

Medical Device Manufacturers Association
Revised Code of Conduct on Interactions with Healthcare Providers
As adopted by the Medical Device Manufacturers Association on October 23, 2019

1. Purpose

The Medical Device Manufacturers Association (MDMA) represents manufacturers that develop and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities for the benefit of patients and advancement of medical care. MDMA seeks to improve the quality of medical care by encouraging the research and development of new medical technology and by advancing the availability of beneficial and innovative products for patients.

MDMA's mission is to ensure that patients have timely access to safe and effective products that improve health outcomes. In pursuing this mission, MDMA recognizes that adherence to ethical standards and compliance with applicable laws and regulations by its Members is critical to ensure that interactions with Healthcare Providers are responsible and within legal and regulatory requirements.

MDMA and this Code recognize that the nature of Member interactions with Healthcare Providers is unique to the medical device industry and the type of technology being employed. Medical technologies include devices such as implants placed in the human body to replace or strengthen a body part, tools that may serve as extensions of a physician's hands in surgery, equipment used to treat or alleviate health conditions and disabilities, and accessory devices. Medical technologies also include noninvasive reagents, instrumentation and/or software to aid in diagnosis, monitoring and treatment decisions made by Healthcare Providers. Some technologies work synergistically with other technologies, or are paired with other products to deploy devices in the safest and most effective manner. Many medical technologies require technical support during and after deployment or use.

Members' interactions with Healthcare Providers should conform to ethical and appropriate business practices. MDMA also recognizes the need for Healthcare Providers to make independent and objective decisions regarding product purchases and utilization for the benefit of patients without unlawful inducement.

There are many forms of beneficial interactions between Members and Healthcare Providers that advance medical technology and improve patient care, including:

- *Advancement of Medical Technology.* Developing new medical technologies and improving existing products are collaborative processes between Members and Healthcare Providers. Innovation and creativity, often occurring through "hands on" interactions with Healthcare Providers, are essential to the development and evolution of medical technology.
- *Safe and Effective Use of Medical Technology.* The safe and effective use of medical technology often requires Members to offer Healthcare Providers appropriate instruction, education, training, product service and technical support. Regulators may also require this type of training as a part of product approval.
- *Research and Education.* Members' support of *bona fide* medical research, medical education, and enhancement of professional skills serves patient safety, effectiveness of medical care and increases awareness of and access to new technology.

- *Encourage Charitable Donations and Giving.* Members support monetary and technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases the quality of patient care and provides access to treatment for patient populations that may not otherwise be reached.

2. Scope

- **Definitions**

For purposes of this Code, the term “**Healthcare Provider**” includes any person or entity that is authorized or licensed in the United States to provide health care services or items to patients, or that is involved in the decision to purchase, prescribe, order, recommend, or use, medical technology products in the United States. The term Healthcare Provider does not include an individual who is a bona fide employee of a Member, when acting in that capacity. This includes both clinical and non-clinical people who make decisions related to product purchase or use. It also includes decision-makers within group purchasing organizations. Although this Code is intended to apply to interactions with Healthcare Providers that treat patients in the United States, it assumes that Members will apply similar standards to their interactions with healthcare providers in locations outside of the United States, such as medical technology association codes of conduct applicable in those locations. Members that do not adhere to other codes of conduct with respect to non-US healthcare providers are encouraged to apply the principles of this Code.

For purposes of this Code, the term “**Member**” means a manufacturer of medical devices, diagnostic products, or healthcare information systems that holds active membership in MDMA. It does not include associate members of MDMA.

- **Guiding Principle**

Whether or not a particular relationship or situation is specifically addressed in this Code, a Member’s conduct should be guided by the following principle:

MDMA encourages ethical business practices and a Member shall not engage in any unlawful inducement. For purposes of this Code, an “unlawful inducement” shall mean the prohibitions of the federal Anti-kickback Statute and other applicable anti-bribery or anti-corruption laws.

