



MITA CODE OF ETHICS (Revised)
ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS
ADOPTED MARCH 19, 2009
EFFECTIVE JULY 1, 2009

I. Preamble: Goal and Scope of MITA Code

The Medical Imaging and Technology Alliance (“MITA”) is a division of the National Electrical Manufacturers Association and represents companies (collectively “Companies,” and individually “Company”) that develop, produce, manufacture, and market medical imaging and radiation therapy equipment, technologies and related technologies and services, such as healthcare information technologies, used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (“Member Technologies” or the “Company’s Technologies”) in order to enable patients to live longer and healthier lives. MITA is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative medical imaging and radiation therapy technologies make toward achieving these goals. MITA recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe medical imaging and radiation therapy technologies in the United States (“Health Care Professionals”).

Medical Imaging and Radiation Therapy Technologies

Member Technologies include medical equipment employing noninvasive imaging modalities such as X-ray, computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), ultrasound, nuclear, and healthcare information technology used in the diagnosis and treatment of disease and illness, which can be deployed to avoid unnecessary and costly exploratory surgery and assist Health Care Professionals in making more timely and accurate health care treatment decisions. Member Technologies include radiation therapy equipment used in the treatment of cancer, and when coupled with imaging technology can result in the application of radiation therapy to diseased tissue while avoiding healthy tissue. The nature of Member Technologies typically requires extensive interactions with Health Care Professionals. Member Technologies need a significant amount of technical support from Company personnel throughout the life of the technology, beginning with clinical trials, continuing through installation, and thereafter with routine maintenance. Member Technologies are also subject to ongoing research, development and improvements that require continuing education and training of and consultation with the user community.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Member Technologies are collaborative processes between Companies and Health Care Professionals. Innovation and creativity are essential to the development and evolution of Member Technologies, which often occur outside a Company's laboratory.
- *Enhance the Safe and Effective Use of Medical Technologies.* The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical, or other Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators often require this type of training as a condition of product approval.
- *Encourage Research and Education.* Companies' support of *bona fide* medical research, education, and enhancement of professional skills improves patient safety and increases access to Member Technologies.
- *Foster Charitable Donations and Giving.* Companies make monetary and MITA Technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to—as well as the quality of—care and treatment in patient populations that may not otherwise be reached.

The Purpose of the Code of Ethics

MITA recognizes that Health Care Professionals' first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. MITA recognizes the obligation to facilitate ethical interactions between Companies and Health Care Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are the subject of this Code of Ethics.¹ To that end, MITA restates and amends its Code of Ethics and Frequently Asked Questions (collectively "Code of Ethics" or "Code"), effective July 1, 2009.

Note: This Amended and Restated Code supersedes and replaces all previous MITA Codes of Ethics. Companies adopting this Code shall communicate the principles of this

¹ The principles of the Code are derived from a variety of authorities, including the federal Anti-kickback Statute. Throughout the Code, we refer to the concept of an "unlawful inducement" to reflect Anti-kickback Statute prohibitions.

Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations. 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 Companies should address any additional questions to their own attorneys. This Code of Ethics is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations. Any interpretation of the provisions of this Code, as well as Companies’ interactions with Health Care Professionals not specifically addressed in this Code, should be made in light of the following principle:

Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

II. Code of Ethics Compliance

All Companies are strongly encouraged to adopt this Code and to implement an effective compliance program – one which includes policies and procedures that foster compliance with the Code with respect to their interactions with Health Care Professionals related to Member Technologies.

Companies are strongly encouraged to follow the following elements of an effective compliance program, appropriately tailored for each Company, 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.

III. Company-Conducted Product Training and Education

Companies have a responsibility to make training and education on their products and Member Technologies available to Health Care Professionals. Companies may also provide education to Health Care Professionals. “Training” means training on the safe and effective use of Medical Technologies. “Education” means communicating information directly concerning or associated with the use of Companies’ Member Technologies, *e.g.*, information about disease states and the benefits of Member 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. In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain Member Technologies. These types of programs often occur at centralized locations (necessitating out-of-town travel for some participants), and may extend more than one day. Companies

should adhere to the following principles when conducting training and education programs concerning Member Technologies for Health Care Professionals:

- 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. In some cases, for example, medical imaging or radiation therapy equipment may not be transportable or because of the number and type of clinicians available at a particular facility, and it may be appropriate for a Company representative to provide training and education at the Health Care Professional's location.
- Programs providing "hands on" training on Member Technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.
- Companies may provide Health Care Professional attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.
- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Member Technologies, Companies may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

IV. 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 Professionals. Companies may support these conferences in various ways:

- *Conference Grants.* Companies 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 Health Care Professionals in training. Companies 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 Health Care Professionals 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 any body accrediting the educational activity.² The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

- *Conference Meals and Refreshments.* Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, Companies themselves may provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are: (1) offered to all Health Care Professional attendees (with the limited exception noted below), and (2) provided 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 offered to fewer than all Health Care Professional attendees if the provision of such meals and refreshments is specifically permitted by another section of this Code relating to meals and refreshments. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.

