

**Comparison of the AdvaMed Code of Ethics on Interactions with Health Care Professionals (2020) and the PhRMA Code on Interactions with Healthcare Professionals (2009)**

	<u>AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals</u>	<u>PhRMA Code on Interactions with Healthcare Professionals</u>
	Effective January 1, 2020	Effective January 1, 2009
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<p><b>Introduction / Preamble</b></p>	<p><b>Section I – Introduction</b></p> <p>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.</p>	<p><b>Preamble</b></p> <p>The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies. Our members develop and market new medicines to enable patients to live longer and healthier lives.</p>
	<p><u>The Value of Interactions with Health Care Professionals</u></p> <p>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.</p> <ul style="list-style-type: none"> <li>• Companies and Health Care Professionals advance medical care and clinical science through <b>research, product development, and product testing</b> that results in new or improved, innovative Medical Technology</li> <li>• Companies <b>instruct, educate, and train</b> Health Care Professionals on the safe and effective use of complex Medical Technology</li> <li>• Companies provide product service and technical support for Health Care Professionals to help ensure the safe and effective use of Medical Technology</li> <li>• Companies support Health Care Professionals’ scientific and medical research, as well as the enhancement of clinical skills and educational opportunities to improve patient care</li> <li>• Companies promote charitable giving and public awareness of medical and health conditions through grants and donations in support of indigent care and patient education</li> </ul>	<p>Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines. An important part of achieving this mission is ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines, which play an ever-increasing role in patient healthcare. This document focuses on our interactions with healthcare professionals that relate to the marketing of our products.</p> <p>Appropriate marketing of medicines ensures that patients have access to the products they need and that the products are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to—</p> <ul style="list-style-type: none"> <li>• inform healthcare professionals about the benefits and risks of our products to help advance appropriate patient use,</li> <li>• provide scientific and educational information,</li> <li>• support medical research and education, and</li> <li>• obtain feedback and advice about our products through consultation with medical experts.</li> </ul>
	<p><u>The Purpose of the AdvaMed Code &amp; Its Cornerstone Values</u></p> <p>The AdvaMed Code provides Medical Technology Companies with guidance on ethical interactions and relationships with Health Care Professionals, based on the following cornerstone values:</p> <ul style="list-style-type: none"> <li>• <b>Innovation:</b> Advance the development and availability of safe and effective Medical Technology that Health Care Professionals use to improve &amp; save lives</li> <li>• <b>Education:</b> Deliver high-quality training and education to help ensure that Health Care Professionals safely and effectively use Medical Technology</li> <li>• <b>Integrity:</b> Conduct business with integrity at all times and avoid real or perceived conflicts of interest with Health Care Professionals</li> <li>• <b>Respect:</b> Respect the independent clinical judgment of Health Care Professionals to decide the best manner and method for treating patients</li> </ul>	<p>In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirements. We are also concerned that our interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large. This Code is to reinforce our intention that our interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine. The Code is based on the principle that a healthcare professional’s care of patients should be based, and should be perceived as being based, solely on each patient’s medical needs and the healthcare professional’s medical knowledge and experience.</p> <p>Therefore, PhRMA adopts this updated and enhanced voluntary Code on relationships with U.S. healthcare professionals. This Code reflects and builds upon the standards and principles set forth in its predecessor, the PhRMA Code on Interactions with Healthcare Professionals that took effect on July 1, 2002. Like the 2002 edition, this Code addresses interactions with respect to marketed products and related pre-launch activities. PhRMA member companies’ relationships with clinical investigators and other individuals and entities as they relate to the clinical research process are addressed in the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.</p>

	<ul style="list-style-type: none"> <li>• <b>Responsibility:</b> Promote socially and ethically responsible business practices that protect patients, their rights, and their safety</li> <li>• <b>Transparency:</b> Conduct interactions with Health Care Professionals fairly, openly, and transparently</li> </ul> <p><b>Companies should review all interactions with Health Care Professionals in light of these values and should always avoid interactions designed to circumvent the Code.</b> 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.</p> <p>Companies and their employees and agents should be mindful of their interactions and the perception of their interactions with Health Care Professionals.</p> <p><b>Q1 – Why does AdvaMed have a Code of Ethics that differs from codes that govern pharmaceutical or biologics companies?</b></p> <p>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.</p>	<p>This updated Code will take effect in January 2009.</p> <p><b>1 Basis of Interactions</b></p> <p>Our relationships with healthcare professionals are regulated by multiple entities and are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education.</p> <p>Promotional materials provided to healthcare professionals by or on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other Food and Drug Administration (FDA) requirements governing such communications.</p>
	<p><u>Scope &amp; Applicability of the Code</u></p> <ul style="list-style-type: none"> <li>• <b>Legal Principles:</b> The Code does not provide legal advice or create legal rights or obligations.</li> <li>• <b>Geographic Reach:</b> 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).</li> <li>• <b>Interactions with Health Care Professionals:</b> 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</li> <li>• <b>Representatives:</b> 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.</li> <li>• <b>Multiple Business Lines:</b> 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.</li> </ul>	<p><b>Q.24 Does the Code apply to interactions with physician office managers, receptionists, and similar personnel who may not be healthcare professionals?</b></p> <p>A. Although the Code does not directly apply to persons who are not healthcare professionals, it would be difficult to separate a company’s interactions with any of a physician’s employees from those directly with the physician. Therefore, the Code should be followed under these circumstances.</p>

	<ul style="list-style-type: none"> <li>• <b>Combination Products:</b> 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.</li> </ul> <p><b>No Unlawful Inducements.</b> 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.</p> <p><b>Q1a – To which Company employees, agents, dealers, or distributors does the AdvaMed Code apply?</b></p> <p>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.</p>	
	<p><u>Complying with the AdvaMed Code</u></p> <p>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.</p> <p>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 <b>appropriately tailored</b> for each Company.</p> <p><b>“Appropriately tailored”</b> 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.</p> <p>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:</p> <p><i>(See “Elements of an Effective Compliance Program” Infographic)</i></p> <p>A Company that adopts the Code is <b>strongly encouraged to submit to AdvaMed an annual certification</b></p>	<p><b>15 Adherence to Code</b></p> <p>All companies that interact with healthcare professionals about pharmaceuticals should adopt procedures to assure adherence to this Code.</p> <p>Companies that publicly announce their commitment to abide by the Code and who complete an annual certification that they have policies and procedures in place to foster compliance with the Code will be identified by PhRMA on a public web site. The certification must be signed by the company’s Chief Executive Officer and Chief Compliance Officer. The web site will identify the companies who commit to abide by the Code; provide contact information for their Chief Compliance Officers; and, at the appropriate time, publish the status of each company’s annual certification.</p> <p>Any comments received by PhRMA relating to a company’s observance of the Code or conduct that is addressed by the Code will be referred by PhRMA to the relevant company’s Chief Compliance Officer.</p> <p>In addition, companies are encouraged to seek external verification periodically, meaning at least once every three years, that the company has policies and procedures in place to foster compliance with the Code. PhRMA will prepare general guidance for such external verification and will identify on its web site if a company has sought and obtained verification of its compliance policies and procedures from an external source.</p>

