments at a Satellite Symposium?

Yes, a Company may offer meals and refreshments at a Satellite Symposium, provided that they comply with (a) the Third-Party Program Organizer's or the relevant accrediting body's standards; and (b) Section VII of the Code (Providing Modest Meals and Refreshments to Health Care Professionals).

[Posted June 14, 2019]

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FREQUENTLY ASKED QUESTIONS

15 Can my Company pay for the travel, lodging, or registration expenses of a Health Care Professional who serves as faculty or attends a Satellite Symposium?

- If a Health Care Professional serves as faculty at the Satellite Symposium: Yes. A Company may engage a Health Care Professional to serve as a bona fide faculty member on its behalf, including at a Satellite Symposium, subject to the requirements in Section II of the Code. This includes covering the Health Care Professional's relevant registration fees (limited, as appropriate, to the time necessary to speak at the Satellite Symposium) as well as modest and reasonable travel and lodging expenses, subject to Section VI of the Code.
- If a Health Care Professional is only attending the Satellite Symposium: No. A Company generally draws its audience for Satellite Symposium from the attendees of the related Third-Party Program. The Code prohibits Companies from directly paying for the travel, lodging, or registration fees for Health Care Professionals to attend a Third-Party Program, including Satellite Symposia held at Third-Party Programs.

This prohibition does not preclude a Company from paying for a Health Care Professional's modest and reasonable travel and lodging expenses to attend a separate, unrelated Company-organized training or educational session or Company-conducted consultant meeting (for example, an advisory board), as described in Sections II and III of the Code.

[Posted Dec. 7, 2018]



16 In evaluating Educational Grant requests or requests for Commercial Sponsorship in support of a Third-Party Program, how should Companies assess the venue of the Third-Party Program?

A Company may give varying weight to different factors when assessing whether to support a Third-Party Program through an Educational Grant and/or Commercial Sponsorship. For those programs with venues that may be considered luxury, resort, or "getaway" locations, a Company may want to consider other factors about the program to determine if, on the whole, the program is appropriate, such as a robust agenda; whether there are significant gaps in the agenda; whether there are entertainment or recreational activities associated with the program; whether the Third-Party Organizer promotes the luxury or resort nature of the venue in its promotional materials; whether the venue maintains appropriate and adequate conference facilities; whether the audience is composed of mostly local physicians; among many other factors. Reviewing Educational Grant requests and Commercial Sponsorship requests requires the Company to look at all of the facts and circumstances surrounding the program to determine whether to fund, partially fund, or deny the request.

[Posted June 14, 2019]

17 What are examples of giveaways or other benefits that a Third-Party Program Organizer cannot use Educational Grant funds to support under the Code?

Section IV of the AdvaMed Code lists the appropriate uses of a Company's Educational Grant. This includes providing HCPs with items of value "permissible under the Code, such as modest meals, refreshments, and educational items." The AdvaMed Code permits a Third-Party Program Organizer to use Educational Grant funds to provide items to HCPs attending the Third-Party Program that are permissible under the Code. Some examples of prohibited items include gift baskets, entertainment or recreational activities, and branded, non-educational promotional items, among others.

(Posted August 21, 2019)

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FREQUENTLY ASKED QUESTIONS

18 Can a Company sponsor a luncheon during a Third-Party Program through the Third-Party Program Organizer?

A Company can provide a meal to an HCP directly under the AdvaMed Code (see Section VII). The AdvaMed Code also permits a Company to provide an Educational Grant to a Third-Party Program Organizer, which can in turn provide a meal to the HCP attendees of a Third-Party Program. In both instances, a meal must be modest; subordinate in time and focus to a bona fide discussion of scientific, educational, or business information; and offered in a setting that is conducive to such discussion.

(Posted August 14, 2019)

19 FAQ 7e – Can a Company sponsor a meal with entertainment during a Third-Party Program (for example, live music)?

No. Section IX of the AdvaMed Code prohibits providing or paying for any entertainment or recreational events. Further, Section VII of the Code requires all Company meals to be subordinate in time and focus to a bona fide discussion of scientific, educational, or business information and "should not be part of an entertainment or recreational event." Accordingly, a Company cannot sponsor a meal with entertainment, even if held in connection with a Third-Party Program.

(Posted August 21, 2019)

20 Is a "journal club" considered a "Third-Party Program" under the AdvaMed Code?

Yes. A "journal club" is a group of HCPs who meet regularly to review and evaluate academic literature on a core medical or clinical topic. Companies should evaluate requests for journal club support based on all of the facts and circumstances of the proposed arrangements. The AdvaMed Code permits Companies to support journal clubs as Third-Party Programs, and Companies can provide such support as outlined under Section IV of the Code.

First, a Company can provide an Educational Grant to the journal club organizer, subject to the requirements of Section IV. The journal club organizer can use a Company's Educational Grant funding to defray the costs of putting on the program (ex: AV needs and space rental) and to provide Code-permissible items to participants (ex: a modest meal).