- *Faculty Expenses.* Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are *bona fide* conference faculty members.

- *Advertisements and Demonstration.* Companies may purchase advertisements and lease booth space for Company displays at conferences.

V. Sales, Promotional, and Other Business Meetings

Companies may conduct sales, promotional, and other business meetings with Health Care Professionals to discuss, for example, Company Technology features, sales terms, or contracts. Programs and events should be conducted in clinical, educational, conference, or other settings, including Company facilities, hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge. Often, these meetings occur close to the Health Care Professional's place of business. Under other circumstances, it is 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 modest meals and refreshments in connection with such meetings. However, it is not appropriate to pay for meals, refreshments, travel, or lodging of guests of Health Care Professionals or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

² To facilitate compliance, Companies should familiarize themselves with the current standards and policies of leading organizations that accredit providers and sponsors of continuing education programs for Health Care Professionals who use Member Technologies. Special attention should be paid to those provisions concerning independence, conflict of interest, the appropriate use of commercial support, promotion, hospitality, the format of educational conferences and disclosures.

See Section VIII for additional principles related to the provision of meals associated with Health Care Professional business interactions.

VI. Consulting Arrangements with Health Care Professionals

Companies engage Health Care Professionals 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 Company-sponsored training and other services. Companies 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. Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:

- Consulting agreements should be written and describe all services to be provided. When a Company 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 Company may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging.
- The venue and circumstances for Company 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.
- Company-sponsored meals and refreshments provided in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. Companies should not provide recreation or entertainment in conjunction with these meetings.

Provisions on Payment of Royalties. Arrangements involving the payment of royalties to a Health Care Professional should meet the contractual standards set forth above. Health

Care Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement. A Company should enter into a royalty arrangement with a Health Care Professional only where the Health Care Professional 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 Health Care Professional 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 Health Care Professional purchase, order or recommend any product or medical technology of the Company or any product or technology produced as a result of the development project; or (2) a requirement to market the product or medical technology upon commercialization.³ Companies are strongly encouraged to consider the exclusion from the calculation of royalties the number of units purchased, used, or ordered by the Health Care Professional and/or members of the Health Care Professional's practice, if it is appropriate and practicable to do so.

VII. Prohibition on Entertainment and Recreation

Company interactions with Health Care Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee Health Care Professional. 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 Company engages the Health Care Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

VIII. Modest Meals Associated with Health Care Professional Business Interactions

A Company's business interactions with Health Care Professionals may involve the presentation of scientific, educational, or business information and include, but are not

³ Companies may, however, elect to enter into separate consulting agreements with Health Care Professionals for marketing services if such services meet the requirements set forth in this Section VI above.

limited to, the different types of interactions described in Sections III through VI of this Code of Ethics. 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 and subordinate in time and place to the *bona fide* presentation of scientific, educational, or business information and provided in a manner conducive to the presentation 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 Health Care Professional'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 Health Care Professional's place of business, for example, (1) where the Company's Technology cannot easily be transported to the Health Care Professional's location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained onsite.

Participants. A Company may provide a meal only to Health Care Professionals who actually attend the meeting. A Company may not provide a meal for an entire office staff where everyone does not attend the meeting. A Company also may not provide a meal where its representative is not present (such as a "dine & dash" program). A Company may not pay for meals for guests of Health Care Professionals or for any other person who does not have a *bonafide* professional interest in the information being shared at the meeting.

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

- Section III: Company-Conducted Product Training and Education.
- Section IV: Supporting Third-Party Educational Conferences.
- Section V: Sales, Promotional, and Other Business Meetings.
- Section VI: Consulting Arrangements with Health Care Professionals.

IX. Educational Items; Prohibition on Gifts

A Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than \$100. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example, a DVD player or MP3 player/I-Pod; however, this prohibition is not intended to restrict unreasonably the appropriate use of a particular type of storage-only media technology

(e.g., printed paper, tape, diskette, CD-ROM, DVD, or thumb-drive) on which material that has a genuine educational function may be provided.

A Company may not give Health Care Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Health Care Professional's work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have a Company's name, logo, or the name or logo of one of its Medical Technologies. Companies also may not provide Health Care Professionals with 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 XIII.

X. Provision of Coverage, Reimbursement and Health Economics Information

As Member Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Company Technology may be dependent on Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, a Company may provide such economic information regarding its technology if it is accurate and objective.

A Company also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Member Technologies.