3. Code of Conduct Compliance

This voluntary Code of Conduct on Interactions with Healthcare Providers (Code) is intended to facilitate ethical and appropriate business interactions between Members and Healthcare Providers by applying principles of this Code to the unique business circumstances of MDMA Members. MDMA encourages each Member to adopt this Code and implement an effective compliance program that is tailored to the unique circumstances of its business, including its size, resources, workforce and particular lines of business and development. This may include policies and procedures to foster compliance with this Code and ethical and appropriate business interactions with Healthcare Providers. Members should annually review their compliance with this Code and consider posting an annual certification on their website that the Member has adopted this Code and implemented a compliance program to ensure compliance with this Code.

Members are encouraged to follow the seven elements of an effective compliance program, appropriately tailored for each Member, namely: (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. Members adopting this Code shall communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. The information provided by the Department of Health and Human Services, Office of Inspector General (“OIG”), as well as applicable laws or regulations, may provide more specificity than this Code, and Members should address any additional questions to their own attorneys.

This Code is not intended to define or create legal standards, nor does this Code constitute legal advice. Different circumstances may be present dependent upon a Member’s stage of development and/or commercialization. Each Member has an independent obligation to ascertain that its interactions with Healthcare Providers comply with all applicable laws and regulations.

4. Member-Conducted Product Training and Education

Members have a responsibility to make training and education on their medical products and technologies available to Healthcare Providers. Members may also provide education to Healthcare Providers. “Training” means training on the safe and effective use of medical products and technologies. “Education” means communicating information directly concerning or associated with the use of Members’ medical products or technologies, e.g., information about disease states and the benefits of such products or technologies to certain patient populations. Training and Education programs include, but are not limited to, “hands on” training sessions, lectures and presentations. In many cases, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain medical products and technologies. Members should adhere to the following principles when conducting training and education programs concerning medical products and technologies for Healthcare Providers:

- Programs and events should be conducted 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 may also be appropriate for a Member representative to provide training and education at the Healthcare Provider’s location.
- Programs providing “hands on” training on products and technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Member should have the proper qualifications and expertise to conduct such training. Training staff may include Healthcare Providers, field sales employees or other personnel who have the technical expertise and experience necessary to perform the training.
- Members may provide Healthcare Provider attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be moderate in value and subordinate in time and focus to the training and/or educational purpose of the meeting. For additional meal guidelines, see Section 9.
- Where there are objective, legitimate reasons to support the need for out-of-town travel to efficiently deliver Training and Education on products and technologies, Members may pay for modest and reasonable travel and lodging costs of the attending Healthcare Providers. It is not appropriate for Members to pay for the travel and lodging costs, or other expenses for guests of Healthcare Providers or for any other person who does not have a *bona fide* professional interest in the training and education program. For additional travel and lodging guidelines, see Section 17.
- The provisions of Section 7 apply when Members engage Healthcare Providers to provide training or education services.
- Members may also collaborate with a Healthcare Providers to jointly promote their products and

services through educational programs or joint advertising. Such programs should comply with the guidelines of Section 16.

5. Supporting Third-Party Educational Conferences

Bona fide independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers, as well as educational programs conducted by hospitals or universities. Members may support these conferences in various ways:

