

NEMA CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROVIDERS

I. Preamble: Goal and Scope of NEMA Code

The National Electronic Manufacturers Association (“NEMA”) is dedicated to the advancement of medical science, the improvement of patient care, and in particular to the contribution that high quality, cost-effective health care technology can make toward achieving those goals. In pursuing this mission, NEMA members (“Members” or “Manufacturers”) recognize that adherence to ethical standards and compliance with applicable laws are critical to the medical device industry’s ability to continue its collaboration with health care professionals and health care institutions. Members encourage ethical business practices and socially responsible industry conduct related to their interactions with these individuals and organizations. Members also respect the obligation of health care professionals and health care institutions to make independent decisions regarding Member products. Consequently, NEMA adopts this voluntary Code of Ethics, effective January 1, 2005 (“Code”), to facilitate Members’ ethical interactions with all those individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Members’ medical technology products in the United States (“Health Care Providers”). It is important to note that the term “Health Care Providers” as used in this Code means both individuals (such as doctors) and institutions or organizations (such as hospitals and medical research facilities).

There are many forms of interactions between Members and Health Care Providers that advance medical science or improve patient care, including:

- *Advancement of Medical Technology.* The development of cutting edge medical technology and the improvement of existing products are collaborative processes between Members and Health Care Providers. Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the laboratories of medical device companies. Heart valves, MRI equipment, cardiac rhythm devices, surgical tools, and infusion pumps are just a few examples of the array of complex medical technologies developed through research collaborations and consulting relationships between Health Care Providers and Members.
- *Safe and Effective Use of Medical Technology.* The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical, or other medical technology often requires Members to offer Health Care Providers appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval.

- *Research and Education.* Members' support of *bona fide* medical research, education, and enhancement of professional skills among Health Care Providers serves patient safety and increases access to new technology.

NEMA recognizes that Members may interact with Health Care Providers for many legitimate objectives other than those related to the sale, lease or prescription of Member products. Any interpretation of the provisions of this Code, as well as Members' interactions with Health Care Providers not specifically addressed in this Code, should be made in light of the following principle:

Members shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of, their products.

II. Member-Sponsored Product Training and Education

Members have a responsibility to make product education and training available to Health Care Providers. In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain medical technology. These types of programs often occur at centralized locations (necessitating out-of-town travel for some participants), and may extend more than one day. With regard to Member-sponsored programs focused on the education and training in the safe and effective use of Member products:

- Programs and events should be conducted in clinical, educational, conference, or other settings, including Member facilities, hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge.
- Programs requiring "hands on" training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities, (including Member facilities that are conducive to this type of training). The training staff should have the proper qualifications, education, experience and expertise to conduct the training.
- Members may provide Health Care Provider attendees with reasonable hospitality in the form of meals, receptions and entertainment in connection with these programs. Any such hospitality should be modest in value and subordinate in time and focus to the educational or training purpose of the meeting. Members should not pay, directly or indirectly, for hospitality in the form of sporting event tickets, theatre tickets or golf.
- Members may pay for reasonable and modest travel and lodging costs incurred by attending Health Care Providers.

- It is not appropriate for Members to pay for the meals, hospitality, 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, or whose presence is not otherwise required to assist the Health Care Professional (e.g., an interpreter; a nurse).

III. Supporting Third Party Educational Conferences

Bona fide independent, educational, scientific, or 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; conferences sponsored by accredited continuing medical education providers; and grand rounds. Members may support these conferences in various ways:

- *Educational Grants.* Members may provide a grant either: (a) directly to the conference sponsor to reduce conference costs; or (b) to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and other medical personnel who are Health Care Providers in training. Members should not make educational grants directly to Health Care Providers so that they might attend the conference. Members may provide educational 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 Providers who are in training. These grants should be paid only to organizations with a genuine educational purpose or function, and may be used only to reimburse the legitimate expenses for *bona fide* educational activities. These grants also should be consistent with relevant and applicable guidelines established by professional societies or organizations of Health Care Providers. Members should familiarize themselves with the “Standards for Commercial Support” adopted by the Accreditation Council for Continuing Medical Education” (September 2004) for the types of requirements and guidelines that Health Care Provider societies or organizations are likely to adopt with respect to independence, conflict of interest, the appropriate use of commercial support, promotion, the format of educational conferences and disclosures. The conference sponsor should be responsible for and control the selection of program content, faculty, educational methods, and materials.
- *Modest Meals and Hospitality.* Members may provide funding to the conference sponsor to support the conference’s meals and hospitality, such as entertainment. Also, Members themselves may provide meals, receptions and entertainment for *all* Health Care Provider attendees, but only if it is provided in a manner that is also consistent with the sponsor’s guidelines. Any meals, receptions, and hospitality provided directly by the Members should be modest in value and should be subordinate in time and focus to the purpose of the conference.