Second, a Company could provide Commercial Sponsorship to the journal club organizer in exchange for marketing and promotional benefits, such as advertising, signage, or display space.

(Posted August 14, 2019)

B. Supporting Other Third-Party Programs through Educational Grants

A Company may provide Educational Grants to training institutions (such as medical schools and teaching hospitals) and to other third-party entities in support of their legitimate educational and training programs and activities. This includes, but is not limited to, Educational Grants to support the education and training of health care and medical personnel (for example, physicians, medical students, residents, fellows, or other Health Care Professionals-in-training), patients, and the public about important health care topics.

A Company may not make an Educational Grant to individual Health Care Professionals or individual Health Care Professionals-in-training, and Companies may not select or influence the selection of the individual Health Care Professionals who might benefit from the Company's support.

Sales personnel should not control or unduly influence the decision of whether a particular institution will receive support or the amount of the support. A Company's sales personnel may provide input about a proposed Third-Party Program.

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C. Supporting Independent Third-Party Research

Supporting third-party research programs and partnering with Health Care Professionals to advance independent research can provide valuable scientific and clinical information, improve clinical care, lead to promising new treatments, promote improved delivery of health care, and otherwise benefit patients. To help meet these objectives, a Company may provide in-kind or monetary research grants in support of independent research with scientific merit.

- **Objectives & Milestones.** A Company may provide support for research that has defined goals, objectives, and milestones. Requests for research grants should be accompanied by clinical protocols that outline these objectives and milestones. Requests for research grants should also document the nature and scope of the research activity, the budget, the approximate duration of the research, and where applicable, the requirements for independent authorizations or approvals.

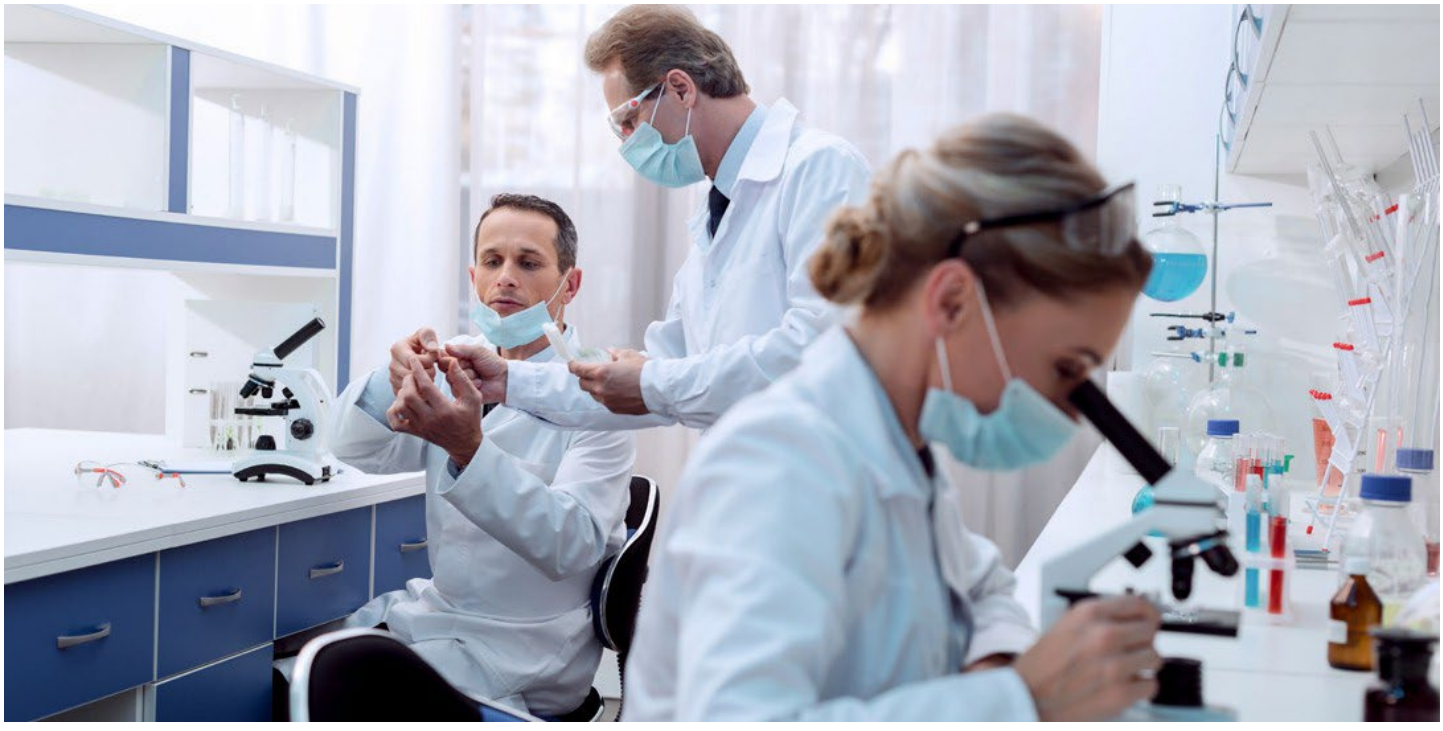
- **Limitations.** Research grants may include in-kind or monetary support for legitimate, study-related, documented expenses or services and/or reasonable quantities of no-charge product for the limited duration of the research.