	<p>stating that the Company has adopted the Code and has implemented an effective compliance program.</p> <p>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.</p>	
	<p><u>Glossary</u></p> <ul style="list-style-type: none"> <li>• <b>Commercial Sponsorship:</b> 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).</li> <li>• <b>Company:</b> A company that develops, produces, manufactures, and markets Medical Technology.</li> <li>• <b>Educational Grant:</b> 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.</li> <li>• <b>Health Care Professionals or HCPs:</b> 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.</li> </ul> <p>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.</p> <ul style="list-style-type: none"> <li>• <b>Medical Technology:</b> Medical Technology is a broad term that means medical devices and products, technologies, digital and software platforms, and related services, solutions, and therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities. Some examples include: <ul style="list-style-type: none"> <li>○ Implantable medical devices that are placed in or on the human body to replace, repair, or strengthen a body part;</li> <li>○ Surgical devices used to perform procedures;</li> <li>○ Digital technology and software platforms that assist in monitoring, diagnosing, and treating patients; and</li> <li>○ Non-invasive reagents, instrumentation, and/or software to aid in the diagnosis and treatment of patients; among other technology.</li> </ul> </li> </ul>	

	<ul style="list-style-type: none"> <li>• <b>Modest:</b> Moderate value, but may differ depending on regional differences.</li> <li>• <b>Occasional:</b> An interaction is considered occasional if it occurs infrequently and not on a routine basis.</li> <li>• <b>Satellite Symposium:</b> 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.</li> <li>• <b>Third-Party Program:</b> 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.</li> <li>• <b>Third-Party Program Organizer:</b> 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.</li> </ul> <p>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.</p> <p>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.</p>	
<p><b>Consulting Arrangements with Health Care Professionals</b></p>	<p><b>Section II – Consulting Arrangements with Health Care Professionals</b></p> <p><b>Key Concepts:</b></p> <ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ 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.</li> </ul>	<p><b>6 Consultants</b></p> <p>Consulting arrangements with healthcare professionals allow companies to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas and the needs of patients. Companies use this advice to inform their efforts to ensure that the medicines they produce and market are meeting the needs of patients. Decisions regarding the selection or retention of healthcare professionals as consultants should be made based on defined criteria such as general medical expertise and reputation, or knowledge and experience regarding a particular therapeutic area. Companies should continue to ensure that consultant arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.</p>

<p>A. <u>Engaging a Health Care Professional to Provide Consulting Services</u></p> <p>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), and arrangements for the development or transfer of intellectual property.</p> <p>Companies should apply the following principles to all consulting arrangements with Health Care Professionals:</p> <ul style="list-style-type: none"> <li>• <b>Legitimate Need.</b> A Company should enter a consulting arrangement with a Health Care Professional only if it has identified a <b>legitimate need</b> for the Health Care Professional’s services in advance.</li> </ul> <p>A <b>legitimate need</b> 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.</p> <ul style="list-style-type: none"> <li>• <b>Consultant Selection.</b> 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.</li> </ul> <p>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.</p> <ul style="list-style-type: none"> <li>• <b>Number of Consultants.</b> A Company should engage only as many consultants as are necessary to fulfill the Company’s requirements for the bona fide services.</li> <li>• <b>Fair Market Value Compensation.</b> 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.</li> <li>• <b>Expenses.</b> A Company may pay for documented, reasonable, and actual expenses incurred by a</li> </ul>	<p>Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement): is appropriate for consultants who provide advisory services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and based on fair market value.</p> <ul style="list-style-type: none"> <li>• a written contract specifies the nature of the consulting services to be provided and the basis for payment of those services;</li> <li>• a legitimate need for the consulting services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;</li> <li>• the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;</li> <li>• the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;</li> <li>• the retaining company maintains records concerning and makes appropriate use of the services provided by consultants;</li> <li>• the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting; specifically, resorts are not appropriate venues.</li> </ul> <p>While modest meals or receptions may be appropriate during company-sponsored meetings with healthcare professional commercial consultants, companies should not provide recreational or entertainment events in conjunction with these meetings.</p> <p>It is not appropriate to pay honoraria or travel or lodging expenses to non-faculty and non-consultant healthcare professional attendees at company-sponsored meetings, including attendees who participate in interactive sessions.</p> <p><b>Q.15 Company A retains a small group of 15 nationally known physicians regarding a therapeutic area relevant to company A’s products to advise on general medical and business issues and provide guidance on product development and research programs for those products. These physicians are paid fees that are typical of the fees paid to thought leaders in this therapeutic area. They normally meet once or twice a year at resort locations to discuss the latest product data, research programs and Company plans. Does this comply with the Code? If it does, is it appropriate to pay for the spouse of the healthcare professional to attend, as well?</b></p> <p>A. No, this arrangement for engaging healthcare professionals to obtain advice on the company’s commercial operations does not appear to comply with the Code. It is appropriate for companies to engage healthcare professionals to provide bona fide 26 advisory services as long as the number of healthcare professionals is</p>
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<p>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.</p> <ul style="list-style-type: none"> <li>• <b>Written Agreement.</b> 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.</li> <li>• <b>Sales Involvement.</b> 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.</li> </ul> <p><b>Q1b – 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?</b></p> <p>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.</p> <p><b>Q2 – How can a Company establish “fair market value” for goods or services?</b></p> <p>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.</p> <p><b>Q3 – Why does the AdvaMed Code restrict the involvement of sales in selecting consultants?</b></p> <p>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.</p> <p><b>Q4 – What should Companies know about Health Care Professionals’ potential conflicts of interest?</b></p>	<p>reasonably necessary to achieve an identified purpose, and they are paid compensation that is reasonable and at fair market value for the services provided. It would not be appropriate, however, to hold such a consultant meeting at a resort venue. In this case, the number of advisors seems reasonably small and the scope of services seems to be reasonably well defined. The advisors seem to have been selected based on their expertise in the areas where advice is needed. The compensation appears consistent with the Code’s provision that consultant fees should be reasonable and based on fair market value. Nevertheless, holding consultant meetings at resort locations is not appropriate under the Code. The facilities chosen should be conducive to the services provided as well as reasonable and appropriate to the conduct of the meeting. In addition, only modest meals may be offered to such consultants, and companies should not provide recreational or entertainment events to the healthcare professional consultants in conjunction with these meetings. It would not be appropriate to pay for the cost of the spouse of the advisor. If the spouse attends, it should be at the cost of the advisor.</p> <p><b>Q.23 Under the Code, may a company compensate a consultant for bona fide services by providing an item with a legitimate patient benefit in lieu of paying an honorarium or fee?</b></p> <p>A. If the consulting arrangement otherwise complies with the Code, and the fair market value of the item represents reasonable compensation for the services provided, this may be permissible. However, it would be important to comply with all applicable recordkeeping and reporting requirements, just as with cash compensation. The written agreement for the consulting services should set forth the compensation and its fair market value, and disclose that this is taxable income.</p> <p><b>8 Healthcare Professionals Who Are Members of Committees That Set Formularies or Develop Clinical Practice Guidelines</b></p> <p>Healthcare professionals who are members of committees that set formularies of covered medicines or develop clinical practice guidelines that may influence the prescribing of medicines often have significant experience in their fields. That experience can be of great benefit to companies and ultimately to patients if these individuals choose to serve as speakers or commercial consultants for companies. To avoid even the appearance of impropriety, companies should require any healthcare professional who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the existence and nature of his or her relationship with the company. This disclosure requirement should extend for at least two years beyond the termination of any speaker or consultant arrangement.</p> <p>Upon disclosure, healthcare professionals who serve as speakers or consultants for companies should be required to follow the procedures set forth by the committee of which they are a member, which may include recusing themselves from decisions relating to the medicine for which they have provided speaking or consulting services.</p> <p><b>Q.16 Company A considers whether to invite 300 physicians/consultants to a two-day and one-night speaker-training program at a regional golf resort. All attendees would be compensated for their participation, and their expenses would be reimbursed. Prospective speakers would be selected based on recommendations of the Company’s district managers and an assessment of their qualifications by the Company’s medical or scientific personnel. Each of the attendees would be required to sign an agreement in advance covering the services they will provide. They would be educated by a faculty on the full range of data surrounding the</b></p>
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	<p>Health Care Professionals' interactions with Companies may potentially create conflicts of interest. For example, in addition to his/her industry interactions, a physician could also hold a leadership role in a medical society, serve as a conference planning chair, or act as a medical journal editor. A physician's professional interest in advancing objective, clinical information may compete with his or her industry relationship. Companies should be aware that Health Care Professionals may have these conflicts. Companies should also be mindful of steps that may need to be taken to address these conflicts, including, for example, recusal from decisions that implicate the conflict.</p>	<p><b>disease state and the Company's drug product, on presentation skills, and on FDA regulatory requirements. The Company needs to train 300 speakers in order to ensure that enough speakers will actually be available when needed. Training sessions take both days, and the Company provides for a few hours of golf and expensive meals, such as lobster and filet mignon. Does this program conform to the Code? If so, is it appropriate to pay for a spouse of the healthcare professional, as well?</b></p> <p>A. No. This arrangement would not conform with the Code. Speaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers. However, the Code provides that speaker training meetings should be held at appropriate venues and specifically states that resorts are not appropriate venues for training speakers. Moreover, providing entertainment (e.g., golf) and expensive meals to a healthcare professional in a speaker training program would not comply with the Code, although modest meals may be offered to attendees. The Company does appear to satisfy provisions in the Code that require potential speakers to be selected based on defined criteria such as medical expertise, knowledge and experience and to undergo extensive training that would result in a valuable service being provided to the company. The arrangement also appears to meet reasonable indicia of a bona fide consulting relationship. The number of speakers being trained is important; if significantly more participants were trained than the company plans to use as speakers, this arrangement would not comply with the Code. The amount of time spent training speakers should be reasonable in relation to the material that has to be covered. The compensation and lodging offered to prospective speakers should be evaluated to assure that it is reasonable compensation for their time and based on fair market value. It would not be appropriate to pay for the cost of the spouse of the healthcare professional. If the spouse attends, it should be at the cost of the healthcare professional.</p> <p><b>Q.25 Does the Code address the issue of disclosure of company interactions with healthcare professionals who are members of committees that develop formularies or clinical practice guidelines?</b></p> <p>A. Yes. The Code states that, to avoid even the appearance of impropriety, companies that have retained a healthcare professional member of a formulary or clinical practice guidelines committee as a commercial consultant or speaker should require the health care professional to disclose to the committee the existence and nature of his or her relationship with the company. This disclosure requirement should extend for at least two years beyond the termination of any consultant or speaker arrangement. Upon disclosure, healthcare professionals should be required to follow the procedures set by the committee of which they are a member; these procedures may include a requirement that healthcare professionals recuse themselves from decisions relating to the medicine about which they provided speaking or consulting services. It is reasonable for a company to rely on healthcare professionals' judgment regarding how to implement these requirements regarding disclosure and subsequent interactions with the committees on which they are members.</p>
	<p><b>B. <u>Royalties</u></b></p> <p>Arrangements involving the payment of royalties to a Health Care Professional should meet the standards listed in this section of the Code.</p> <p>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.</p> <p>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</p>	