Under no circumstances should an agreement for the purchase or continuing use of a Company's Technologies include a provision to provide coverage, reimbursement or health economic information to the Health Care Professional that would constitute an unlawful inducement. A Company may not interfere with a Health Care Professional's independent clinical decision-making with respect to the acquisition of or appropriate use of a Company's Technology. For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional 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 Company should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

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

- Identifying the clinical value of the Company's Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health

economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payors.

- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Health Care Professionals regarding the Company's Technologies, including identifying coverage, codes and billing options that may apply to those Member Technologies or the services and procedures in which they are used.
- Providing accurate and objective information about the economically efficient use of the Company's Technologies, including where and how they can be used within the continuum of care.
- Providing information related to the Company's Technologies regarding available reimbursement revenues and associated costs.
- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes with respect to the use of a Company's Technologies.
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Technologies.

XI. Research Grants

Given the current and growing importance of industry support for independent medical research, medical education and advances in medical care, it is important to encourage this important function, while ensuring that such support does not place Companies or Health Care Professionals at undue risk of legal liability. Companies should therefore comply with the following with respect to research grants to Health Care Professionals:

- The research must be legitimate, with well-defined milestones and deliverables contained in a written agreement.
- The proposed research must be evaluated by and any resulting research agreements must be negotiated and managed by Member representatives who have no role in selling products or services to the Health Care Professional that will receive or benefit from the research grant.
- There can be no conditions linking the research funding with the Health Professional's purchases of products or services from the Member (unless the products or services are being purchased for that research). The research funding must not be linked to or contingent upon past, present or future sales of the Member's products or services to the Health Care Professional.

- Companies should handle research requests and research funding in accordance with the Office of Inspector General Compliance Guidance for Pharmaceutical Companies (68 Fed. Reg. 23,731) with respect to “Educational and Research Funding.”

XII. Charitable Donations

Members may make donations for a charitable purpose, such as providing funds or equipment for indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. Donations should be made only to charitable organizations separate from the Health Care Professional or, in rare instances, to individuals engaged in genuine charitable missions for the support of that mission. It is not appropriate for Members to make charitable donations for the purpose of inducing Health Care Professionals to purchase, lease, recommend, or use the Members’ products, and Members should not make a charitable donation if the proposed donation is linked to a past, present or future purchase, lease, recommendation or use of a Member’s products. For example, a Member should not fund a charitable request from a Health Care Professional in which that Health Care Professional describes its past purchase of the Member’s products as a reason for the Member to fund the charity. All donations should be appropriately documented and it is recommended that Members adopt a process of evaluating requests for Charitable Donations that ensures a separation between the Member’s commercial and charitable activities. Examples of appropriate charitable grants and related considerations are:

- **Advancement of Medical Education.** Members may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs, which are charitable or have an academic affiliation or, where consistent with the preamble to this section, other medical personnel. (For additional considerations regarding educational grants outside of the context of charitable donations, see Section IV, Supporting Third Party Educational Conferences.)
- **Public Education.** Members may make grants for the purpose of supporting education of patients or the public about important health care topics.

XIII. Evaluation and Demonstration Products

Providing products to Health Care Professionals 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 Health Care Professional regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Health Care Professionals 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. Company products that may be provided to Health Care Professionals 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 Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Company products 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. Companies 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 Health Care Professional’s location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products.

Demonstration. Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. 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 the product. A Company should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

FREQUENTLY ASKED QUESTIONS REGARDING MITA’S CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

This document is designed to address some anticipated questions that persons may have about the practical application of the Code of Ethics adopted by the Medical

Imaging Technology Alliance (MITA), a division of the National Electrical Manufacturers Association, effective July 1, 2009, whose Members include the Companies of medical imaging and radiation therapy equipment in North America. The application of the principles articulated in the Code of Ethics might be very fact specific and each Company should consult appropriate personnel familiar with the Code of Ethics within their Company for advice.

Goal and Scope of MITA Code

Q. Should Companies provide copies of this Code to Health Care Professionals?

- A. Yes. Companies are strongly encouraged to provide this Code to Health Care Professionals and to participate in educational efforts to help them to understand the ethical and legal requirements and limitations facing Companies.

Q. What should Companies do if a Health Care Professional asks the Company to engage in activities prohibited by the Code?

- A. Companies are encouraged to educate Health Care Professionals about the Code as the primary and preferred method to address efforts by Health Care Professionals to encourage Companies to participate in prohibited behaviors. In appropriate circumstances, Companies may also choose to involve their own legal counsel, legal counsel for the Health Care Professional or the authorities.

Q. If Companies that adopt this Code have divisions or units that offer health care technologies or services to Health Care Professionals other than Member Technologies, are those divisions or units expected to comply with the Code?