- **Company Involvement.** The recipient of a Company's monetary or in-kind research support should retain independent control over the research.

- **Company Review Processes.** A Company should establish controls for reviewing requests for research grants.

- **Sales Involvement.** Sales personnel should not control or unduly influence the decision of who will receive support or the amount of the support. A Company's sales personnel may provide input about the proposed research program or recipient.

Company-initiated or directed research involving a Company's Medical Technologies (such as clinical study agreements) is addressed separately in Section II of the Code.



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D. Supporting Charitable Programs through Charitable Donations and Commercial Sponsorship

A Company may make monetary or in-kind charitable donations of product or equipment for charitable purposes, such as indigent care, patient or public education. A Company may also provide Commercial Sponsorships in support of events where the proceeds are intended for charitable purposes.

- **Charitable or Philanthropic Mission.** Donations should be made for bona fide charitable purposes and should be made only to charitable organizations or other non-profit entities with bona fide charitable and/or philanthropic purposes.

  A Company should exercise diligence to ensure the charitable organization or charitable purpose is bona fide. Relevant factors to consider may include (1) the entity's tax status, (2) the entity's corporate status under state law, and (3) whether the organization has a charitable mission or purpose, among other factors.

- **Use of Funds.** A Company must require that any donation is used only towards charitable or philanthropic purposes.

- **Indigent Care Donations.** A Company may make charitable donations of product for indigent patients, provided that these donations serve exclusively to benefit patients and are permitted under applicable laws. Companies should consider making product donations for indigent cases contingent upon a hospital's agreement that no third parties will be billed for the donated product.

- **Charitable Events.** A Company may not pay for or provide tickets to Health Care Professionals or their spouses or guests to attend charitable events, such as galas and golf outings.

- **Sales Involvement.** Sales personnel should not control or unduly influence the decision of whether a particular entity will receive support or the amount of the support. A Company's sales personnel may provide input about a proposed charitable program or recipient.

FREQUENTLY ASKED QUESTIONS

21 My Company has been asked to sponsor a local hospital's heart walk to raise money for heart disease research. In exchange for a fee, my Company will receive exhibit space at a health care expo the hospital is holding in connection with the charitable walk. My Company will also receive prominent placement in the relevant advertising. Is this OK?

Yes. A Company may provide a Commercial Sponsorship in support of a charitable fundraiser, separate from a charitable donation. As with Commercial Sponsorship of a Third-Party Program:

- ✔ The level of Commercial Sponsorship should reflect a commercially reasonable fee in exchange for the marketing and promotional benefits received by the Company, such as advertising, signage, display/exhibit space, or other promotional opportunities; and
- ✔ The Commercial Sponsorship must comply with applicable laws governing the marketing and promotion of its products.

[Posted Dec. 7, 2018]

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KEY CONCEPTS

Companies may partner with Health Care Professionals to conduct joint education and marketing programs designed to highlight both Medical Technology and a Health Care Professional's ability to diagnose or treat medical conditions.

A Company and a Health Care Professional should serve as bona fide partners, and contributions and costs should be shared fairly and equitably between the parties.

Medical Technology Companies may partner with Health Care Professionals to jointly conduct education and marketing programs. These programs serve an important purpose by allowing Companies and Health Care Professionals to educate patients and other Health Care Professionals on medical conditions and the range of testing or treatment options available, including the availability of Medical Technology and the Health Care Professional's ability to diagnose or treat related medical conditions.

Companies should apply the following principles:

- There must be a bona fide, legitimate need for the Company to engage in the activity for its own educational or marketing benefit.
- 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 Health Care Professionals participating in these arrangements 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.
- Jointly conducted education and marketing programs should be balanced and promote both the Company and its Medical Technologies, and the Health Care Professional and the range of services offered for the diagnosis and treatment of related medical conditions.

ADDITIONAL INSIGHTS

These programs could include, for example, an event in which a Company shares information about its Medical Technologies to an audience of Health Care Professionals or patients, and a physician speaks about the medical conditions that the Medical Technology is intended to treat, the procedures that use the Medical Technology, and the physician's ability to perform these procedures.