- *Conference Grants.* Members may provide a grant to the conference organizer to reduce conference costs when the event is primarily dedicated to promoting objective scientific and educational activities and discourse. Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with applicable standards established by the conference organizer and anybody accrediting the educational activity. The conference organizer should independently control and be responsible for the selection of program content, faculty, educational methods, and materials, provided that Members may recommend qualified faculty or appropriate categories of attendees when permitted by applicable standards. "Legitimate expenses" include the cost of conducting the educational components of the conference or program; modest meals, refreshments, and educational items; reasonable compensation and expenses of individuals (including Healthcare Providers) who are *bona fide* conference faculty, and reasonable costs of attendance by Healthcare Providers in training, as further described below.
- *Conference Meals and Refreshments.* Members may provide funding to the conference organizer to support the provision of meals and refreshments to conference attendees. Also, Members themselves may provide meals and refreshments for Healthcare Provider attendees if such meals and refreshments are provided: (1) to all Healthcare Provider attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference organizer and the body accrediting the educational activity. Meals and refreshments may be provided to fewer than all Healthcare Provider attendees if the Member providing such meals and refreshments satisfies all other principles related to meals set forth in Section 9. Any meals and refreshments should be reasonable in value, subordinate in time and focus to the purpose of the conference, and separate from the continuing medical education portion of the conference.
- *Expenses of Healthcare Providers in Training.* Members may make grants to a training institution or the conference organizer to allow attendance by medical students, residents, fellows, and others who are Healthcare Providers in training, provided that beneficiaries are selected by the training institution or conference organizer.
- *Advertisements and Demonstration.* Members may purchase advertisements, exhibit space, and other promotional arrangements at conferences, provided that the amount paid reflects commercially reasonable consideration for the promotional benefit provided to the Member. Such arrangements may include product-specific educational opportunities, such as satellite symposia. All arrangements must be consistent with the applicable standards of the meeting.
- *Speaker Arrangements.* When permitted by applicable standards, Members may select and send faculty to speak on their behalf at third-party conferences, provided that unless the selected faculty member is an employee of the Member, the arrangement must be documented in a consulting agreement between the Member and the faculty member, and provided further that appropriate disclosure must be made to conference attendees that the faculty is presenting on behalf of the Member and paid by the Member.

No Direct Sponsorship. Members may not contribute directly (whether in cash or in kind) to the costs of registration, travel or lodging in order for individual Healthcare Providers to attend third-party conferences. This clause shall not prohibit Members from making payments or arrangements reasonably necessary to secure consulting services (including permitted speaker arrangements) or organizing meetings (such as clinical trial investigator meetings) or product training, when an objective, legitimate reason supports the need for such arrangements in connection with a third-party conference. However, such arrangements shall not be entered in order to avoid the prohibition on direct sponsorship and should not exceed what is reasonably required to facilitate the needed services, meetings, or training. Any such arrangements should comply with the other applicable provisions of this Code, e.g., Section 7 for consulting arrangements and Section 4 for product training and education.

6. Business Meetings

Members may conduct sales, promotional and other business meetings with Healthcare Providers when a legitimate need to meet exists (for example, to discuss medical product and technology features, sales terms, or contracts). These meetings often occur close to the Healthcare Provider's place of business or at another centralized location. In all events the setting must be conducive to the exchange of relevant information. Members may provide occasional modest meals and refreshments in connection with such meetings, subject to the guidelines in Section 9. Where an objective, legitimate reason supports the need for travel to a business meeting (such as for manufacturing plant tours, or demonstrations of non-portable equipment) members may pay for modest and reasonable travel costs of attendees, subject to the guidelines in Section 17.

7. Consulting Arrangements with Healthcare Providers

Members engage Healthcare Providers to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Member-sponsored training and other services. Members may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. Members should implement safeguards to ensure that consulting arrangements are not entered as a reward or improper inducement for past or future usage or purchases, and should comply with the following standards in connection with consulting arrangements with Healthcare Providers:

- Consulting agreements should be written and describe all services to be provided. When a Member contracts with a consultant to conduct clinical research services, there should also be a written research protocol.
- Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance. A Member should engage only as many consultants as are necessary to fulfill the Member's requirements for the services.
- Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need. A Member may not select or compensate consultants as a reward for past usage or as an unlawful inducement for future purchases.
- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided. Fair market value should be based on objective criteria, and should not be based on the volume or value of the consultant's past, present or anticipated business. Members should confirm the performance of services in accordance with the applicable consulting agreement.

- A Member may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, meals, and lodging. See Sections 9 and 17 for further guidance on meals, travel and lodging.
- The venue and circumstances for Member meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Member-sponsored meals and refreshments provided in conjunction with a consultant meeting should be reasonable in value and should be subordinate in time and focus to the primary purpose of the meeting. Members should not provide recreation or entertainment in conjunction with these meetings.
- A Member's sales personnel may provide input about the qualifications of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Healthcare Provider as a consultant. Members should consider implementing appropriate procedures to monitor compliance with this section.