- A. The Code was drafted with Member Technologies in mind, and may not be completely applicable to other health care technologies and services offered to Health Care Professionals, e.g., pharmaceuticals, implantable devices, and clinical services. Companies should carefully consider whether the Code can be effectively applied to those units or divisions offering other healthcare technologies or services, and if not, a Company should take the following steps to ensure the integrity of its compliance program:
 - 1) Adopt a code of ethics appropriate to the unit or division's business, based if possible on an applicable, alternative industry code of ethics; and
 - 2) Publicize clearly and transparently those units or divisions that have chosen to adopt an alternative code of ethics.

- Q. What is meant by “modest,” as used in this Code?*
- A. As used in the Code, "modest" means middle-tier, in the sense that the food, travel expense, or hospitality is neither the most expensive nor the least expensive as measured against the local community standard. When the term “modest” is used, Companies are always free to choose an even lower cost food, travel expense or hospitality option.
- Q. Is a group purchasing organization (GPO) a Health Care Professional within the meaning of the Code?*
- A. Yes. Health Care Professionals include persons or entities that purchase, lease, recommend, use, arrange for the purchase or lease of medical technology products. A GPO meets this definition.
- Q. When a Health Care Professional seeks to trade in its existing equipment in connection with purchasing new medical equipment, can the parties value the trade-in equipment above fair market value for determining the net price of the equipment?*
- A. No. The valuation of used equipment above its fair market value could be considered illegal remuneration under Medicare law anti-kickback rules. There are sources of information available to Members and Health Care Professionals to help establish fair market value for used equipment, and Members should turn to those sources and document that they used a credible source for the determination of fair market value.
- Q. Are combination products covered by the Code?*
- A.. Yes, interactions related to combination products (*e.g.*, those that are both biologics and Member Technology devices or drugs and Member Technology devices) are covered by the Code. Interactions related to combination products also may be subject to the ethical codes of other trade associations.
- Q. Does the Code address arrangements between a Company and a Health Care Professional relating to licensing a new product to the Company?*
- A. If these arrangements involve providing services to a Company, they are a type of consulting arrangement addressed in Section VI.

Q May a Company's employee or agent pay for meals or refreshments for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the meals or refreshments nor reimburses the employee or agent?

A. No. The Code should be viewed as applying to a Company's employees and agents even if they pay for benefits themselves. Depending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.

Q May a Company provide support for a Health Care Professional-sponsored social event, such as an office holiday party?

A. No, such support would be inappropriate.

Q Does the Code govern the actions of Companies' agents and distributors?

A. As stated in Section II, Companies adopting the Code are required to communicate the Code's provisions to their employees, agents, dealers and distributors with the expectation that they will adhere to them. It is important that these entities are informed that MITA has revised its Code of Ethics and that they are aware of the ethical standards reflected in it.

Q. What does "appropriately tailored" mean with respect to implementation of the elements of an effective compliance program?

A. "Appropriately tailored" means that each Company's implementation of the seven elements of an effective compliance program should take into account the Company's size, resources, particular lines of business, and work-force. MITA recognizes that, given the wide diversity within the medical technology industry, there is no single best compliance program. MITA strongly encourages Companies to develop and implement compliance elements that address the specific types of risks that apply to their operations.

Company Sponsored Product Training and Education

Q. If a Company is training a group of Health Care Professionals on the use of portable medical equipment and/or software, is it appropriate to provide the "hands-on" training in a hotel or other meeting facility, other than a clinical facility?

A. Yes, so long as the facility used is conducive to the training purpose.

Q. Do the provisions of the Code of Ethics speak to the practice of conducting a demonstration site visit for a prospective customer to an existing Health Care Professional/customer's facility, where the existing customer's personnel and facility will be compensated by a Company?

A. Yes, Section III acknowledges that "in some cases, because medical imaging or radiation therapy equipment may not be transportable or because of the number and type of clinicians available at a particular facility, it may be appropriate for a Company representative to provide training and education at a Health Care Professional's location." Site visit arrangements should only be entered into where a legitimate need and purpose for the services is identified in advance, and the selection of Health Care Professional's site is on the basis of their qualifications and suitability for conducting the demonstration and not the volume of business generated. It is important that the arrangements with the health care Professional be documented by a written agreement, signed by both of the parties, specifying the services to be provided by the Health Care Professional. Compensation to the health care Professional should be consistent with the fair market value for the services actually provided, and should be spelled out in the agreement. Under no circumstances should the compensation be based in any way on the volume of sales generated by prospective customers who visit the Health Care Professional/customer's facility.

Q. May a Company pay for travel to a Company-sponsored general educational Program?

A. It may be appropriate for a Company to conduct a general educational session about imaging and radiation therapy technology, but it is not the type of program for which Company-supported travel would be appropriate under the Code. In contrast, paying for a Health Care Professional's travel may be appropriate when the Company is conducting training and education on the safe and effective use of the Company's Technologies, which are operated by the Health Care Professional..