	<p>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.</p> <p>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.</p> <p>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.</p>	
	<p>C. <u>Clinical Studies &amp; Research Agreements</u></p> <p>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.</p> <p>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.</p>	
<p><b>Company-Conducted Programs &amp; Meetings With Health Care Professionals</b></p>	<p><b>Section III – Company-Conducted Programs &amp; Meetings with Health Care Professionals</b></p> <p><b>Key Concepts:</b></p> <ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ 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).</li> <li>✓ 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.</li> </ul>	

	<p>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.</p> <p>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, thirdparty educational conferences), see Section IV of the Code.</p>	
	<p>A. <u>Company-Conducted Training &amp; Education</u></p> <p>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:</p> <ul style="list-style-type: none"> <li>✓ Medical Technology may involve complex equipment, devices, and/or sophisticated software platforms that require technical instruction.</li> <li>✓ Procedures in which Medical Technologies are used may be complex and require skilled clinical instruction.</li> <li>✓ Health Care Professionals need training and education on disease states and treatment options, patient selection criteria, clinical treatment standards and outcomes, care pathways, and how Medical Technologies benefit certain patient populations, among other important topics.</li> </ul> <p>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.</p> <p>Companies should apply the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals:</p> <ul style="list-style-type: none"> <li>• <b>Setting.</b> Companies should conduct live or virtual training and education programs in settings that are conducive to the effective transmission of information. These 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.</li> </ul> <p>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.</p> <ul style="list-style-type: none"> <li>• <b>Faculty.</b> 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.</li> </ul> <p>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 <b>servicing as faculty</b> at a Company conducted</p>	<p><b>7 Speaker Programs and Speaker Training Meetings</b></p> <p>Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks and appropriate uses of company medicines. Any healthcare professional engaged by a company to participate in such external promotional programs on behalf of the company will be deemed a speaker for purposes of this Code, and the requirements of Section 7 apply to company interactions with that healthcare professional in his or her capacity as a speaker. Company decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communications skills. Companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment.</p> <p>Speaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers. It is appropriate for healthcare professionals who participate in programs intended to train speakers for company-sponsored speaker programs to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses. Such compensation and reimbursement should only be offered when (1) the participants receive extensive training on the company’s drug products or other specific topic to be presented and on compliance with FDA regulatory requirements for communications; (2) this training will result in the participants providing a valuable service to the company; and (3) the participants meet the general criteria for bona fide consulting arrangements (as discussed in Section 6 above). Speaker training sessions should be held in venues that are appropriate and conducive to informational communication and training about medical information; specifically, resorts are not appropriate venues.</p> <p>Any compensation or reimbursement made to a healthcare professional in conjunction with a speaking arrangement should be reasonable and based on fair market value. Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements. Each company also should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time.</p> <p>Speaker programs may include modest meals offered to attendees and should occur in a venue and manner conducive to informational communication.</p> <p>While speaker programs offer important educational opportunities to healthcare professionals, they are distinct from CME programs, and companies and speakers should be clear about this distinction. For example, speakers and their materials should clearly identify the company that is sponsoring the presentation, the fact that the</p>