Provisions on Payment of Royalties. Arrangements involving the payment of royalties to a Healthcare Provider should meet the contractual standards set forth above. Healthcare Providers, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve medical products and technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement. A Member should enter into a royalty arrangement with a Healthcare Provider only where the Healthcare Provider makes a novel, significant, or innovative contribution to the development of a product, technology, process, or method, subject to intellectual property protections. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

The calculation of royalties payable to a Healthcare Provider in exchange for intellectual property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, royalties paid in exchange for intellectual property should not be conditioned on: (1) a requirement that the Healthcare Provider purchase, order or recommend any product or medical technology of the Member or any product or technology produced as a result of the development project; or (2) a requirement to market the product or medical technology upon commercialization. Members may, however, elect to enter into separate agreements with Healthcare Providers for marketing services if such services meet the requirements set forth in this Section 7 above. Members 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 Healthcare Provider and/or members of the Healthcare Provider's practice.

8. Prohibition on Entertainment and Recreation

Member interactions with Healthcare Providers should be professional in nature and should facilitate the exchange of medical or scientific information that will advance medical care and benefit patients. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Member should not provide or pay for any entertainment or recreational event or activity for any Healthcare Provider. Such activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips. Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether the Member engages the Healthcare Provider as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

9. Meals Associated with Healthcare Provider Business Interactions

A Member's business interactions with Healthcare Providers may involve the presentation of scientific, educational, or business information and include, but are not limited to, the different types of interactions described in Sections 4 through 7 of this Code. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section.

Purpose. The meal should be incidental to the *bona fide* discussion of scientific, educational, or business information and provided in a manner conducive to the discussion of such information. Meals should be subordinate in time and focus to the purpose of the meeting or event. The meal should not be part of an entertainment or recreational event.

Setting and Location. Meals should be in a setting that is conducive to *bona fide* scientific, educational, or business discussions. Meals may occur at the Healthcare Provider's place of business, or in another location (such as a restaurant or conference room) that is conducive to the discussion.

Participants. A Member may provide a meal only to Healthcare Providers who actually attend and have a *bona fide* purpose for attending the meeting. A Member may not provide a meal for an entire office staff where everyone does not attend the meeting. A Member also may not provide a meal where its representative is not present (such as a "dine & dash" program). A Member may not provide meals to spouses or guests of Healthcare Providers or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Modest Meals and Travel. For purposes of this Code, when applied to meals, refreshments, travel and lodging, the term "modest" means of moderate value, which may vary depending on regional differences.

Other principles. Depending on the type of business interaction or meeting, additional principles may apply, as described in other sections of this Code. Specifically:

- Section 4: Member-Conducted Product Training and Education.
- Section 5: Supporting Third-Party Educational Conferences.
- Section 6: Sales, Promotional, and Other Business Meetings.
- Section 7: Consulting Arrangements with Healthcare Providers.

10. Medically-Relevant Items; Prohibition on Personal Gifts

A Member occasionally may provide educational items to Healthcare Providers that benefit patients or serve a genuine educational function for Healthcare Providers. Other than medical textbooks and anatomical models, any such item should have a fair market value of less than \$100. A Member may not provide items that are suitable for non-educational or non-patient-related use by Healthcare Providers (or their family members, office staff or friends), such as office supplies, scrubs, or tablet computers. Members also may not provide Healthcare Providers (or their staff) with personal gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents. This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section 13.

11. Provision of Coverage, Reimbursement and Health Economics Information

As medical products and technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary medical products and technology may be dependent on Healthcare Providers and/or patients having timely and complete coverage, reimbursement, and

health economic information. Consequently, a Member may provide such information regarding its medical products and technologies if it is accurate and objective. A Member also may collaborate with Healthcare Providers, 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 products and technologies.