Company Support for Third Party Educational Conferences

Q. What is meant by “third party,” as in “Third Party Educational Conference?”

A. A third party is an individual or entity that is neither a Company nor a Health Care Professional.

Q. May a Company provide financial support to a bona fide educational program sponsored by a Health Care Professional?

A. Yes, if the educational program is accredited for continuing medical education credits or if it is sponsored by the Health Care Professional’s charitable foundation, then the Company may treat the educational program as a Third Party Educational program.

Q. If a Company provides one hundred percent of the funds for an educational program being put on by a Third Party, and that Third Party controls how the funds are spent, does this still qualify as Third Party Educational program or does this then become a Company-sponsored Educational program?

A. This remains a Third Party Educational Program, so long as the Company does not control the content of the program or the manner in which the Third Party spends the funds.

Q. Is it appropriate for a Company to provide a speaker for an educational program sponsored by a Health Care Professional, if the Health Care Professional requests the Company to do so?

A. Yes.

Q. May a Company recommend a faculty speaker who will speak at a third-party educational conference?

A. The Code does not preclude a Company from recommending a knowledgeable faculty member, where the recommendation is permitted by the conference sponsor’s guidelines. The ultimate selection should be made by the conference sponsor.

Q. A professional society or trade organization sponsors an educational conference, trade show, or annual meeting, and provides to Manufacturers guest badges to send to Health Care Professionals to attend the conference? Is it appropriate for a Manufacturer to distribute the guest badges to Health Care Professionals?

- A. No. This would constitute a grant or other remuneration to a Health Care Professional. It is appropriate only for Members to provide support directly to the conference sponsor.

Q. Is it appropriate to pay an exhibit fee for the privilege of displaying product information at an educational conference sponsored by a Health Care Professional?

- A. Yes, but only if the exhibit fee reflects the reasonable rental space valuation. Exhibit fees should not reflect a premium for access to the Health Care Professional.

Q. One or more Health Care Professionals have a financial interest in a for-profit third party entity (which is not a Health Care Professional) that provides education to other Health Care Professionals. Continuing medical education credit is offered through the training provided by this third-party. May a Member make a grant to the third-party entity to cover education related expenses?

- A. No. While members are generally encouraged to support accredited educational activities, providing financial support for these types of for-profit ventures of a Health Care Professional, even where such ventures include the provision of accredited education, would be viewed as an improper benefit extended to the Health Care Professional.

Q. May a Company sponsor an off-site sales, promotional, or other business meeting that is ancillary to a third-party educational conference?

- A. Yes, provided that the sales and promotional meeting or other activity has a legitimate business purpose and meets all applicable requirements of the Code. The Company also should comply with applicable conference sponsor guidelines. A Company may not pay for travel to the conference since the Health Care Professional is already attending the conference.

Sales and Promotional Meetings

Q. As part of a Sales or Promotional meeting, may a Company take the Health Care Professional golfing or to a professional sporting activity that is conducive to the thorough exchange of information about the Company's products and services, at the Company's expense?

- A. No. Even if these activities are conducive to the thorough exchange of information about the Company's products and services, they are viewed as improper inducements by relevant governmental authorities.

Q. As part of a Sales or Promotional meeting, may a Company take the Health Care Professional to a recreational activity that is conducive to the thorough exchange

of information about the Company's products and services, such as a driving trip to a vineyard or to the coast, at the Company's expense?

A. No. Even if these activities are conducive to the thorough exchange of information about the Company's products and services, they are viewed as improper inducements by the relevant governmental authorities.

Q. *As part of a Sales or Promotional meeting, may a Company take the Health Care Professional to the theatre or to a concert?*

A. No, because these activities are not conducive to the thorough exchange of information about the Company's products and services.

Q. *May a Company indirectly provide meals or refreshments when the provision of meals or refreshments does not conform to the Code, for example, by reimbursing a distributor who provides these meals while marketing the Company's Technologies?*

A. No. Companies should always promote adherence to the Code by intermediaries when they are engaged in marketing the Company's Medical Technologies. A Company should never knowingly encourage or condone an intermediary's engaging in conduct that would be prohibited by the Code if a Company engaged in it directly.

Q. *Is it ever appropriate for a Company to conduct a sales, promotional, or other business meeting for Health Care Professionals at a resort location?*

A. Generally, this would not be appropriate. The Code provides that "programs and events should be conducted in clinical, educational, conference, or other settings, including Company facilities, hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge," and a resort location will not likely meet this standard. Sales meetings at a resort location could also give rise to an appearance that is inconsistent with the objectives of the Code.

Q. *A professional society or trade association has chosen to hold its annual or regular meeting at a resort location, and the Company will be sending personnel to the association's meeting. Is it appropriate for a Company to conduct a sales, promotional, or other business meeting at the resort for Health Care*

Professionals who are already attending this meeting, either just before or just after the association's meeting?