FREQUENTLY ASKED QUESTIONS

22 What are examples of the types of programs that fall under Section V?

The following are examples of jointly conducted education and marketing programs:

- A promotional advertisement that appears in a magazine or periodical, on a billboard, a television or radio spot, an online advertisement or social media, featuring he benefits of the Company's Medical Technology and highlighting the skills and expertise of the HCP to perform procedures that use the Medical Technology.
- An educational program for patients or referring physicians during which a Company and an HCP provide clinical information about specific Medical Technology; and an HCP describes what patients should expect when undergoing a procedure, relevant treatment options, and his/her own ability to perform the procedure that uses the Medical Technology.

This list is not meant to be exhaustive. There are other types of programs on which Companies and HCPs can collaborate to deliver high-quality, effective educational content to patients, other physicians, or the public.

[Posted June 14, 2019]

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- The Company and the Health Care Professional should serve as *bona fide* partners in the program and should make equitable contributions towards the activity and costs (for example, developing content, invitations, space rental, AV needs, and other production costs).

- The arrangement should be documented in a written agreement that describes the purpose of the arrangement and the roles, responsibilities, and contributions of each party, including payment of costs.

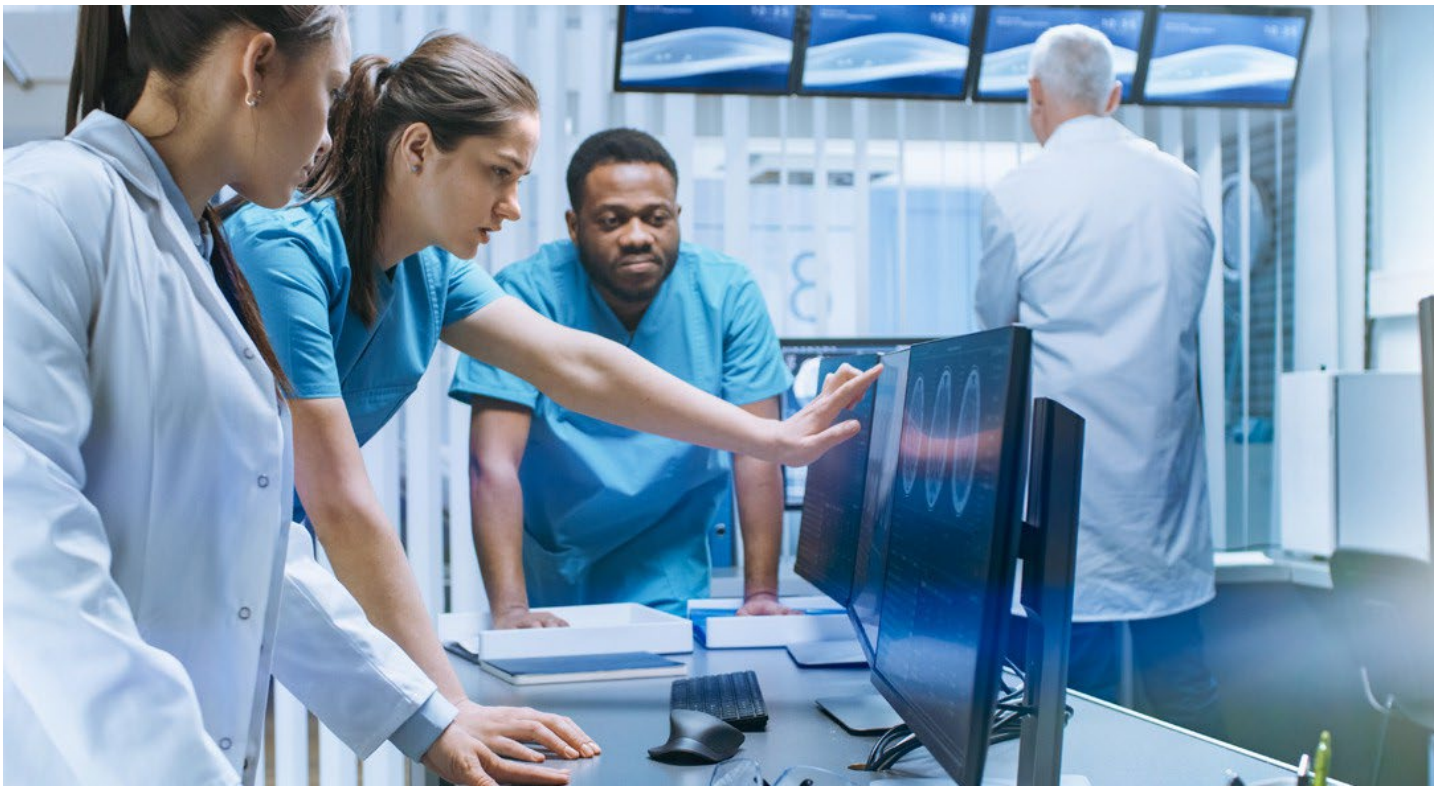
FREQUENTLY ASKED QUESTIONS

23 What types of controls should companies implement in connection with jointly conducted programs?

Companies and HCPs engaged in a jointly conducted educational and marketing program may adopt many types of controls. Some examples include appropriate governing policies; periodic assessment of the appropriate business need for the program; focused training; a process for evaluating the fair market value of jointly conducted education and marketing programs; and field-based monitoring, among others.