- *Faculty Expenses.* Members may make grants to conference sponsors for reasonable honoraria, travel, lodging, and meals for Health Care Providers who are *bona fide* conference faculty members who actually participate in the educational conferences. Members should not make grants to the Health Care Providers directly for these purposes.
- *Advertisements and Demonstration.* Members may purchase advertisements and lease booth space for company displays at conferences.

IV. Sales and Promotional Meetings

It is appropriate for Members to meet with Health Care Providers to discuss product features, contract negotiations, and sales terms. Often, these meetings occur close to or at the Health Care Provider's place of business. Any hospitality provided by the Member in connection with these meeting should be modest in value and should be: (a) subordinate in time and focus to the purpose of the meeting; (b) conducive to the exchange of information; and (c) in the form of a modest meal. 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). However, it is not appropriate to pay for meals, hospitality, travel, or lodging of guests of Health Care Providers or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

V. Arrangements with Consultants

Many Health Care Providers serve as consultants to Members, providing valuable *bona fide* consulting services, including research, participation on advisory boards, presentations at Member-sponsored training, and product development collaboration. It is appropriate to pay reasonable compensation to Health Care Providers for needed services actually performed. The following requirements support the existence of a *bona fide* consulting arrangement between Members and Health Care Providers:

- Member consulting arrangements must be written, signed by the parties, specify all services to be provided, and should not be made on the basis of the volume or value of business generated by the consultant or affiliates of the consultant.
- Compensation paid to consultants should be consistent with fair market value for the services actually provided.
- Consulting agreements should be entered into only where a legitimate need and purpose for the services is identified in advance.
- Selection of consultants should be on the basis of the consultant's qualifications and expertise to address the identified purpose, and should not be on the basis of volume or value of business generated by the consultant or affiliates of the consultant.

- 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 setting, including Member facilities, hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Member-sponsored hospitality such as meals or entertainment that occurs 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. Members should not pay, directly or indirectly, for hospitality in the form of sporting event tickets, theatre tickets or golf.
- Members may pay for reasonable and actual expenses incurred by consultants in carrying out the subject of the consulting arrangement, including reasonable and actual travel, modest meals and lodging costs incurred by consultants attending meetings with, or on behalf of, Members.
- When a Member contracts with a consultant for research services, there must be a written research protocol for a *bona fide* research purpose (See Section IX Research Grants below).

VI. Gifts

Members occasionally may provide modest gifts to Health Care Providers, but only if the gifts benefit patients or serve a genuine educational function. Other than the gift of medical textbooks or anatomical models used for educational purposes, any gift from a Member should have a fair market value of less than \$100.

In addition, Members may occasionally give Health Care Providers branded promotional items of minimal value related to the Health Care Provider's work or for the benefit of patients. Gifts may not be given in the form of cash or cash equivalents.

This section on Gifts is not intended to address other types of interactions between Members and Health Care Providers that are addressed more specifically elsewhere in this Code nor to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation.

VII. Provision of Reimbursement and Other Economic Information

Members may support accurate and responsible billing to Medicare and other payors by providing general reimbursement information to Health Care Providers regarding Members' products, including identifying appropriate coverage, coding, or billing of Member products, or of procedures using those products. However, this is only acceptable if: (a) the information provided is accurate; (b) the information is of a general nature; and (c) the reimbursement information is of insubstantial fair market value.

VIII. Charitable Donations

Members may make donations for a charitable purpose, such as providing funds 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 Provider 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 Providers 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 Provider in which that Health Care Provider 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, see Section III, 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.

IX. 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 Members or Health Care Providers at undue risk of legal liability. Members should therefore comply with the following with respect to research grants to Health Care Providers:

- 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 Provider that will receive or benefit from the research grant.
- There can be no conditions linking the research funding with the Health Provider'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 Provider.
- Members should handle research requests and research funding in accordance with the Office of Inspector General Compliance Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23,731) with respect to "Educational and Research Funding."

Note: This Code supersedes and replaces all previous NEMA Codes of Ethics. Members will communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Members have an independent obligation to ascertain that their interactions with Health Care Providers comply with all applicable laws and regulations. The information provided by the Department of Health and Human Services Office of Inspector General, 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 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.

