The table below provides an overview of key sections of the existing AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals, effective as of 2009 (the "2009 Code"), and how such sections have been revised under the recent update, effective January 1, 2020 (the "2020 Code"). New sections introduced by the 2020 Code are described at the end of the table.

Topic	Overview of 2009 Code Provisions	Overview of 2020 Code Provisions
Introduction	Sections I, II Section I (Preamble) provides background information about AdvaMed as an organization, the role that Medical Technologies play in health care delivery, and the scope of beneficial interactions between HCPs and companies that manufacture Medical Technologies. It also explains that AdvaMed developed the Code based on a variety of authorities (including the Anti-Kickback Statute) in order to facilitate ethical interactions between companies and HCPs. Section II (Code of Ethics Compliance) urges companies to adopt the Code, implement an effective compliance program, and submit an annual certification in order to be listed on AdvaMed's website. It also requires AdvaMed members (and allows non-members) to supply contact information for their compliance department or anonymous hotline to be published on AdvaMed's website. Finally, Section II identifies the standard seven elements of an effective compliance program: (1) implementing written policies and procedures; (2) designating a compliance officer and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication (including an anonymous reporting function); (5) conducting internal monitoring and auditing; (6) enforcing standards through well-publicized disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action.	Section I The new Introduction combines the introductory Preamble and Code of Ethics Compliance sections from the prior version. It also includes new "cornerstone values" that shape AdvaMed's industry guidance: innovation, education, integrity, respect, responsibility, and transparency. The Introduction expands the discussion of the second standard element of an effective compliance program, and, consistent with recent practice and guidance, specifically identifies risk assessments as a compliance program standard: (1) written policies and procedures that incorporate and foster compliance with the Code; (2) appropriate oversight and management of the compliance program through a board and senior management who are knowledgeable about and oversee the compliance program, individuals in leadership who are responsible for the compliance program, compliance personnel with day-to-day program responsibility who have appropriate access to the Board and compliance reporting systems, and retention of personnel who have not engaged in conduct inconsistent with the compliance program; (3) effective training and education; (4) effective lines of communication, including an anonymous reporting hotline; (5) internal risk assessments, monitoring, and auditing; (6) standards enforced through disciplinary action; and (7) prompt responses to detected problems and the undertaking of corrective action. A self-contained glossary provides definitions for new terms: Commercial Sponsorship, Educational Grant, Satellite Symposium, Third-Party Program, and Third-Party Program Organizer. The glossary also broadens the definition of Medical Technology to include digital and software platforms; provides examples of Medical Technologies; and changes the definition of Health Care Professional to provide specific examples of HCPs (*e.g.*, individual providers, provider entities, administrative personnel

Topic	Overview of 2009 Code Provisions	Overview of 2020 Code Provisions
		at provider entities) and to specify that the term does not include HCPs who are employees of a company.
Travel & Lodging; Venue	No standalone section, but discussed in Sections III–VI The 2009 Code discusses travel and lodging across multiple sections, providing that companies may (1) pay for reasonable travel and modest lodging costs for HCPs (but not their guests) when objective reasons support the need for such costs; (2) make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for HCPs who are *bona fide* faculty members of the conference; and (3) pay an HCP for documented, reasonable, and actual expenses necessary for a consulting arrangement. It also requires the venue of a meeting to be conducive to information exchange and in a setting appropriate for the subject matter of the meeting.	Section VI This new section consolidates travel guidance from the 2009 Code into a single section, and also provides clarification on when travel is permitted (*e.g.*, for consulting, to attend training, to speak on the company's behalf at a third-party program, and when a legitimate need for the HCP's presence exists) and prohibited (for general education, to attend a third-party program, and when no legitimate need exists). In addition, Section VI advises that the venue of meetings with HCPs be conducive to information exchange, and provides considerations for deciding whether specific geographic locations are appropriate, including (1) whether the company has offices nearby; (2) whether the program is for HCPs local to the area; and (3) whether the company is hosting the meeting in conjunction with a third party. Section VI discourages the use of "top category or luxury hotels or resort facilities" absent an appropriate justification.
Consulting Arrangements with Health Care Professionals	Section VI This section explains that companies may have HCPs provide consulting services if they pay the HCPs fair market value for services that fulfill a legitimate business need, and the arrangement does not constitute an unlawful inducement. The section also provides standards for arrangements with HCPs, such as: • Agreements should be written, describe all services provided, and include research protocols if applicable; • There should be a legitimate need for the services that is identified and documented in advance; • The consultant should be selected based on individual qualifications and expertise to meet the defined need; • Compensation must be fair market value and may not be based on the volume or value of the HCP's actual or potential business; and • Company meetings with HCPs should take place in venues conducive to information exchange and	Section II In addition to the guidance provided by the 2009 Code, the updated Code provides examples of when a company may have a legitimate need to enter into a consulting arrangement with an HCP, such as to train HCPs on the technical components of using a product or to obtain a physician's expertise on clinical issues associated with a product. The company should engage only as many consultants as are necessary to fulfill its requirements for bona fide services. The update also provides guidance for developing a methodology for calculating the fair market value for goods and services that the HCP renders to the company. In brief, the methodology should incorporate objective criteria, such as the HCP's specialty, experience, and geographic location, and the type of service performed. The updated Code also states that sales personnel should have a limited role in selecting consultants in order to avoid the perception that the arrangement rewards the HCP for purchasing, using, or recommending the company's products.