A documented, jointly conducted program between a Company and an HCP should also entail both parties making equitable contributions towards the costs of the program. While costs do not need to be split evenly between the parties (for example, monetary or in-kind contributions of both parties), each party should contribute to the program in a way that is commensurate with the benefits it receives.

[Posted June 14, 2019]



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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, as outlined in Sections III (A) and (B). As an alternative to in-person programs, companies may wish to consider whether the legitimate need could be met via a virtually-conducted program.

When does the Code PERMIT a Company to pay for a Health Care Professional'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 Health Care Professional'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 Health Care Professional'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 a Health Care Professional's modest travel and lodging costs to attend. Some examples could include plant tours and demonstrations of equipment, among others. In all instances, there must be an objective, legitimate reason that supports the Health Care Professional's in-person attendance at the program.

FREQUENTLY ASKED QUESTIONS

24 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.

[Posted Dec. 7, 2018]

25 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.

[Posted Dec. 7, 2018]

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When does the Code PROHIBIT a Company from paying for a Health Care Professional's travel & lodging?

- To attend any Company meeting without an objective, legitimate reason that supports the need for travel
- To attend a Third-Party Program (see Section IV)

- **Modest and Reasonable Travel and Lodging.** Travel and lodging accommodations and costs must be modest and reasonable under the circumstances. Companies are encouraged to establish controls on the appropriate class of travel service and the appropriate level of lodging accommodations.

- **Travel Time & Destination.** Companies are also encouraged to establish controls on the timing and location of travel arrangements for Health Care Professionals.

- **Guests.** Companies may not pay for or otherwise subsidize the travel or lodging of spouses or guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the Company's meeting.

- **Personal Travel & Lodging.** Companies may not pay for a Health Care Professional's personal travel or lodging.

- **Setting.** The setting for a Company-conducted program or meeting of Health Care Professionals 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:
  - 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.
  - 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).
  - Companies should avoid **top category or luxury hotels or resort facilities** without an appropriate justification.

- **Other Laws.** Companies should be aware that other laws or regulations may apply to paying for Health Care Professionals' travel and lodging, including potentially more restrictive state laws.

FREQUENTLY ASKED QUESTIONS

26 What types of controls should Companies consider with respect to limiting Health Care Professionals' travel and lodging costs associated with a Company-conducted meeting?

Companies may consider many types of controls with respect to HCP travel and lodging. Some examples include, among others: limiting the duration of Company-funded travel and lodging to arrangements that are the closest in time and in location to the Company program or meeting for which the Health Care Professional is traveling; applying limits to class of travel and lodging; placing restrictions on how travel and lodging arrangements can be changed, by whom, and whether the Company or the HCP must pay for any related change fees or additional costs.

[Posted June 14, 2019]

ADDITIONAL INSIGHTS

Ski resorts, island or beach resorts, and other resorts in geographic locations renowned primarily as seasonal vacation destinations may not be appropriate during the season in question.

Companies may assess the appropriateness of these venues differently, for example:

- If the Company is headquartered or has a significant facility in one of these geographic areas;
- If the Company is hosting a strictly local Company-conducted program attended by local Health Care Professionals (for example, a technical training program held in Hawaii for local Hawaiian physicians); or
- If the Company is hosting a meeting held in conjunction with a Third-Party Program.

[Posted Dec. 7, 2018]

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KEY CONCEPTS

Meals and refreshments provided to Health Care Professionals must be provided in a manner and place that are conducive to the presentation of scientific, educational, or business information.

Meals and refreshments should be subordinate in time and in focus to the discussion and presentation of scientific, educational, or business information.

A Company occasionally may provide Health Care Professionals with modest meals and refreshments, subject to the following principles:

- **Purpose.** The meal or refreshments should be subordinate in time and in focus to the bona fide discussion and presentation of scientific, educational, or business information. Companies should provide meals and refreshments in a manner conducive to the presentation or discussion of such information. The meal or refreshments should not be part of an entertainment or recreational event.

- **Setting and Location.** Meals and refreshments should be provided in a setting that is conducive to bona fide scientific, educational, or business discussions. This may include, for example, the Health Care Professional's place of business or an off-site space that is conducive to the discussion, such as a restaurant.

- **Participants.** A Company may provide a meal or refreshments only to Health Care Professionals who actually attend and have a bona fide purpose for attending the meeting.

  A Company may not provide a meal or refreshments:

  - For an entire office staff where everyone does not attend the meeting;
  - If a Company representative is not present (such as a "dine & dash" program); or
  - For guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

ADDITIONAL INSIGHTS

ESTABLISHING MEAL POLICIES

Companies are strongly encouraged to develop policies on providing modest and occasional meals to Health Care Professionals.