	<p>training and education program.</p> <ul style="list-style-type: none"> <li>• <b>Attendees.</b> 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).</li> <li>• <b>Travel &amp; Lodging.</b> 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.</li> <li>• <b>Meals &amp; Refreshments.</b> 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.</li> </ul>	<p>speaker is presenting on behalf of the company, and that the speaker is presenting information that is consistent with FDA guidelines. Beyond providing all speakers with appropriate training, companies should periodically monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines.</p> <p><b>Q.13 Company Y would like to engage an expert physician to discuss recent advances in therapy for a group of local healthcare professionals, and would like to meet and provide a meal to attendees in the private room of a local restaurant. Under what circumstances can this comply with the Code? Could a local field representative in the company’s sales organization attend the event for purposes of assisting the outside speaker and helping to assure that the content of the presentation complies with FDA requirements?</b></p> <p>A. The Code contemplates that a company may engage a healthcare professional to provide medical or scientific information to a group of healthcare professionals on behalf of the company. Such speaker programs may include modest meals offered to attendees and may occur in locations outside of the office or hospital setting, as long as they occur in a venue and manner conducive to informational communication. In this case, Company Y’s chosen location of a private room in a local restaurant may be conducive to informational discussion, and the meal provided to attendees should be modest as judged by local standards. In addition, Company Y should follow the provisions of Section 7 of the Code on speaker programs. For example, Company Y should make sure that the speaker is appropriately trained and that the speaker and her materials clearly identify the company sponsoring the presentation and the fact that the speaker is presenting on behalf of the company. In addition, Company Y should periodically monitor its speaker programs for compliance with FDA regulatory requirements. It would be appropriate for a local field representative in the company’s sales organization to attend a speaker program for purposes of assisting the speaker with logistics and helping to assure that the content of the presentation complies with FDA requirements.</p>
	<p>B. <u>Company Business Meetings</u></p> <p>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, or meetings to explore product development or clinical testing needs.</p> <p>Companies should apply the following principles when organizing and conducting business meetings:</p> <ul style="list-style-type: none"> <li>• <b>Legitimate Need.</b> 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.</li> <li>• <b>Setting.</b> Companies may hold meetings at or close to a Health Care Professional’s place of business or facility; another centralized location; or at a Company’s own facility that may be a more appropriate setting for the meeting, depending upon the topics discussed. In all instances, the setting for a Company conducted program or meeting must be conducive to the discussion of relevant information.</li> <li>• <b>Attendees.</b> Each Health Care Professional in attendance must have an objective, legitimate need to</li> </ul>	

	<p>attend a Company’s business meeting.</p> <ul style="list-style-type: none"> <li>• <b>Travel &amp; Lodging.</b> See Section VI of the Code for information on providing travel and lodging to Health Care Professionals attending a Company’s business meeting.</li> <li>• <b>Meals &amp; Refreshments.</b> See Section VII of the Code for information on providing meals and refreshments to Health Care Professionals attending a Company’s business meeting.</li> </ul>	
<p><b>Educational &amp; Research Grants, Charitable Donations, and Commercial Sponsorships</b></p>	<p><b>Section IV – Educational &amp; Research Grants, Charitable Donations, and Commercial Sponsorships</b></p> <p><b>Key Concepts:</b></p> <ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ Medical Technology Companies may support third-party educational, charitable, and research programs through monetary, in-kind, and other contributions.</li> <li>✓ 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.</li> </ul> <p>Companies provide monetary, in-kind, and other contributions to third parties in support of their educational, charitable, and research programs.</p> <p>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.</p> <p><b>Documentation.</b> 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.</p> <p><b>Funding Requests.</b> 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.]\</p>	<p><b>5 Pharmaceutical Company Support for Third-Party Educational or Professional Meetings</b></p> <p>Third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. A conference or meeting is any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.</p> <p>Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference’s sponsor, which, in turn, can use the money to reduce the overall conference registration fee for all attendees. When companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.</p> <p>Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference’s sponsor (except as set out in Section 9 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.</p> <p><b>13 Independence and Decision Making</b></p> <p>No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional’s prescribing practices.</p>
	<p>A. <u>Supporting Third-Party Programs through Educational Grants and Commercial Sponsorship</u></p> <p>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.</p> <p>Companies should apply the following principles when supporting Third-Party Programs through</p>	<p><b>4 Pharmaceutical Company Support for Continuing Medical Education</b></p> <p>Continuing medical education (CME), also known as independent medical education (IME), helps physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. Such financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine. Accordingly, a company should separate its CME grant-making functions from its sales and marketing</p>

<p>Educational Grants and/or Commercial Sponsorship.</p> <p><b>Supporting Third-Party Programs Through Educational Grants:</b></p> <p>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.</p> <p>A Third-Party Program Organizer (or training institution or designee) may use an Educational Grant:</p> <ul style="list-style-type: none"> <li>✓ To defray or reduce the costs of conducting the educational components of a Third-Party Program</li> <li>✓ 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</li> <li>✓ 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</li> <li>✓ 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.</li> </ul> <p>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.</p> <p>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.</p> <p>A Company may provide Commercial Sponsorship, even if the Company determines not to provide the Third-Party Program Organizer with an Educational Grant.</p> <ul style="list-style-type: none"> <li>• <b>No Support to Individuals.</b> 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.</li> <li>• <b>Adherence to Program Standards.</b> Companies should adhere to all standards established by the Third-Party Program Organizer or the body accrediting the Third-Party Program, as applicable.*</li> </ul> <p>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.</p>	<p>departments. In addition, a company should develop objective criteria for making CME grant decisions to ensure that the program funded by the company is a bona fide educational program and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.</p> <p>Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the CME provider, which, in turn, can use the money to reduce the overall CME registration fee for all participants. The company should respect the independent judgment of the CME provider and should follow standards for commercial support established by the Accreditation Council for Continuing Medical Education (ACCME) or other entity that may accredit the CME. When companies underwrite CME, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines. The company should not provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the company.</p> <p>Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME, either directly to the individuals participating in the event or indirectly to the event’s sponsor (except as set out in Section 9 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals participating in the CME event.</p> <p>A company should not provide meals directly at CME events, except that a CME provider at its own discretion may apply the financial support provided by a company for a CME event to provide meals for all participants.</p> <p><b>Q.19 A company is asked to fund a CME program as a “platinum” level supporter. This level of support includes the opportunity for the company to directly sponsor a lunch at the event. May the company become a “platinum” level supporter?</b></p> <p>A. It is appropriate under the Code for a company to provide funding to a CME provider, which the provider can use at its discretion to provide meals for all participants. However, a company should not control how the provider spends the funding, and a company should not sponsor or host a meal directly at a CME program. A company may fund a CME program at a particular level of support designated by the CME provider and be publicized for providing that level of support, as long as the company does not separately promote, publicize or otherwise take advantage of any option to be identified as the sponsor of a meal.</p> <p><b>Q.20 A national specialty society is holding its three-day annual conference, which includes business meetings, entertainment, and a half day of educational programs for which physicians may receive CME credit. May a company sponsor a reception or lunch at the conference?</b></p> <p>A. The Code provides that a company should not provide or sponsor meals directly at CME events. However, at third party conferences or professional meetings at which CME activities comprise only a part of the conference or meeting, a company may sponsor a meal or reception at the conference if it is permitted by the group holding the conference or meeting and is clearly separate from the CME portions of the program. In such cases, any meals or receptions sponsored by a company should be modest and clearly subordinate to the amount of time spent at other aspects of the meeting. In addition, companies should be mindful of standards set forth by ACCME or other accrediting bodies that may apply in these circumstances.</p>
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<p>*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.</p> <p style="text-align: center;"><b>Review Processes</b></p> <p>Companies are encouraged to adopt controls for reviewing requests to support Third-Party Programs. Companies should consider the following questions when reviewing such requests:</p> <ul style="list-style-type: none"> <li>✓ Is the request for funding reasonable and reflective of the educational purpose of the program?</li> <li>✓ Do the topics, faculty, attendees, and educational materials reflect an objective, legitimate, educational purpose?</li> <li>✓ Are the venue and setting conducive to the exchange of educational information?</li> <li>✓ Does the agenda reflect the legitimate educational, medical, scientific, or policymaking purpose of the meeting?</li> <li>✓ Do any of the meals or refreshments, recreational activities, or free time provided detract from the primary purpose of the Third-Party Program?</li> <li>✓ 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)?</li> </ul> <p><b>Q5 – 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?</b></p> <p>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.</p> <p><b>Q6 – Does the Code permit my Company to host a Satellite Symposium?</b></p> <p>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.</p> <p><b>Q7 – 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?</b></p>	<p><b>Q.21 May a company publicize its interest in a general topic for a CME program for which a grant would be provided?</b></p> <p>A. Yes, a company may communicate to multiple CME providers or the public a general topic for a CME program that might be of interest to physicians. For example, a company may publicize that it will consider funding the topics of new treatments or disease management techniques in a particular therapy area such as diabetes or hypertension. However, the company should follow CME accreditation standards considering the nature and specificity of the CME topics that the company may propose, keeping in mind the Code’s statement that financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine. In addition, the company may not suggest the speakers or review or make any suggestions concerning the specific content of a particular CME program, even if asked by the CME provider.</p>
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- *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 ThirdParty 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.

