

Medical Device Manufacturers Association
Revised Code of Conduct on Interactions with Healthcare Providers
As adopted by the Medical Device Manufacturers Association on July 1, 2009

1. Purpose

The Medical Device Manufacturers Association (MDMA) represents smaller and less diversified independent medical device manufacturers that develop, produce, manufacture, 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 promote advancement of medical care through the advocacy of innovative, research-driven medical device technology. 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. Often these interactions lead to implantable devices placed in the human body to replace or strengthen a body part. Medical devices often serve as extensions of a physician's hands in surgery. In other circumstances, technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Healthcare Providers. Some technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Often these technologies require technical support at and after deployment.

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 cutting edge medical technology 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. Many of these technologies have been developed through formal and informal research collaborations and relationships between Members and Healthcare Providers.

- *Safe and Effective Use of Medical Technology.* The safe and effective use of medical technology on patients often requires Members to offer Healthcare Providers appropriate instruction, education, training, 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, education, and enhancement of professional skills serves patient safety, effectiveness of medical care and increases awareness and access to new technology.
- *Encourage Charitable Donations and Giving.* Members support monetary and technology donations for charitable purposes, such as supporting indigent or third world care, as well as physician, patient and public education. This increases access to quality patient care and treatment and to patient populations that may not otherwise be reached.

2. Scope

- **Definitions**

For purposes of the Code, the term “**Healthcare Provider**” includes any person or entity in a position to purchase, lease, recommend, use, or arrange for the purchase or lease of medical technology products. This includes both clinical and non-clinical people who make decisions related to product purchase. It also includes decision-makers within group purchasing organizations. The definition is broad, and is intended to encompass anyone with material influence over purchasing decisions.

For purposes of the 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 the Code, a Member’s conduct should be guided by the following principle:

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

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 compliance to the unique business circumstances of MDMA Members. These unique circumstances include being an association of smaller and less diversified medical device manufacturers. MDMA encourages each Member to adopt the 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 the Code and ethical and appropriate business interactions with Healthcare Providers. Members should annually review their compliance with the Code and consider posting an annual



certification on their website that the Member has adopted the Code and implemented a compliance program to ensure compliance with the 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 the 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, cadaver workshops, lectures and presentations, and grand rounds. 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 field sales employees or other agents who have the technical expertise necessary to perform the training.
- Members may provide Healthcare Provider attendees with reasonable meals and refreshments in connection with these programs. Any such meals and refreshments should be reasonable in value and subordinate in time and focus to the training and/or educational purpose of the meeting.

- Where there are business reasons to support the need for out-of-town travel to efficiently deliver Training and Education on products and technologies, Members may pay for 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 information being shared at the meeting.

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. Members may support these conferences in various ways:

- *Conference Grants.* Members may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Healthcare Providers in training. Members may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Healthcare Providers who are in training. 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 sponsor and anybody accrediting the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.
- *Conference Meals and Refreshments.* Members may provide funding to the conference sponsor 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 sponsor 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.
- *Faculty Expenses.* Members may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Healthcare Providers who are *bona fide* conference faculty members.
- *Advertisements and Demonstration.* Members may purchase advertisements and lease booth space for Member displays at conferences.

6. Sales, Promotional, and Other Business Meetings

Members may conduct sales, promotional and other business meetings with Healthcare Providers to discuss, for example, medical product and technology features, sales terms, or contracts. These meetings often occur close to the Healthcare Provider's place of business. It is also appropriate to pay for

reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment) and/or to provide occasional reasonable meals and refreshments in connection with such meetings. However, it is not appropriate to pay for travel or lodging costs of 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.

See Section 9 for additional principles related to the provision of meals associated with Healthcare Provider business interactions.

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 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 and documented.
- Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.
- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business.
- 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.
- 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 suitability 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 is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method. 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. Reasonable 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, reasonable 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. 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. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Healthcare Provider's place of business, for example, (1) where the

medical product or technology cannot easily be transported to the Healthcare Provider's location, (2) when it is necessary to discuss confidential product development or improvement information, (3) where a private space cannot be obtained onsite, or (4) where the demands of a Healthcare Provider's practice dictate limited opportunities for interactions or meetings at other than offsite locations, i.e., during non-business hours or non-work days.

Participants. A Member may provide a meal only to Healthcare Providers who actually attend 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 invite 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 and is discouraged from providing meals to such persons except, in the rare circumstances, where it is unavoidable as a matter of civility and common courtesy.

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 items to Healthcare Providers that benefit patients or serve a genuine medically-relevant function for Healthcare Providers. Other than medical textbooks, anatomical models or other similar medically-relevant items useful to the advancement of medical care, any such item should have a fair market value of less than \$100. A Member may not provide items that are for personal use by the Healthcare Provider (or his or her family members, office staff or friends), for example, a DVD player, computer or digital music player. Members also may not provide Healthcare Providers 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 when providing coverage, reimbursement and health

economics information and materials to Healthcare Providers, professional organizations, patient organizations, and payors.

- 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 of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement. 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. 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. 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 sponsors or training institutions. A Member may not make educational grants as an unlawful inducement.

- *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.)
- *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 *bona fide* charitable organizations or, in other instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission. Members should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

13. Evaluation and Demonstration Products

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 and disclosure regarding the no-charge status of evaluation and demonstration products.