- A. Arranging sales, promotional or business meetings that are ancillary to the meetings of trade associations or professional societies can be more cost effective in these cases than arranging a separate business meeting at a different location at a different time. The fact that the sales, promotional or business meeting takes place at a resort under this circumstance generally does not raise an appearance that is inconsistent with the objectives of the Code, provided that other requirements of this Code with respect to recreation, entertainment, meals and hospitality, and gifts are observed. A Company should not pay for the Health Care Professional's lodging expense for any additional nights that the Health Care Professional stays at the resort in order to attend the sales, promotional or business meeting.

Arrangements With Consultants

Q. *May a Company enter a Consulting arrangement with a Health Care Professional as part of a Sales Transaction?*

- B. So long as the consulting relationship is *bona fide*, in that it meets the requirements of Section VI, it may be entered as a separate agreement contemporaneously with a sales agreement.

Q. *Is a clinical investigator considered a "consultant" under Section VI?*

- A. If the clinical investigator is providing services to the Company in return for compensation, he or she is a consultant under Section VI.

Q. *Is there a limit to the number of consultants a Company may retain under Section VI?*

- A. Companies may retain only as many consultants as are necessary to fulfill the Company's requirements for *bona fide* services; moreover, the requirements of Section VI must be satisfied for each consultant.

Q. *What is the role of Sales personnel with regard to a Company's engagement of a Health Care Professional as a consultant?*

- A. The role of Sales personnel should be limited to being a source of information to identify Health Care Professionals who may have the qualifications and expertise to meet a previously identified legitimate need for services by the Company. Sales personnel

should not attempt to influence the decision on engaging a particular Health Care Professional as a consultant.

- Q. What happens if a consultant is engaged but the project is cancelled or modified without using the consultant's services?*
- A. The Code contemplates that if the requirements of Section VI were met when the consultant was engaged and then unanticipated circumstances prevented performance, then the question of whether or how much payment is made to a consultant would be a matter determined by the underlying consulting agreement. However, any such payment should be reasonable under the circumstances.
- Q. What factors should a Company consider when evaluating the venues and circumstances for meetings with consultants?*
- A. A Company should assess (a) whether there is a *bona fide* business justification for holding the meeting; (b) whether the location and venue are suitable for and conducive to the exchange of information; (c) whether the value of any Company-sponsored lodging is reasonable; (d) whether any ancillary meals and refreshments are modest in value and are subordinate in time and focus to the business part of the meeting; and (e) whether the overall meeting has a genuine business purpose and tenor and does not constitute an unlawful inducement.
- Q. Do the restrictions of the MITA Code apply to Company interactions with consultants in the same way as they do to interactions with other Health Care Professionals?*
- A. Yes. All interactions with Health Care Professionals must meet the requirements of the Code. These include the requirements of Section VI as well as other applicable sections of the Code.
- Q. When is a Health Care Professional considered a "consultant"? What types of arrangements with consultants are covered under Section VI?*
- A. Any relationship between a Health Care Professional and a Company where services provided to the Company by the Health Care Professional are exchanged for remuneration constitutes a consulting arrangement and should comply with Section VI. Examples of consulting arrangements include agreements to provide education and training, speaking engagements, proctoring and preceptorships, reference center or center of excellence arrangements, participation on advisory boards or focus groups,

medical technology development and research services arrangements (such as post-market research agreements, research and development agreements and clinical studies), and arrangements for the development and/or transfer of intellectual property. Research and educational grants are not considered consulting arrangements. They are addressed in Section XI.

Q. Can the selection of a consultant include his or her experience, usage or familiarity with a specific Company Medical Technology?

A. Section VI provides that a consultant should be selected on the basis of his or her qualifications and expertise to meet a defined need. It is possible that these qualifications could include experience with, usage of, or familiarity with a specific Medical Technology. However, neither selection of, nor compensation paid to, consultants should be to reward past usage or constitute an unlawful inducement.

Q. How are Clinical Study Agreements treated under the Code?

A. Arrangements that involve the provision of clinical research services by a Health Care Professional in return for compensation are a type of consulting arrangement and are subject to the same principles as other consulting arrangements under the Code. They should be governed by a written services agreement, and compensation should be based on fair market value for the services provided. The clinical program for which the services are being provided should fulfill a legitimate research purpose. A Clinical Study Agreement typically is entered into between a Company and a Health Care Professional that is a facility, institution, or practice group, and compensation for the clinical research services is paid to that entity. An individual Health Care Professional may act as a study investigator but also provide related services in his or her individual capacity that is outside the scope of the services covered in the clinical study agreement (*e.g.*, protocol development). In that case, it may be appropriate to enter into a separate consulting arrangement with that Health Care Professional.