**Q7a – 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.

**Q7b– 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.

**Q7c – When can a Company send an HCP to speak at a Third-Party Program?**

The following flowchart is intended to help Companies determine whether it is appropriate under the



<p>AdvaMed Code for a Company to send an HCP to speak on its behalf at a Third-Party Program.</p> <p><i>(See “Elements of an Effective Compliance Program” Infographic)</i></p> <p><b>Q7d – Can a Company sponsor a luncheon during a Third-Party Program through the Third-Party Program Organizer?</b></p> <p>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 <i>bona fide</i> discussion of scientific, educational, or business information; and offered in a setting that is conducive to such discussion.</p> <p><b>Q7e – Can a Company sponsor a meal with entertainment during a Third-Party Program (for example, live music)?</b></p> <p>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.</p> <p><b>Q7f – Is a “journal club” considered a “Third-Party Program” under the AdvaMed Code?</b></p> <p>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.</p> <p>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).</p> <p>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.</p>	
<p>B. <u>Supporting Other Third-Party Programs through Educational Grants</u></p> <p>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.</p>	<p><b>9 Scholarships and Educational Funds</b></p> <p>Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. “Carefully selected educational conferences” are generally defined as the major educational, scientific, or policymaking meetings of national, regional, or specialty medical associations.</p>

	<p>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.</p> <p>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.</p>	
	<p>C. <u>Supporting Independent Third-Party Research</u></p> <p>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.</p> <ul style="list-style-type: none"> <li>• <b>Objectives &amp; Milestones.</b> 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 or 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.</li> <li>• <b>Limitations.</b> 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.</li> <li>• <b>Company Involvement.</b> The recipient of a Company's monetary or in-kind research support should retain independent control over the research.</li> <li>• <b>Company Review Processes.</b> A Company should establish controls for reviewing requests for research grants.</li> <li>• <b>Sales Involvement.</b> 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.</li> </ul> <p>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.</p>	
	<p>D. <u>Supporting Charitable Programs through Charitable Donations and Commercial Sponsorship</u></p> <p>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.</p> <ul style="list-style-type: none"> <li>• <b>Charitable or Philanthropic Mission.</b> Donations should be made for bona fide charitable purposes</li> </ul>	<p><b>Q.22 Under the Code, may a company make a charitable contribution such as purchasing a table at a fundraising dinner or a foursome slot at a fundraising golf tournament?</b></p> <p>A. Yes, but the company may not invite healthcare professionals to attend the event at its expense. The company may use some or all of its allotment for its own employees, and return any unused portion to the sponsoring organization to use as it wishes.</p>

	<p>and should be made only to charitable organizations or other non-profit entities with bona fide charitable and/or philanthropic purposes.</p> <p>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.</p> <ul style="list-style-type: none"> <li>• <b>Use of Funds.</b> A Company must require that any donation is used only towards charitable or philanthropic purposes.</li> <li>• <b>Indigent Care Donations.</b> 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.</li> <li>• <b>Charitable Events.</b> 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.</li> <li>• <b>Sales Involvement.</b> 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.</li> </ul> <p><b>Q8 – 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?</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>✓ 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</li> <li>✓ The Commercial Sponsorship must comply with applicable laws governing the marketing and promotion of its products.</li> </ul>	
<p><b>Jointly Conducted Education and Marketing Programs</b></p>	<p><b>Section V – Jointly Conducted Education and Marketing Programs</b></p> <p><b>Key Concepts:</b></p> <ul style="list-style-type: none"> <li>✓ 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.</li> </ul>	

- ✓ 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.

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.

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.
- 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.

**Q8a – 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 the benefits of the Company’s Medical Technology and highlighting the skills and expertise of the HCP to perform procedures that use the Medical Technology.

	<ul style="list-style-type: none"> <li>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.</li> </ul> <p>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.</p> <p><b>Q8b – What types of controls should companies implement in connection with jointly conducted programs?</b></p> <p>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.</p> <p>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.</p>	
<p><b>Travel &amp; Lodging; Venue</b></p>	<p><b>Section VI – Travel &amp; Lodging; Venue</b></p> <p><b>Key Concepts:</b></p> <ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ In all instances, there must be objective, legitimate reasons that support the need for travel and lodging for Health Care Professionals.</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>• <b>Legitimate Need.</b> There must be objective, legitimate reasons that support the need for out-of-town travel, such as the need to deliver training and education concerning Medical Technologies, the inability to effectively deliver the content of the program through means other than an in-person meeting, or the need to demonstrate equipment. Companies are encouraged to document the legitimate need for travel.</li> </ul>	