This may include establishing a per meal spending limit for meals and refreshments with a Health Care Professional and whether the amount should vary to account for geographic areas (for example, New York City) that are generally more expensive.

FREQUENTLY ASKED QUESTIONS

27 For Companies that have chosen to place per-meal spending limits on meals with Health Care Professionals, does AdvaMed recommend a specific dollar value?

No. AdvaMed does not recommend a specific dollar amount for a per-person spending limit on meals with Health Care Professionals. AdvaMed maintains benchmarking and best practices information on its website, and Companies take differing factors into account in establishing their spending limits. The fact that a meal costs less than a Company's spending limit does not mean the meal complies with the Code; rather, all meals and refreshments provided to HCPs must meet all of the requirements of Section VII of the Code.

[Posted June 14, 2019]

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FREQUENTLY ASKED QUESTIONS

28 Is a general discussion to build good business relationships an appropriate purpose for providing a meal to a Health Care Professional?

No. A meal should only be provided to a Health Care Professional as part of a bona fide business discussion. This includes, for example, discussions on Medical Technology development and improvement, pricing, or contract negotiations, among other legitimate topics. The discussion should account for most of the time spent during the meal. A casual get-together or the development of general goodwill should not be the primary purpose of a meal with a Health Care Professional.

[Posted Dec. 7, 2018]

29 May Companies provide meals or refreshments for Company-Conducted Meetings that are held virtually?

Yes. Modest meals or refreshments may be provided in accordance with Section VII of the Code. To properly consider and manage the provision of meals to Health Care Professionals during Company-Conducted Meetings that are held virtually, Companies may create a process to control ordering and delivery, track attendance to ensure that only appropriate participants in the meeting receive the meals/refreshments, and/or prohibit home delivery.

[Posted March 15, 2022]



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KEY CONCEPTS

Companies may not provide branded, promotional items or "gifts" to Health Care Professionals.

Companies may provide modest, appropriate educational items or patient benefit items to Health Care Professionals.

A Company may occasionally provide modest, appropriate educational items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals.

Companies may not provide gifts to Health Care Professionals. This means that a Company may not provide Health Care Professionals with the following:

- Items that the Health Care Professional (or his or her family members, office staff, or friends) can use for non-educational or non-patient-related purposes (for example, office supplies, scrubs, a tablet, Smart Phone, laptop, or other mobile device capable of personal use)
- Branded, non-educational promotional items, even if the item is of minimal value, related to the Health Care Professional's work, or for the benefit of patients (for example, pens, notepads, mugs, and other items with a Company or product name or logo)
- Gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents (for example, gift cards)

Other important principles include:

- Any item given to a Health Care Professional's staff should be treated as though it is given to the Health Care Professional and is subject to all applicable provisions of the Code.
- A Company may not raffle or give away an item that it could not otherwise give a Health Care Professional under the Code.

FREQUENTLY ASKED QUESTIONS

30 What are "modest" educational items?

Other than medical textbooks or anatomical models used for educational purposes, any educational item provided to a Health Care Professional should have a fair market value of less than US $100.

[Posted Dec. 7, 2018]

31 What is an item for the benefit of patients?

Items considered to be intended for the benefit of patients could include starter kits, and educational brochures, for example. With respect to starter kits, a Company should adopt appropriate safeguards regarding the provision of such kits to ensure they are not offered as an unlawful inducement.

[Posted Dec. 7, 2018]

32 May a Company or its representative provide a gift to recognize a life event for a Health Care Professional, such as a wedding, birth, anniversary, or death of a family member?

No. A Company or its representative acting on the Company's behalf may only provide items to Health Care Professionals that are intended for the benefit of patients or serve a genuine educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, etc. do not meet this requirement, even if provided to recognize a significant life event.

[Posted Dec. 7, 2018]

33 Does the AdvaMed Code include any restrictions on a Company employee or representative accepting a gift from a Health Care Professional?

No. The AdvaMed Code does not address whether a Company employee or representative can accept a gift from a Health Care Professional. Companies are encouraged to develop their own internal policies on this concept, recognizing that the giving and acceptance of gifts could create a real or perceived conflict of interest.

[Posted June 14, 2019]

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KEY CONCEPTS

Companies may not provide entertainment or recreation to Health Care Professionals in any form.

A Company may not provide or pay for any entertainment or recreational event for a Health Care Professional.

Entertainment and recreational activities are inconsistent with the appropriate business purpose of a Company's interactions with Health Care Professionals. Some examples of entertainment and recreational activities include, among others, theater, sporting events, golf, skiing, hunting, or vacation trips.

This prohibition applies regardless of (1) the value of the activity; (2) whether the Company engages the Health Care Professional as a consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.



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KEY CONCEPTS

Access to truthful and non-misleading information relating to Medical Technologies is critical to a Health Care Professional's ability to exercise his or her 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.