Q. How can a Company establish “fair market value”?

A. There are different valuation methods that may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria. The method or methods used by a Company should be documented.

Q. What is considered a “legitimate need” to engage a Health Care Professional as a consultant?

A. A legitimate need arises when a Company requires the services of a Health Care Professional in order to achieve a proper business objective. There are many proper business objectives. However, engaging a Health Care Professional for the purpose of generating business directly from such Health Care Professional (or a health care provider that is affiliated with the Health Care Professional) is not a proper business objective. Thus, there is a legitimate need to engage a Health Care Professional only if the arrangement would have been entered into absent an opportunity to generate business directly from the Health Care Professional. Further, the level of consulting services to be obtained from a Health Care Professional should not exceed the amount that is reasonably necessary to achieve a Company’s proper business objective.

Q. NEW: Does Section VI of the MITA Code apply to entities owned or controlled by or affiliated with (e.g., institutions or firms providing consulting services that employ or engage the services of) a Health Care Professional?

A. Yes.

Gifts

Q. May a Company fund an endowed chair at a Health Care Professional that is also an educational institution?

A. No. Funding an endowed chair to a Health Care Professional is the same as providing an unrestricted cash gift to the Health Care Professional. Typically, the Health Care Professional can use these funds for any purpose, including the payment of salaries, the purchase of medical equipment for the department being endowed, or to otherwise defray departmental operating expenses. The endowed chair would not meet the standard for an appropriate gift to a Health Care Professional. Under the Code’s standards for “Charitable Donations,” the funds would be going to a Health Care Professional as opposed to a charitable organization and would not be used for a charitable purpose.

Q. A conference sponsor requests that manufacturers donate raffle prizes that will be won by Health Care Professionals attending the conference. Is this considered a gift?

A. Yes, it would be considered a gift. Gifts must benefit patients or serve a genuine educational function and, with the exception of

medical textbooks or anatomical models, should have a fair market value of less than \$100.00.

Q. I understand it is not appropriate to give a Health Care Professional a projector, an MP3 player, DVD player or other device capable of reading, or displaying, viewing, or delivering the content on electronic storage media that can be used for non-educational or non-patient-related purposes, but is it permissible to provide medical literature or a medical textbook to a Health Care Professional on an electronic storage medium as opposed to providing it in print form?

A. The Code of Ethics provides that materials that serve a genuine educational function may be provided to a Health Care Professional on electronic storage media as long as it is appropriate. In considering whether it is appropriate, a Company should consider the value of the storage media itself--which should be negligible if the media can be reused for other purposes--and whether the storage capacity of the media corresponds to the size of the educational materials.

Modest Meals Associated with Health Care Professional Business Interactions

Q. Is a general discussion to build good business relationships a “business presentation” such that it is appropriate to provide a business meal?

A. No. A business presentation may include substantial discussions related to medical technology development and improvement of a medical technology, pricing, or contract negotiations. The business discussion should account for most of the time spent during the meal. Development of general goodwill and business relationships should not be the primary purpose of a business meal, and a business meal should not be used for entertainment or recreational purposes.

Educational Items; Prohibitions of Gifts

Q. May a Company provide a gift such as flowers, gift baskets, meals, snacks, wine, or other refreshments to a Health Care Professional or a Health Care Professional’s office or staff?

A. No. These types of gifts and refreshments are not considered educational items or for the benefit of patients.

Q. May a Company give gifts to staff of a Health Care Professional who are not themselves Health Care Professionals?

- A. Gifts given to the staff of a Health Care Professional should be treated as though they are given to the Health Care Professional and are subject to all applicable provisions of the Code.

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

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

Q. May a Company raffle an item during a trade show, such as two round-trip airline tickets, that it could not otherwise give as a gift?

- A. No. A Company may not raffle or give away at a trade show an item that it could not otherwise give a Health Care Professional under Section IX.

Q. What types of items are considered to be for the benefit of patients?

- A. Items intended for the benefit of patients could include starter kits, and educational brochures, for example. However, “scrubs” and office supplies would not be considered an item for the benefit of patients.

Research Grants

Q. Certain terminology is commonly used with respect to requests for research grants. What are the differences between a “Research and Development Grant” (also known as an “R&D Grant”) and a “Research and Development Agreement Project (also known as an “ R&D Agreement Project?”)

- A. An R&D Grant is generally *non-restricted* money to be used at the Healthcare Professional’s discretion. There are no well-defined objectives or deliverables and no expectation on the Company’s part of learning or other benefits with regard to their product improvement.

An R&D Agreement Project is funding that is restricted to specific goals, objectives, milestones and deliverables. Money is paid for work that is performed.