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

- Identifying the clinical value of the Member's products and technologies and the services and procedures in which they are used.
- Collaborating with Healthcare Providers, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Healthcare Providers and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Healthcare Providers regarding the Member's products and technologies, including identifying coverage, codes and billing options that may apply to those products and technologies or the services and procedures in which they are used.
- Providing accurate and objective information about the economically efficient use of the Member's products and technologies, including where and how they can be used within the continuum of care.
- Providing information related to the Member's products and technologies regarding available reimbursement revenues and associated costs.
- Providing information related to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Healthcare Provider's decision to buy or use the Member's products or technologies.
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Member's products or technologies.
- Facilitating patient access to the Member's products or technologies by providing Healthcare Providers with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of a Healthcare Provider to facilitate patient access to the Member's products or technology, and subject to appropriate privacy safeguards, the Member 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 Member's own product or technology; however such assistance should not be provided as an unlawful inducement.

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

12. Research and Educational Grants and Charitable Donations

A Member may provide research and educational grants and charitable donations to entities or organizations with a genuine scientific, educational or charitable mission or function. However, a Member may not provide such grants or donations as an unlawful inducement. Therefore, a Member should: (a) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented. A Member's sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular Healthcare Provider or institution will receive a grant or donation or the amount of such grant or donation. Members should consider implementing procedures to monitor compliance with this section.

a. Research Grants

Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of health care, and otherwise benefits patients. In furtherance of these objectives, a Member may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined

objectives and milestones and may not be linked directly or indirectly to the purchase of Member products or technologies. Grants should be made pursuant to written grant requests from the proposed recipient, including a protocol describing the proposed activity and its objectives, milestones and timeline; a budget for the research project; and requirements (if any) for third-party authorizations (including institutional or regulatory approvals). Both monetary and in-kind grants should be appropriately documented (for example by a written agreement between the Member and the recipient).

Recipients of research grants should maintain independent control over the research. Member-initiated or directed research involving a Member's products technologies (such as clinical study agreements) is addressed separately in Section 7.

b. Educational Grants

Educational grants may be provided for legitimate purposes, including, but not limited to, the examples below. As noted in Section 5, a Member may make educational grants to conference organizers or training institutions. A Member may not make educational grants as an unlawful inducement and may not make grants to individual Healthcare Providers or Healthcare Providers in training.

- *Advancement of Medical Education.* A Member may make grants to support the genuine medical education of physicians, medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel. (For additional considerations regarding educational grants, see Section 5). Members may not select, or influence the selection of individuals who benefit from such grants.
- *Public Education.* A Member may make grants for the purpose of supporting education of patients or the public about important health care topics.

c. Charitable Donations

A Member may make monetary or product donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to non-profit organizations with a bona fide charitable or philanthropic purpose. Members should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable purpose. When donating free products, Members should require the recipient to agree not to charge a third party for the products (for example, by including this provision in a written agreement relating to the donation).

13. Evaluation and Demonstration Products; Product Consignment

Providing products to Healthcare Providers at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating Healthcare Providers regarding the use of products and technologies. Under certain circumstances described below, a Member may provide reasonable quantities of products to Healthcare Providers at no charge for evaluation and demonstration purposes. This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement. Member products that may be provided to Healthcare Providers for evaluation include single use (*e.g.*, consumable or disposable products) and multiple use products (sometimes referred to as “capital equipment”). These products may be provided at no charge to allow Healthcare Providers 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. Member products provided for evaluation are typically expected to be used in patient care.

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

Multiple Use/Capital. Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Members should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the Healthcare Provider’s location at the conclusion of the evaluation period unless the Healthcare Provider purchases or leases the products.

Demonstration. Member demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Healthcare Provider and patient awareness, education, and training. For example, a Healthcare Provider may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as “Sample,” “Not for Human Use,” or other suitable designation on the product, the product packaging, and/or documentation that accompanies Members’ products or technologies.

A Member should provide Healthcare Providers with documentation to disclose the no-charge status of evaluation and demonstration products and permit Healthcare Providers to comply with applicable reimbursement reporting obligations.

In addition to evaluation and demonstration products, members may provide free products in connection with charitable donations or research grants complying with the provisions of Section 12 or Member-sponsored research complying with the provisions of Section 7.