	<p><b>When does the Code permit a Company to pay for a Health Care Professional’s travel &amp; lodging?</b></p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• 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)</li> <li>• To speak on a Company’s behalf at a Third-Party Program, subject to the conditions described in Section IV</li> <li>• 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.</li> </ul> <p><b>When does the Code prohibit a Company from paying for a Health Care Professional’s travel &amp; lodging?</b></p> <ul style="list-style-type: none"> <li>• To attend any Company meeting without an objective, legitimate reason that supports the need for travel</li> <li>• To attend a Third-Party Program (see Section IV)</li> </ul> <hr/> <ul style="list-style-type: none"> <li>• <b>Modest and Reasonable Travel and Lodging.</b> 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.</li> <li>• <b>Travel Time &amp; Destination.</b> Companies are also encouraged to establish controls on the timing and location of travel arrangements for Health Care Professionals.</li> <li>• <b>Guests.</b> 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.</li> <li>• <b>Personal Travel &amp; Lodging.</b> Companies may not pay for a Health Care Professional’s personal travel or lodging.</li> <li>• <b>Setting.</b> 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. Companies should consider the following principles when choosing a setting:</li> </ul>	
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<ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ 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).</li> <li>✓ Companies should avoid <b>top category or luxury hotels or resort facilities</b> without an appropriate justification.</li> </ul> <ul style="list-style-type: none"> <li>• <b>Other Laws.</b> 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.</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>• If the Company is headquartered or has a significant facility in one of these geographic areas;</li> <li>• 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</li> <li>• If the Company is hosting a meeting held in conjunction with a Third-Party Program.</li> </ul> <p><b>Q9 – Does the Code permit Companies to pay for travel to attend Company-conducted training or education program?</b></p> <p>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.</p> <p><b>Q10 – Does the Code permit a Company to pay for travel to a Company-conducted general educational program not concerning a Medical Technology?</b></p> <p>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.</p> <p><b>Q10a – What types of controls should Companies consider with respect to limiting Health Care Professionals’ travel and lodging costs associated with a Company-conducted meeting?</b></p> <p>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</p>	
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	for any related change fees or additional costs.	
<p><b>Providing Modest Meals and Refreshments To Health Care Professionals</b></p>	<p><b>Section VII – Providing Modest Meals and Refreshments To Health Care Professionals</b></p> <p><b>Key Concepts:</b></p> <ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ Meals and refreshments should be subordinate in time and in focus to the discussion and presentation of scientific, educational, or business information.</li> </ul> <p>A Company occasionally may provide Health Care Professionals with modest meals and refreshments, subject to the following principles:</p> <ul style="list-style-type: none"> <li>• <b>Purpose.</b> 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.</li> <li>• <b>Setting and Location.</b> 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.</li> <li>• <b>Participants.</b> 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.</li> </ul> <p>A Company may not provide a meal or refreshments:</p> <ul style="list-style-type: none"> <li>✓ For an entire office staff where everyone does not attend the meeting;</li> <li>✓ If a Company representative is not present (such as a “dine &amp; dash” program); or</li> <li>✓ 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.</li> </ul> <p style="text-align: center;"><b>ESTABLISHING MEAL POLICIES</b></p> <p>Companies are strongly encouraged to develop policies on providing modest and occasional meals to Health Care Professionals.</p> <p>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.</p>	<p><b>2 Informational Presentations by Pharmaceutical Company Representatives and Accompanying Meals</b></p> <p>Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide healthcare providers with valuable scientific and clinical information about medicines that may lead to improved patient care.</p> <p>In order to provide important scientific information and to respect healthcare professionals’ abilities to manage their schedules and provide patient care, company representatives may take the opportunity to present information during healthcare professionals’ working day, including mealtimes. In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.</p> <p>Any such meals offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings. Inclusion of a healthcare professional’s spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate. Offering “take-out” meals or meals to be eaten without a company representative being present (such as “dine &amp; dash” programs) is not appropriate.</p> <p><b>Q.7 The Code states that company representatives or their immediate managers working in company field sales organizations may conduct informational presentations and discussions accompanied by occasional, modest meals in the healthcare professional’s office or hospital setting. What types of presentations and meals would this include?</b></p> <p>A. An informational presentation or discussion conducted by company representatives or their immediate managers working in field sales may be accompanied by an occasional modest meal in the office or hospital setting. Such modest meals may only be offered provided that the manner of presentation is conducive to a scientific or educational interchange and is not part of an entertainment or recreational event. For example, a sales 21 representative who is providing scientific or educational information regarding a company’s products to one or a few healthcare practitioners working in the same office, could provide a modest meal (e.g., sandwiches or pizza) to physicians and staff attending the representative’s informational presentation in the physician’s office at lunch time. Providing such modest meals on more than an occasional basis would not be appropriate.</p> <p><b>Q.8 Can a field sales representative of Company B conduct an informational presentation accompanied by a meal for a healthcare professional in a restaurant down the street from a hospital?</b></p> <p>A. No. An informational presentation or discussion conducted by a field sales representative or her immediate manager may only be accompanied occasionally by a meal if the presentation is held in the healthcare professional’s office or hospital. This is to ensure that any meal offered by field sales representatives or their managers is merely incidental to a substantive interaction with a healthcare professional in the office or hospital setting where the healthcare professional typically conducts professional conversations. In addition, any meal offered must be modest as judged by local standards; the presentation must not be part of an</p>



	<p><b>Q10b – For Companies that have chosen to place per-meal spending limits on meals with Health Care Professionals, does AdvaMed recommend a specific dollar value?</b></p> <p>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.</p> <p><b>Q11 – Is a general discussion to build good business relationships an appropriate purpose for providing a meal to a Health Care Professional?</b></p> <p>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.</p>	<p>entertainment or recreational event; and the presentation must be provided in a manner conducive to informational communication. If a hospital practitioner does not have an office conducive to informational communication, then a presentation may be provided in a hospital cafeteria or other meeting space within the hospital and may be accompanied by a modest meal.</p> <p><b>Q.9 A field sales representative of Company X provides pizza for the staff of a medical office during lunch time. Is this consistent with the Code?</b></p> <p>A. Providing an occasional meal would be consistent with the Code if the sales representative will provide an informational presentation to the medical staff in conjunction with the meal of modest value, so long as the location of the in-office presentation is conducive to scientific or educational communication. Merely dropping off food for the office staff, however, would not be consistent with the Code.</p> <p><b>Q.10 A field sales representative of Company X invites physicians to meet to hear a scientific and educational presentation about a new drug at the café at a nearby bookstore. Lunch is provided by the representative and, following the presentation (which is in small groups), each physician is given a gift certificate for books in the amount of \$30. Does this conform to the Code?</b></p> <p>A. No. While the presentation may present scientific or educational information, a company field sales representative should not provide even a modest meal to healthcare professionals outside of the office or hospital setting (except under the limited circumstances where the field sales representative attends a company-sponsored speaker program to provide logistical support and help monitor compliance with FDA requirements – see Question 13 below). In addition, an open-ended gift certificate is a cash equivalent. A medical textbook, a book on patient care, or a gift certificate redeemable solely for a medical textbook or book on patient care could be provided if it is not of substantial value (\$100 or less).</p> <p><b>Q.12 Under the Code, could a senior business executive employed by a company provide a healthcare professional with an occasional meal outside of the healthcare professional’s office or hospital?</b></p> <p>A. The Code does not prohibit company employees other than field sales representatives or their immediate managers from providing an occasional meal incidental to a substantive interaction with a healthcare professional outside of his or her office or hospital, as long as (1) the meal is modest as judged by local standards; (2) the meal is not part of an entertainment or recreational event; and (3) the interaction takes place in a venue and manner conducive to informational communication.</p> <p><b>Q.18 Under the Code, may a healthcare professional’s spouse or other guest be included in a meal with a pharmaceutical company representative that is provided in connection with an informational presentation by or on behalf of the company, if the healthcare professional pays for the spouse or guest?</b></p> <p>A. No. The Code provides that it is not appropriate to include a spouse or guest at a meal in connection with an informational presentation, regardless of who pays for their meal, unless the spouse or guest would independently qualify as a healthcare professional for whom the informational presentation is appropriate.</p>
<p><b>Educational &amp; Patient Benefit Items; Prohibition on</b></p>	<p><b>Section VIII – Educational &amp; Patient Benefit Items; Prohibition on Gifts</b></p> <p><b>Key Concepts:</b></p>	<p><b>10 Prohibition of Non-Educational and Practice-Related Items</b></p> <p>Providing items for healthcare professionals’ use that do not advance disease or treatment education — even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar “reminder” items</p>