- Q. Are R&D Grants and R&D Agreement Projects both permitted under the Code?*
- A. No. Only R&D Agreement Projects are permitted under the Code.
- Q. What is the role of a Company's Sales personnel with regard to research and development relationships between Health Care Professionals and Companies?*
- A. Sales may be a source of information about the Health Care Professional and it may refer the Health Care Professional's request for an R&D grant to others within the Company. However, the Sales organization/member must not attempt to influence decision-making with respect to the research and development relationship and cannot actually make decisions on selection of research and development projects or funding.
- Q. Why does the Code prohibit research funding that is linked to or contingent on "past" sales of Companies products or services to the Healthcare Professional?*
- A. Research funding should not be used to influence a Health Care Professional's decision-making with respect to a purchase of equipment from a Company, whether or not the research funding and sales transactions take place concurrently.

Charitable Donations

- Q. May a Company make a charitable contribution to a Healthcare Professional's golfing event or gala party, when the proceeds earned from the event or party will be used for the general funding of the recipient Health Care Professional?*
- A. No.
- Q. May a Company sponsor a Health Care Professional's golfing event or gala party, when the proceeds earned from the event or party will be used for charitable purposes?*
- A. No.
- Q. May a Company contribute to or sponsor a golfing event or gala party given by a charitable foundation connected to a Health Care Professional, when the proceeds earned from the event or party will be used for charitable purposes?*
- A. Yes, so long as: (a) the charitable foundation is truly a separate charitable organization independent of the Health Care Professional; (b) the charitable purpose will not likely result in the purchase of the Company's products or services (e.g., Companies should not fund a gala designed to purchase medical equipment for

the Health Care Professional or to build a facility to house medical equipment for the Health Care Professional; and (c) the donation is not made to induce the Health Care Professional to purchase, lease, recommend, or use the Companies' products or services.

Q. How should a Company determine whether the proceeds will be used for a charitable purpose?

A. The Company should conduct due diligence into the proposed charity to determine whether the funds will be used for a bona fide charitable purpose (such as indigent patient care or patient education) as opposed to being used for general operating expenses of the Health Care Professional such as salaries, capital improvements and equipment purchases.

Q. How should a Company determine whether a charitable organization connected to a Health Care Professional is truly a separate charitable organization independent of the Health Care Professional?

A. The Company should conduct due diligence into the charitable organization to determine whether or not is incorporated as a separate 501(c)(3) corporation and to determine whether its board and management are independent of the Health Care Professional.

R. What is the role of Sales personnel with regard to a Company's charitable giving to a foundation connected to a Health Care Professional?

A. Sales may be a source of information about the foundation's charitable events or requests and it may refer the foundation's charitable requests to others within the Company, but that referral should be the end of Sales personnel involvement in the Company's charitable giving. The Company's personnel who make decisions on charitable giving should be entirely independent of sales and marketing staff, and the Sales organization/member must not attempt to influence decision-making with respect to the charitable request.

Q. May a Company donate charitable money to a Health Care Professional that links the charitable funding to a past purchase, but the Health Care Professional later resubmits its request without the linkage?

A. No. This is entirely improper and the passage of time will not cure the impropriety.

Q. What is meant by “rare instances” as that phrase is used in Section VIII of the Code with respect to charitable donations?

A. “Rare instances” means only under extraordinary circumstances and should be no more than 1% of the Company’s charitable giving to Health Care Professionals.

Q. May a Company make a charitable contribution to a not-for-profit institution to pay the registration or seminar fees and travel expenses for an affiliated Health Care Professional to attend a third-party educational conference?

A. In general, Section IV does not permit a Company to pay directly for the registration, seminar fees or travel expenses of a Health Care Professional’s attendance at a third-party educational conference. Consequently, the Company should not provide these benefits indirectly as a charitable contribution to a Health Care Professional’s not-for-profit institution for the purpose of defraying the costs of particular individuals’ attendance. However, it can provide grants to sponsors to: 1) pay the expenses of faculty members selected by the conference sponsor; 2) support the participation of Health Care Professionals in training; or 3) reduce the costs of participation by all participants.

Demonstration or Evaluation Products or Equipment

Q. A Health Care Professional has requested that a Company provide it with a multiple use product to evaluate. How long can the Company provide the product at no charge to the Health Care Professional?

A. Medical imaging and radiation therapy equipment are by their nature multiple use products, and a proper evaluation necessarily requires multiple uses. The specific length of time reasonably necessary for a Health Care Professional to assess a multiple use product will depend on the frequency of anticipated use, the duration of required training, the number of Health Care Professionals who will need to evaluate the product, the length of time necessary to evaluate different product features, and similar considerations. A Company should provide a Health Care Professional with documentation and disclosure regarding the no-charge status of evaluation products, and the written document should specify the evaluation period.

Q. Is a demonstration or evaluation product that is provided at no charge to a Health Care Professional by a Company a gift?

- A. Provided that the Company comports with the requirements of Section XIII, demonstration and evaluation products are not considered gifts.