Topic	Overview of 2009 Code Provisions	Overview of 2020 Code Provisions
	in settings appropriate for the subject matter of the consultation. Although royalty-based arrangements may be appropriate when an HCP is expected to make or has made a significant or new contribution, the company should document that contribution. Moreover, the royalty should comply with the other requirements for consulting arrangements and should not be structured in a way that risks influencing medical decision-making improperly. Companies should exclude the number of units used or purchased by the HCP or the HCP's practice in the royalty calculation.	The updated Code also explains that companies may have to address conflicts of interests that HCPs may present, including by recusing HCPs from decisions that implicate potential conflicts. The Code provides as examples of potential sources of conflicts physicians who hold leadership roles in medical societies, serve as conference planning chairs, or act as medical journal editors.
Providing Modest Meals and Refreshments to Health Care Professionals	Section VIII; also discussed in Sections III–VI Companies may provide modest and occasional meals and refreshments at gatherings where scientific, educational, or business information is presented (*e.g.*, trainings, conferences), as long as the meal is provided in a setting and manner conducive to the presentation. Companies should provide meals only to HCPs in attendance who have a *bona fide* interest in the presentation. As a result, companies are prohibited from providing meals or refreshments (1) to an entire office staff when not everyone attends the meeting, (2) if a company representative is not present, or (3) to guests of HCPs who lack a *bona fide* professional interest in the presentation.	Section VII In addition to the guidance provided in the 2009 Code, the 2020 Code strongly encourages companies to develop policies that govern the provision of meals to HCPs. Such policies may include spending limits, the amounts of which may vary geographically. In addition to the 2009 Code's prohibition on meals to "build good business relationships," the updated Code goes further by prohibiting companies from providing meals in connection with "a casual get-together or the development of general goodwill."
Educational & Patient Benefit Items; Prohibition on Gifts	Section IX Companies may provide items to HCPs that benefit patients or serve a genuine educational function for HCPs. Such items must be valued at less than $100, except for medical textbooks and anatomical models used for educational purposes. Items may not be capable of use by the HCP for purposes unrelated to education or patient care. Prohibited gifts to HCPs and their office or staff include, but are not limited to, non-educational branded promotional items; gifts of cookies, wine, flowers, or chocolates; gift baskets; holiday gifts; and cash or cash equivalents.	Section VIII The 2020 Code revises its expression of the scope of items that companies may give to HCPs to those that both are "modest" and "appropriate" for the permissible functions named in the 2009 Code. It also updates the examples of prohibited gifts to include items such as tablets, smart phones, and other mobile devices capable of personal use, and moved into the body of the Code document a statement previously appearing only in FAQs, that a company may not give an HCP a gift to recognize a "life event" such as a wedding, birth, anniversary or death of a family member.
Educational & Research Grants, Charitable Donations, and Commercial Sponsorships	Section XI Companies may provide research and educational grants and charitable donations, as long as such payments do not serve as an unlawful inducement. **Research Grants** may be provided to support independent medical research with scientific merit. Grants should include well-defined objectives and	Section IV The updated Code adopts the term "commercial sponsorship" to describe companies' support of third-party programs. Further, the updated Code combines prior sections on third-party educational conferences with the prior section on grants and charitable donations.