Health Care Professionals 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 otherwise consistent with such labeling, but it could also include uses that are not approved or cleared (i.e. "off-label" uses). As recognized under U.S. law and by the FDA, off-label use of these Medical Technologies can be an important part of medical practice and may even constitute a medically recognized standard of care.

Access to truthful and non-misleading information relating to Medical Technologies, including information on both on- and off-label uses, is critical to a Health Care Professional's ability to exercise his or her medical judgment in the best interest of patients, to provide high-quality care, and to safely use available Medical Technology. Industry appropriate communications of such information can include, among other activities:

- 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 an investigational use (taking care that no claims are made regarding safety and effectiveness); and
- Discussions with consultants and Health Care Professionals to obtain advice or feedback relating to topics such as unmet patient needs, product research and development, and the like.

The following principles recognize industry's responsibility to communicate about medical and scientific information to assist in achieving positive patient outcomes and support of the public health:

1. Company responses that contain information regarding unapproved or uncleared uses should be provided by authorized personnel.
2. Company communications must be truthful and non-misleading.
3. Information related to unapproved or uncleared uses should be identified as such.

Companies are encouraged to develop policies and controls that apply the principles above and that incorporate the requirements of applicable guidance (for example, judicial decisions related to appropriate product communications, guidance from the FDA, and the like).

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KEY CONCEPTS

Medical Technology Companies may support patients in obtaining access to a Company's Medical Technology by providing Health Care Professionals with timely and complete coverage, reimbursement, and health economics information.

Medical Technology Companies may not, however, interfere with a Health Care Professional's independent clinical decision making or provide coverage, reimbursement and health economics support as an unlawful inducement.

As Medical Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Medical Technology depends on Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. To promote patient access to Medical Technologies:

- A Company may provide this information regarding its Medical Technologies if it is accurate and objective.
- A Company may also collaborate with Health Care Professionals, patients, and organizations representing their interests to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Medical Technologies.

FREQUENTLY ASKED QUESTIONS

34 May a Company provide coverage, reimbursement, and health economics information to a Health Care Professional for the purpose of developing or negotiating a value- or outcomes-based contract between the Company and the Health Care Professional?

Yes, subject to the conditions described in this section, a Company may provide accurate and objective information relating to the economically efficient use of its Medical Technologies, including in the context of value- and outcomes-based contracting. A Company may not, however, interfere with a Health Care Professional's independent clinical decision-making or provide such information as an unlawful inducement.

[Posted March 15, 2022]

Permissible activities involving the provision of coverage, reimbursement, and health economic information may include, but are not limited to:

- Identifying the clinical value of the Company's Medical Technologies and the services and procedures in which they are used
- Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement, and health economics issues
- Supporting Health Care Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Health Care Professionals regarding the Company's Medical Technologies, including identifying coverage, codes, and billing options that may apply to those Medical Technologies or the services and procedures in which they are used
- Providing accurate and objective information about the economically efficient use of the Company's Medical Technologies, including where and how they can be used within the continuum of care and/or in the context of advancing value-based care arrangements

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- Providing information related to the Company's Medical Technologies regarding available reimbursement and associated costs

- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes to help a Health Care Professional in the decision to buy or use the Company's Medical Technologies

- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Medical Technologies

- Facilitating patient access to the Company's Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions from payors, including providing information on payor policies and training on procedures for obtaining prior authorization, providing sample letters and information on medical necessity and appeals of denied claims

  In addition, at the request of a Health Care Professional to facilitate patient access to the Company's Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a Company's own Medical Technology; however, such assistance should not be provided as an unlawful inducement.

A Company may not interfere with a Health Care Professional's independent clinical decision making or provide coverage, reimbursement, and health economics support as an unlawful inducement. For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise have incurred as part of its business operations. Further, a Company should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.



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KEY CONCEPTS

Companies may provide reasonable quantities of products to Health Care Professionals at no charge to permit Health Care Professionals to evaluate and assess whether to purchase the product.

Companies may also provide Health Care Professionals with non-sterile demonstration units to use in educating patients about the product and its use.

A. Demonstration & Evaluation Products

Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can improve patient care, facilitate the safe and effective use of products, enhance patient awareness, and educate Health Care Professionals regarding the use of products. Under certain circumstances, a Company may provide reasonable quantities of products to Health Care Professionals at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future.

Company products that may be provided to Health Care Professionals for evaluation include single use (for example, samples of consumable or disposable products) and multiple use products (sometimes referred to as capital equipment).

Company products provided for evaluation are typically expected to be used in patient care. Companies should provide Health Care Professionals with appropriate documentation to allow the Health Care Professional to address any reimbursement reporting obligations, including providing information on the no-charge status of these products.

- **Single Use/Consumables/Disposables.** The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

- **Multiple Use/Capital.** Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation and consistent with any applicable transparency reporting requirements.

FREQUENTLY ASKED QUESTIONS

35 What are examples of appropriate reasons for providing single-use or multiple-use evaluation products to a Health Care Professional?