FREQUENTLY ASKED QUESTIONS REGARDING NEMA'S CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROVIDERS

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 NEMA Medical Division, effective January 1, 2005, whose Members include the Manufacturers of medical imaging and treatment 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 NEMA Code

Q. Should Manufacturers provide copies of this Code to Health Care Providers?

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

Q. What should Manufacturers do if a Health Care Provider asks the Manufacturer to engage in activities prohibited by the Code?

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

Q. What should Manufacturers do to assure internal compliance with this Code?

A. Manufacturers should consider adopting adequate compliance programs to assure conformity with applicable laws and regulations, and this Code. This compliance program could involve executive management, legal, and accounting personnel in the following activities: (i) educating Manufacturer personnel about their obligations under applicable laws and regulations; (ii) setting procedures to approve the types of funding, payments, expenses, grants, gifts, donations, compensation, or activities discussed in the Code; (iii) conducting due diligence with respect to the activities discussed in the Code; and (iv) monitoring and auditing the types of funding, payments, expenses, grants, gifts, donations, compensation, or activities discussed in the Code for compliance with law and regulations.

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, Manufacturers are always free to choose an even lower cost food, travel expense or hospitality option.

Manufacturer Sponsored Product Training and Education

Q. If a Manufacturer is training a group of Health Care Providers 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.

Manufacturer 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 Manufacturer nor a Health Care Provider.

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

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

Q. If a Manufacturer 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 Manufacturer-sponsored Educational program?

A. This remains a Third Party Educational Program, so long as the Manufacturer 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 Manufacturer to provide a speaker for an educational program sponsored by a Health Care Provider, if the Health Care Provider requests the Manufacturer to do so?

A. Yes.

Sales and Promotional Meetings

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

A. No. Even if these activities are conducive to the thorough exchange of information about the Manufacturer'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 Manufacturer take the Health Care Provider to a recreational activity that is conducive to the thorough exchange of information about the Manufacturer's products and services, such as a driving trip to a vineyard or to the coast, at the Manufacturer's expense?

A. No. Even if these activities are conducive to the thorough exchange of information about the Manufacturer'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 Manufacturer take the Health Care Provider to the theatre or to a concert?

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

Arrangements With Consultants

Q. May a Manufacturer enter a Consulting arrangement with a Health Care Provider as part of a Sales Transaction?

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

Gifts

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

A. No. Funding an endowed chair to a Health Care Provider is the same as providing an unrestricted cash gift to the Health Care Provider. Typically, the Health Care Provider 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 Provider. Under the Code's standards for "Charitable Donations," the funds would be going to a Health Care Provider as opposed to a charitable organization and would not be used for a charitable purpose.

Charitable Donations

Q. May a Manufacturer make a charitable contribution to a Healthcare Provider'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 Provider?

A. No.

Q. May a Manufacturer sponsor a Health Care Provider'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 Manufacturer contribute to or sponsor a golfing event or gala party given by a charitable foundation connected to a Health Care Provider, 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 Provider; (b) the charitable purpose will not likely result in the purchase of the Manufacturer's products or services (e.g., Manufacturers should not fund a gala designed to purchase medical equipment for the Health Care Provider or to build a facility to house medical equipment for the Health Care Provider; and (c) the donation is not made to induce the Health Care Provider to purchase, lease, recommend, or use the Manufacturers' products or services.

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

A. The Manufacturer 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 Provider such as salaries, capital improvements and equipment purchases.

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

A. The Manufacturer 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 Provider.

Q. What is the role of Sales personnel with regard to a Manufacturer's charitable giving to a foundation connected to a Health Care Provider?

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 Manufacturer, but that referral should be the end of Sales personnel involvement in the Manufacturer's charitable giving. The Manufacturer'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 Manufacturer donate charitable money to a Health Care Provider that links the charitable funding to a past purchase, but the Health Care Provider 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 Manufacturer's charitable giving to Health Care Providers.

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 Provider’s discretion. There are no well-defined objectives or deliverables and no expectation on the Manufacturer’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 Manufacturer’s Sales personnel with regard to research and development relationships between Health Care Providers and Manufacturers?

A. Sales may be a source of information about the Health Care Provider and it may refer the Health Care Provider’s request for an R&D grant to others within the Manufacturer. 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 Manufacturers products or services to the Healthcare Provider?

A. Research funding should not be used to influence a Health Care Provider’s decision-making with respect to a purchase of equipment from a Manufacturer, whether or not the research funding and sales transactions take place concurrently.