Topic	Overview of 2009 Code Provisions	Overview of 2020 Code Provisions
	milestones, with no connection to the purchase of the company's Medical Technologies. **Educational Grants** to conference sponsors or training institutions must be for legitimate purposes (*e.g.*, the advancement of medical education or educating the public about healthcare topics), and such grants may not be made to individual HCPs. **Charitable Donations** should be motivated by *bona fide* charitable purposes and made to *bona fide* charitable organizations. In rare cases, such donations may be provided to individuals acting in support of a *bona fide* charitable mission. Companies must exercise diligence to ensure these conditions are met. Companies should take the following steps to prevent unlawful inducements: • Adopt objective criteria for payments that do not take into account the actual or anticipated volume or value of purchases made by the recipient of the payment; • Implement policies and procedures governing such payments to prevent unlawful inducements; and • Document appropriately all grants and donations. Sales personnel should not control or unduly influence the decision to make grants or charitable donations to HCPs.	**Educational Grants and Commercial Sponsorships**: Through third-party programs, companies may support training and education, participate in exchanges of information regarding their Medical Technologies, and advertise their products and services. The updated Code sets forth a checklist of considerations that companies can use to evaluate requests to support third-party programs, which includes: • Whether the topics, attendees, and materials of the program reflect an objective, legitimate, and educational purpose; • Whether the venue of and meals provided at the program are conducive to the primary educational purpose of the third-party program; and • Whether the third-party program promotes a specific provider, rather than appropriate educational topics. The updated Code prohibits companies from "pass[ing] along" to HCPs any benefits they receive for commercial sponsorship. In addition, the updated Code permits companies to host satellite symposia, as long as they are transparent in promoting the events as company-conducted. Hosting companies may not pay for the travel, lodging, or registration expenses of HCPs who are attending only a satellite symposium, unless the HCP serves as a *bona fide* faculty member at the symposium. **Supporting Third-Party Research**: Companies may support third-party research programs and partner with HCPs for research purposes through in-kind or monetary grants. The updated Code provides additional guidance for companies' support of such programs, including limiting in-kind or monetary support to legitimate expenses or services, providing only reasonable quantities of products at no charge, ensuring that the recipients of the Company's support retain independent control over the research, requiring that the company establish an internal review process for reviewing and awarding research grants, and limiting the involvement of sales personnel in the decision of which third-party researchers receive support. **Charitable Donations and Commercial Sponsorships**: The updated Code expands on the 2009 guidance, including by (1) expressly requiring companies to specify that donations must be used for

Topic	Overview of 2009 Code Provisions	Overview of 2020 Code Provisions
		only charitable or philanthropic purposes, and (2) advising companies to consider conditioning product donations for indigent patients on a recipient hospital's agreement not to bill third parties for the donated products.
Demonstration, Evaluation, and Consigned Products	Section XII A company may provide reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes under the following circumstances: • **Single Use** (consumable or disposable products): The number of single use products provided should not exceed the amount reasonably necessary for adequate evaluation. • **Multiple Use/Capital Equipment**: These products should be furnished for evaluation purposes for only a time period reasonable for adequate evaluation. The terms of such an evaluation should be set in advance and in writing. Companies should retain title to these products during the evaluation and should have a process for promptly removing such products from the HCP's location at the end of the evaluation period. • **Demonstration Products**: Demonstration products are typically unsterilized single use products or mock-ups used for HCP and patient awareness, education, and training and are typically not intended to be used in patient care. Companies should provide HCPs with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.	Section XII In addition to the guidance provided by the 2009 Code, the updated section includes examples of appropriate reasons for providing evaluation products (single or multiple use) to HCPs, including that the HCP may not have recently purchased or used the product or the product is marketed for a new indication or new technique. The updated section again notes that companies should provide HCPs with appropriate documentation to allow them to address reimbursement reporting obligations, including information on the no-charge status of the products, and adds that companies should consider the effect of federal or state sunshine laws that require reporting the value of the evaluation products provided. The updated section adds the following details to the multiple use evaluation product guidelines: • The length of time necessary for an HCP to evaluate a multiple use product can vary among products and may depend on the frequency of use, duration of training, number of HCPs evaluating, and length of time needed to evaluate, among other considerations. • The terms of the evaluation of a multiple use product should be set in advance and in writing, and should also specify the length of the evaluation period and address products that have not been returned within the evaluation period. The updated section provides new guidance on consigned products, which the Code defines as Medical Technologies (1) that a company provides to an HCP for use in and storage at the HCP's care setting and (2) to which the company retains title until the product is used. • Consignment arrangements should generally be subject to an agreement that addresses the terms of consignment (such as number of products, any requirements to segregate consigned products from other products, and any storage space rental terms). • Companies should consider implementing appropriate controls, which could include taking