<p><b>Gifts</b></p> <ul style="list-style-type: none"> <li>✓ Companies may not provide branded, promotional items or “gifts” to Health Care Professionals.</li> <li>✓ Companies may provide modest, appropriate educational items or patient benefit items to Health Care Professionals.</li> </ul> <p>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.</p> <p>Companies may not provide gifts to Health Care Professionals. This means that a Company may not provide Health Care Professionals with the following:</p> <ul style="list-style-type: none"> <li>✓ 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)</li> <li>✓ 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)</li> <li>✓ Gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents (for example, gift cards)</li> </ul> <p>Other important principles include:</p> <ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ A Company may not raffle or give away an item that it could not otherwise give a Health Care Professional under the Code.</li> </ul> <p><b>Q12 – What are “modest” educational items?</b></p> <p>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.</p> <p><b>Q13 – What is an item for the benefit of patients?</b></p> <p>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.</p> <p><b>Q14 – 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?</b></p> <p>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</p>	<p>with company or product logos) — may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues. Such non-educational items should not be offered to healthcare professionals or members of their staff, even if they are accompanied by patient or physician educational materials.</p> <p>Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) likewise should not be offered.</p> <p>Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in Sections 6 and 7). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.</p> <p>It is appropriate to provide product samples for patient use in accordance with the Prescription Drug Marketing Act.</p> <p><b>11 Educational Items</b></p> <p>It is appropriate for companies, where permitted by law, to offer items designed primarily for the education of patients or healthcare professionals if the items are not of substantial value (\$100 or less) and do not have value to healthcare professionals outside of his or her professional responsibilities. For example, an anatomical model for use in an examination room is intended for the education of the patients and is therefore appropriate, whereas a DVD or CD player may have independent value to a healthcare professional outside of his or her professional responsibilities, even if it could also be used to provide education to patients, and therefore is not appropriate.</p> <p>Items designed primarily for the education of patients or healthcare professionals should not be offered on more than an occasional basis, even if each individual item is appropriate.</p> <p><b>Q.1 Under the Code, may items such as stethoscopes be offered to healthcare professionals?</b></p> <p>A. No. Under the Code only items designed primarily for the education of patients or healthcare professionals may occasionally be offered to healthcare professionals, if the items are not of substantial value and do not have a value to healthcare professionals outside of their professional responsibilities. While medical equipment, such as stethoscopes, obviously plays an important role in patient care, such equipment is primarily designed for patient treatment, not for patient or healthcare professional education, and therefore it would be inappropriate for companies to offer such equipment to healthcare professionals.</p> <p><b>Q.2 Under the Code, could a company provide healthcare professionals with pens or clipboards designed to be used by healthcare professionals or patients in the healthcare professional’s office along with brochures that provide educational information about the company’s product?</b></p> <p>A. No. The Code states that providing healthcare professionals with items that do not advance disease or treatment education is not appropriate, even if these items are practice-related items of minimal value, such as clipboards, pens, mugs or similar items with or without company logos or product names printed on them. Providing such non-educational items could foster misperceptions that the company’s interactions with healthcare professionals are not based on providing information about products or health conditions, and</p>
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	<p>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.</p> <p><b>Q14a – Does the AdvaMed Code include any restrictions on a Company employee or representative accepting a gift from a Health Care Professional?</b></p> <p>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.</p>	<p>therefore companies should not offer non-educational items to healthcare professionals or their staff, even if they are accompanied by educational materials. It would, however, be appropriate for a company to distribute educational brochures without pens or clipboards. These same guidelines apply with regard to the distribution of items to healthcare professionals at third-party scientific and educational conferences or professional meetings.</p> <p><b>Q.3 Under the Code, what are examples of permissible items that may be provided to educate healthcare professionals?</b></p> <p>A. The Code states that it is appropriate for companies, where permitted by law, to occasionally offer items primarily designed for the education of patients or healthcare professionals, as long as such items are not of substantial value (\$100 or less) and do not have a value to the healthcare professionals outside of their professional responsibilities. For example, companies may provide educational items such as a medical text book, a subscription to a relevant scientific journal, or copies of relevant clinical treatment guidelines.</p> <p><b>Q.4 Under the Code, what types of patient education items may companies provide to healthcare professionals to help them in educating their patients?</b></p> <p>A. Where permitted by law, companies may occasionally offer to healthcare professionals items designed to help educate patients, such as anatomical models for examination rooms, informational sheets and brochures, patient self-assessment and tracking tools, or written materials that inform patients about adherence to medicine regimens, healthy lifestyle choices or the availability of patient assistance programs. Such items should not be of substantial value, i.e. they should be \$100 or less.</p> <p>Companies may also provide to healthcare professionals educational items designed for use by patients to assist in the administration of their treatment or management of their conditions. Such items should only be provided to healthcare professionals for patients where the items are permitted by law, may be considered essential to proper treatment or compliance and where delivery through a healthcare professional is an appropriate method of delivery to the patient. For example, companies may provide through healthcare professionals patient starter kits that help enhance the patients’ appropriate use of the prescribed medicine. Providing non-educational items to healthcare professionals for patient use is not appropriate, even if these items are of minimal value, such as pedometers, stopwatches, or other general fitness items.</p> <p><b>Q.5 Under the Code, may golf balls and sports bags be provided if they bear a company or product name?</b></p> <p>A. No. As stated in the prior version of the Code, golf balls and sports bags, even if of minimal value, do not advance disease or treatment education and therefore should not be offered, regardless of whether they bear a company or product name.</p> <p><b>Q.6 Under the Code, may healthcare professionals be provided with gasoline for their cars if they are provided with product information at the same time?</b></p> <p>A. No. As stated in the prior version of the Code, items intended for the personal benefit of a healthcare professional should not be offered.</p>
<b>Prohibition on</b>	<b>Section IX – Prohibition on Entertainment &amp; Recreation</b>	<b>3 Prohibition on Entertainment and Recreation</b>