Examples may include the Health Care Professional may have not recently purchased or used the products (i.e. the Health Care Professional is not familiar with the product); or the product may be marketed for a new indication or new surgical technique; among other reasons.

[Posted Dec. 7, 2018]

ADDITIONAL INSIGHTS

Transparency.
A Company should consider whether federal or state law (for example, the U.S. Physician Payments Sunshine Act) requires reporting the value of evaluation products provided to Health Care Professionals.

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- The length of time necessary for a Health Care Professional to evaluate a multiple use product can vary among products and may depend on the frequency of anticipated use, the duration of required training, the number of Health Care Professionals who need to evaluate the product, the length of time needed to evaluate different product features, and similar considerations.

- The terms of an evaluation of such multiple use products should be set in advance in writing, specifying the length of the evaluation period and addressing products that have not been returned within the evaluation period.

- Companies should retain title to multiple use products during the evaluation period and should have a process in place for promptly removing multiple use products from the Health Care Professional's location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products.

- Demonstration. Company demonstration products are typically unsterilized single use products or mock-ups that are used for Health Care Professional and patient awareness and education. For example, a Health Care Professional may use a demonstration product to show a patient the type of device that will be implanted in the patient.

- Demonstration products typically are not intended to be used in patient care.

- Demonstration products typically are identified as not intended for patient use through designations like "Sample" or "Not for Human Use" on the product, the packaging, or documentation that accompanies the product.

FREQUENTLY ASKED QUESTIONS

36 What additional asset management principles should companies consider adopting?

In addition to the principles outlined in Section XII of the AdvaMed Code, Companies may also want to consider other controls regarding asset management, including product provided at no charge (for example, demonstration and evaluation units, loaned products, in-kind grants/donations) or for charge (for example, rental products, placed capital, consignment product). Possible examples of these controls may include the following:

- Written policies, procedures and work instructions that govern when assets can be supplied to an HCP, including related auditing and monitoring;
- Specialized training and education for Company representatives; and
- Clear documentation, recordkeeping, and asset tracking requirements, including any obligations to compensate or return Medical Technology to the Company, as appropriate.

[Posted June 14, 2019]

B. Consigned Products

Consigned products are Medical Technologies (a) that a Company provides to a Health Care Professional for use in and storage at the Health Care Professional's patient care setting and (b) to which the Company retains title until the product is used.

- Consignment arrangements should generally be subject to an agreement that addresses the terms of consignment, for example, the number of products, any requirements to segregate consigned products from other products, and storage space rental terms (if applicable).

- Companies are encouraged to consider implementing appropriate controls. This could include (among other measures) taking periodic inventory of consigned devices for purposes such as billing and restocking; reconciling discrepancies between the Company's records and the number of products used or verified during inventory; and return or removal of expired product.

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SECTION XIII Company Representatives Providing Technical Support in the Clinical Setting

KEY CONCEPTS

Access to truthful and non-misleading information relating to Medical Technologies is critical to a Health Care Professional's ability to exercise his or her 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.

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

- 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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KEY CONCEPTS

Data-driven medical technologies play a critical role in transforming healthcare and create tremendous value with respect to improved patient outcomes and the quality and efficiency of healthcare delivery.

Companies are encouraged to apply the principles outlined in this section and develop related controls.

Data-driven medical technologies play a critical role in transforming healthcare. Emerging and converging technologies are enabling the collection of novel kinds of data, aggregation of ever-larger data sets, increasingly sophisticated data analysis, and augmented intelligence. These transformative advances in digital health create tremendous value with respect to improved patient outcomes and the quality and efficiency of healthcare delivery.

Companies should apply the following principles:

Principles of Trust

- Use data for the benefit of patients– to improve access and outcomes; to advance research, development, and safety goals; and to benefit the healthcare ecosystem at large.
- Minimize personal data, as appropriate, to protect individuals' privacy and prevent inappropriate identification of specific individuals.
- Use data for the purposes articulated to individuals or authorized by customers.

Principles of Privacy, Transparency, Consent & Control

- Protect patient privacy in compliance with industry best practices and international standards where applicable.
- Personal data and the systems that process it are protected through appropriate organizational security measures designed to preserve confidentiality, integrity, and availability.
- Collect data transparently with appropriate notice and permission.
- Individuals have appropriate control over their personal data.



Principles of Responsibility in Data Management

- Manage personal data in accordance with appropriate medical technologies standards of ethics and trustworthiness.
- Healthcare stakeholders, innovator personnel and external vendors collaborate to deliver a clear understanding of the data that is collected, how it is used, and how it is protected.
- Manage data in accordance with requirements of healthcare stakeholders where applicable.
- Deploy appropriate technology to protect data and continuously improve our systems and processes and train teams in relevant aspects of data protection and cybersecurity to maintain a consistently high level of threat awareness.

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