Topic	Overview of 2009 Code Provisions	Overview of 2020 Code Provisions
		periodic inventory of consigned products 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.
Jointly Conducted Education and Marketing Programs	N/A	Section V The updated Code includes a new section on jointly conducted education and marketing programs between companies and HCPs. Companies should apply the following principles to these joint programs: • **Legitimate Need**: There must be a *bona fide*, legitimate need for the company to engage in the activity for its own educational or marketing benefit. • **Controls**: Companies should establish controls to ensure that these joint programs are not conducted as an unlawful inducement for purchase or use of the companies' products. Companies should also require HCPs participating in the joint program to comply with company guidelines on providing information related to product labeling and health economics information, among other controls. • **Balanced Content**: Content should be balanced and promote both the company and its technology as well as the HCP and the HCP's services offered for the treatment of related medical conditions. • **Equitable Contributions**: The company and HCP should be *bona fide* partners and make equitable contributions toward the activity and costs. • **Written Agreement**: The arrangement should be documented in a written agreement that specifies the purpose of the arrangement, the roles and responsibilities of each party, and the contributions of each party, including payment of costs.
Communicating for the Safe & Effective Use of Medical Technology	N/A	Section X This new section provides guidance on communicating the safe and effective use of Medical Technologies, including information on both on- and off-label uses. The Code describes that industry-appropriate communication of truthful and non-

Topic	Overview of 2009 Code Provisions	Overview of 2020 Code Provisions
		misleading information related to Medical Technologies (including both on- and off-label uses) can include: • Proper dissemination of peer-reviewed scientific and medical journal articles, reference texts, and clinical practice guidelines; • Presentations at educational and medical meetings on clinical trial results or research and development data for an investigational use, as long as claims are not made regarding safety and effectiveness; and • Discussions with consultants and HCPs to obtain feedback relating to topics such as unmet patient needs and product research and development. Companies should adhere to the following principles in their communications about medical and scientific information: • Company responses containing information on unapproved or uncleared uses should be provided by authorized personnel; • Communications must be truthful and non-misleading; and • Information related to unapproved or uncleared uses should be identified as such. Companies are encouraged to develop policies and controls that adhere to these principles and incorporate requirements of other applicable guidance.
Company Representatives Providing Technical Support in the Clinical Setting	N/A	Section XIII This new section provides guidelines for company representatives who provide technical support in a clinical setting. Examples of technical support include company representatives explaining how technology settings and controls function or assisting a clinical team to ensure the appropriate range of devices and accessories are available during a procedure. Companies should apply the following principles: • Company representatives should enter and be present in the clinical setting only at the request of and under the supervision of an HCP. • Company representatives should be transparent that they are acting on the company's behalf in a technical support capacity.

Topic	Overview of 2009 Code Provisions	Overview of 2020 Code Provisions
		• Company representatives should not interfere with an HCP's independent clinical decision-making. • Company representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements. • A company's technical support should not eliminate an overhead or other expense that the HCP would otherwise incur while providing patient care.
Reorganization	The substantive content of the following sections from the 2009 Code remains largely the same but has been reorganized as part of the formatting changes in the 2020 Code: • 2009 Sections III (Company-Conducted Product Training and Education), IV (Supporting Third-Party Educational Conferences), and V (Sales, Promotional, and Other Business Meetings)—this content now appears in Section III (Company-Conducted Programs & Meetings with Health Care Professionals). • 2009 Section VII (Prohibition on Entertainment and Recreation)—this content now appears in Section IX. • 2009 Section X (Provision of Coverage, Reimbursement and Health Economics Information)—this content now appears in Section XI.	