<p><b>Entertainment &amp; Recreation</b></p>	<p><b>Key Concept:</b></p> <p>✓ Companies may not provide entertainment or recreation to Health Care Professionals in any form.</p> <p>A Company may not provide or pay for any entertainment or recreational event for a Health Care Professional.</p> <p>Some examples of entertainment and recreational activities include, among others, theater, sporting events, golf, skiing, hunting, or vacation trips.</p> <p>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.</p>	<p>Company interactions with healthcare professionals are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, companies should not provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company. Such entertainment or recreational benefits should not be offered, regardless of (1) the value of the items; (2) whether the company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.</p> <p>Modest, occasional meals are permitted as long as they are offered in the appropriate circumstances and venues as described in relevant sections of this Code.</p> <p><b>Q.11 A district sales manager at Company C invites 30 physicians to a corporate suite at a professional baseball game for a 45- minute scientific and educational presentation followed by a buffet and the three-hour game. Does this conform to the Code?</b></p> <p>A. No. The provision of entertainment and/or recreational activities, including entertainment at sporting events in connection with an educational or scientific presentation or discussion, is inconsistent with the Code, just as in the prior version. In addition, under the Code, informational presentations by company representatives or their immediate managers in field sales organizations may only be accompanied by a modest meal if the presentations occur in the healthcare professional’s office or hospital setting.</p> <p><b>Q.14 Under what circumstances would the Code permit a company to provide entertainment or recreational activities to healthcare practitioners?</b></p> <p>A. Under the Code, companies may not provide entertainment or recreational activities to healthcare practitioners who are not employees of the companies in any context, including situations where those practitioners are providing a legitimate service to the companies, such as when they act as bona fide consultants on an advisory board or are trained at a speaker-training meeting. Thus, companies should not invite healthcare professionals to sporting events, concerts, or shows, or provide them with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are intended to facilitate informational interchanges between the company representative and the healthcare professional. Similarly, it would be inappropriate to provide these types of entertainment and recreational events in conjunction with promotional scientific presentations by medical experts.</p> <p><b>Q.17 A sales representative invites a physician out for a round of golf and lunch following the golf. The physician is very busy and is difficult to see in her office. The cost of the golf and the lunch combined are \$65. Does this comply with the Code?</b></p> <p>A. No. As stated in the prior version of the Code, it is inconsistent with the Code to provide entertainment or recreational activities such as golf. In addition, occasional, modest meals provided by a representative or his immediate manager working in a field sales organization are limited to in-office or in-hospital settings in conjunction with informational presentations and discussions.</p>
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<p><b>Communicating for The Safe &amp; Effective Use of Medical Technology</b></p>	<p><b>Section X – Communicating for The Safe &amp; Effective Use Of Medical Technology</b></p> <p><b>Key Concepts:</b></p> <ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ Companies are encouraged to apply the principles outlined in this section and develop related controls.</li> </ul> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>• Proper dissemination of peer-reviewed scientific and medical journal articles, reference texts, and clinical practice guidelines;</li> <li>• 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</li> <li>• 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.</li> </ul> <p>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:</p> <ol style="list-style-type: none"> <li>1. Company responses that contain information regarding unapproved or uncleared uses should be provided by authorized personnel.</li> <li>2. Company communications must be truthful and non- misleading.</li> <li>3. Information related to unapproved or uncleared uses should be identified as such.</li> </ol> <p>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</p>	
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	<p>appropriate product communications, guidance from the FDA, and the like).</p>	
<p><b>Provision of Health Economics &amp; Reimbursement Information</b></p>	<p><b>Section XI – Provision of Health Economics &amp; Reimbursement Information</b></p> <p><b>Key Concepts:</b></p> <ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ 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.</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>• A Company may provide this information regarding its Medical Technologies if it is accurate and objective.</li> <li>• 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.</li> </ul> <p>Permissible activities involving the provision of coverage, reimbursement, and health economic information may include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Identifying the clinical value of the Company’s Medical Technologies and the services and procedures in which they are used</li> <li>• Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement, and health economics issues</li> <li>• Supporting Health Care Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies</li> <li>• 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</li> </ul>	<p><b>12 Prescriber Data</b></p> <p>Companies use non-patient identified prescriber data to facilitate the efficient flow of information to healthcare professionals. Such prescriber data, which does not identify individual patients, may serve many purposes, including enabling companies to: (a) impart important safety and risk information to prescribers of a particular drug; (b) conduct research; (c) comply with FDA mandated risk management plans that require drug companies to identify and interact with physicians who prescribe certain drugs; (d) track adverse events of marketed prescriptions drugs; and (e) focus marketing activities on those healthcare professionals who would most likely benefit from information about a particular drug.</p> <p>Companies that choose to use non-patient identified prescriber data to facilitate communications with healthcare professionals should use this data responsibly. For example, companies should (a) respect the confidential nature of prescriber data; (b) develop policies regarding the use of the data; (c) educate employees and agents about those policies; (d) maintain an internal contact person to handle inquiries regarding the use of the data; and (e) identify appropriate disciplinary actions for misuse of this data.</p> <p>In addition, companies should respect and abide by the wishes of any healthcare professional who asks that his or her prescriber data not be made available to company sales representatives. Companies may demonstrate this respect by following the rules of voluntary programs that facilitate prescribers’ ability to make this choice.</p>

	<ul style="list-style-type: none"> <li>• 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</li> <li>• Providing information related to the Company’s Medical Technologies regarding available reimbursement and associated costs</li> <li>• 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</li> <li>• 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</li> <li>• 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</li> </ul> <p>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.</p> <p>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.</p>	
<p><b>Demonstration, Evaluation, and Consigned Products</b></p>	<p><b>Section XII – Demonstration, Evaluation, and Consigned Products</b></p> <p><b>Key Concepts:</b></p> <ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ Companies may also provide Health Care Professionals with non-sterile demonstration units to use in educating patients about the product and its use.</li> </ul>	
	<p>A. <u>Demonstration &amp; Evaluation Products</u></p> <p>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</p>	

	<p>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.</p> <p>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).</p> <p>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.</p> <ul style="list-style-type: none"> <li>• <b>Single Use/Consumables/Disposables.</b> 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.</li> <li>• <b>Multiple Use/Capital.</b> 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.             <ul style="list-style-type: none"> <li>○ The <b>length of time necessary</b> 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.</li> <li>○ The <b>terms of an evaluation</b> 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.</li> <li>○ 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.</li> </ul> </li> <li>• <b>Demonstration.</b> 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.             <ul style="list-style-type: none"> <li>○ Demonstration products typically are not intended to be used in patient care.</li> <li>○ 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.</li> </ul> </li> </ul>	
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	<p><b>Q15 – What are examples of appropriate reasons for providing single-use or multiple-use evaluation products to a Health Care Professional?</b></p> <p>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.</p> <p><b>Transparency.</b> 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.</p> <p><b>Q16 – What additional asset management principles should companies consider adopting?</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>• Written policies, procedures and work instructions that govern when assets can be supplied to an HCP, including related auditing and monitoring;</li> <li>• Specialized training and education for Company representatives; and</li> <li>• Clear documentation, recordkeeping, and asset tracking requirements, including any obligations to compensate or return Medical Technology to the Company, as appropriate.</li> </ul>	
	<p>B. <u>Consigned Products</u></p> <p>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.</p> <ul style="list-style-type: none"> <li>• 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).</li> <li>• 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.</li> </ul>	
<p><b>Company Representatives Providing</b></p>	<p><b>Section XII – Company Representatives Providing Technical Support in the Clinical Setting</b></p> <p><b>Key Concepts:</b></p>	<p><b>14 Training and Conduct of Company Representatives</b></p> <p>Pharmaceutical company representatives play an important role in delivering accurate, up-to-date information</p>

<p><b>Technical Support in the Clinical Setting</b></p>	<ul style="list-style-type: none"> <li>✓ Company representatives can play an important role in the clinical setting by providing technical support on Medical Technology.</li> <li>✓ Companies are encouraged to apply the principles outlined in this section and develop related controls.</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>• Company representatives may need to explain how a Medical Technology’s unique settings and technical controls function and may make recommendations.</li> <li>• 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.</li> </ul> <p>Companies should apply the following principles:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. Company representatives should be transparent that they are acting on behalf of the Company in a technical support capacity.</li> <li>3. Company representatives should not interfere with a Health Care Professional’s independent clinical decision-making.</li> <li>4. Company representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements.</li> <li>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.</li> </ol>	<p>to healthcare professionals about the approved indications, benefits and risks of pharmaceutical therapies. These representatives often serve as the primary point of contact between the companies who research, develop, manufacture and market life-saving and life-enhancing medicines and the healthcare professionals who prescribe them. As such, the company representatives must act with the highest degree of professionalism and integrity.</p> <p>Companies should ensure that all representatives who are employed by or acting on behalf of the companies and who visit healthcare professionals receive training about the applicable laws, regulations and industry codes of practice, including this Code, that govern the representatives’ interactions with healthcare professionals. In addition, companies should train their representatives to ensure that they have sufficient knowledge of general science and product-specific information to provide accurate, up-to-date information, consistent with FDA requirements.</p> <p>Companies should provide updated or additional training in all of these areas as needed for their representatives who visit healthcare professionals.</p> <p>Companies should also assess their representatives periodically to ensure that they comply with relevant company policies and standards of conduct. Companies should take appropriate action when representatives fail to comply.</p>
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