Members may also arrange for consignment of their products on customer premises. Such arrangements should be properly documented and managed, with a view to ensuring that products used or removed from inventory by the customer are invoiced to the customer. Members should consider implementing internal controls to address recordkeeping and inventory management.

Whenever Members provide free or loaned products and equipment, they must comply with applicable transparency reporting laws and regulations.

14. Technical Support in Clinical Setting

Healthcare Providers may require or request product support from Member representatives. Such support may include, for example, advising on the technical controls and functionality of a product, or ensuring that appropriate product types and sizes are available during a procedure.

Member representatives should only be present at the request of and under the supervision of a Healthcare Provider when providing product support in a clinical setting and should always comply with applicable policies and procedures of the clinical facility, including vendor credentialing requirements, as well as policies and procedures designed to protect patient privacy. Member representatives should be transparent that they are acting on behalf of the company in a technical support capacity. Member representatives should not interfere with the clinical decision making of Healthcare Providers, and should not provide support that eliminates and overhead or other expense that a Healthcare Provider would otherwise incur while providing clinical care to patients.

15. Providing Product Information.

Members are encouraged to implement policies and procedures to ensure that product-related communications comply with applicable laws and regulations, including those that govern off-label information (i.e., information about unapproved or uncleared uses of Member products). Member responses that include off-label information should be provided by authorized Member personnel. Product-related communications must be truthful and non-misleading. Whenever Members provide off-label information, it should be clearly identified as such.

16. Joint Education and Marketing with Healthcare Providers.

Members may collaborate with Healthcare Providers in educational or marketing activities designed to promote both the Members' products and/or services and the services or facilities of the Healthcare Provider. Members should engage in such activities only when they have a bona fide, legitimate need to engage in the activity for their own educational or marketing purposes, and should implement controls to help ensure that such arrangements are not made with an intent to provide an improper inducement. These should include the following requirements:

- The Member and the Healthcare Provider(s) should contribute equitably to the conduct and costs of the activity.
- The arrangements should be documented in a written agreement between the Member and the Healthcare Provider(s).
- The program or activity should be balanced and promote both the Member's medical technologies and the Healthcare Provider(s) services and/or facilities.
- The Member should require participating Health Care Provider(s) to comply with applicable Company guidelines, including on providing information related to a product's labeling and furnishing appropriate reimbursement and health economics information.
- The provisions of Section 9 apply to meals and refreshments provided in connection with joint education and marketing events.

17. Travel and Lodging Arrangements.

Whenever this Code permits Members to arrange or pay for travel or lodging for Healthcare Providers, they must do so in a manner does not constitute an unlawful inducement or create a perception of impropriety. Members are encouraged to adopt policies and procedures to ensure that arrangements meet the requirements of this Section and other relevant Code provisions.

- There must be an objective, legitimate reason for out-of-town travel, such as the need to deliver product-related training and education, or the inability to effectively deliver the content of the meeting through means other than an in-person meeting. Members are encouraged to document the legitimate need for travel.
- Travel and lodging arrangements may be provided only as reasonably required in connection with the need for which travel is being arranged, and should correspond to the duration for which the individual's attendance is required. When a Healthcare Provider requests the extension of time of travel or lodging arrangements for personal reasons or for professional reasons unrelated to the Member's legitimate reason for providing the arrangements, the Member should ensure that the Healthcare Provider assumes all additional costs of the extension.
- Members may not pay additional travel or lodging costs related to a spouse or guest travelling or staying with a Health Care Professional.
- Travel and lodging arrangements should be modest (as defined in Section 9) and reasonable under the circumstances. Members are encouraged to implement controls to ensure appropriate class of travel and appropriate level of accommodations.
- Members should select meeting and lodging locations and venues based on a convenient and accessible location and the suitability of the facilities for the business purpose of the meeting. They should not select a meeting or lodging location or venue based on entertainment or recreational value, and should not select top category or luxury hotels or resort facilities unless a reasonable justification supports such venues (in which case Members are encouraged to document the reason for the venue).
- Members 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

18. Effective Date.

This Code shall be effective on January 1, 2020.