




POLICIES AND PROCEDURES

Title:	Business Integrity	Responsibility Of:	Chief Compliance Officer
Category:	Compliance	Oversight By:	
Policy #:	Version#:	Approved By:	 President & CEO
Effective:	July 24, 2006		

POLICY

NMFF is committed to conducting its business with integrity and in accordance with all relevant and applicable laws. Moreover, NMFF seeks to maintain a culture of ethics in its business relations and to avoid even the appearance of impropriety. NMFF recognizes that relationships with Vendors/Referral Recipients and Referral Sources (as defined below), under certain circumstances, may have the potential to improperly influence, or appear to improperly influence, clinical, purchasing or prescribing decisions; inappropriately increase Medicare/Medicaid or other insurance costs; increase the risk of overutilization of health care services; or create patient safety or quality of care concerns. Accordingly, NMFF has developed this Policy to provide guidance to NMFF Employees regarding common relationships with Vendors/Referral Recipients and Referral Sources.

This Policy is intended to establish parameters in conducting these relationships and not to prohibit all such relationships. In all circumstances, however, NMFF Employees must exercise independent judgment, free from influence by relationships with Vendors/Referral Recipients and Referral Sources, and may not enter into any relationships with Vendors/Referral Recipients or Referral Sources that might negatively impact patients or potentially bring discredit to NMFF. This Policy should be read in conjunction with NMFF's Conflict of Interest Policy, as many of the relationships described herein are reportable as potential conflicts of interest.

This Policy applies to all NMFF employees, including Members, as well as directors and officers (referred to collectively herein as "Employees"). For purposes of this Policy, a "Referral Source" means any person or entity that is a source or potential source of patient referrals to NMFF, such as community physicians who refer patients to NMFF for specialty services. A "Vendor/Referral Recipient" means any person or entity that sells to or obtains health care business or referrals from NMFF, or potentially could sell to or obtain health care business of referrals from NMFF, including pharmaceutical companies, medical device companies, hospitals, nursing homes, ambulatory surgical centers, imaging facilities, health care suppliers, non-medical suppliers and their employees or agents.

This Policy addresses the following specific relationships:

Section I	Gifts (Money and Tangible Items)
Section II	Meals and Other Business Courtesies
Section III	Consulting and Other Compensation Arrangements
Section IV	Third Party Medical Education Programs
Section V	Educational Grants and Donations
Section VI	Training and Education Regarding Use of Medical Devices
Section VII	Purchase Contracts; Discounts and Other Reductions in Price

Questions regarding this Policy should be directed to the Chief Compliance Officer or Legal Services. Employees are encouraged to seek guidance from the Chief Compliance Officer or Legal Services prior to engaging in interactions not covered under this Policy. All interactions with Vendors/Referral Recipients or Referral Sources not covered by specific Sections of this Policy will be governed by reference to the federal Anti-Kickback Law and Stark Law, as well as other applicable federal, state and local laws. In addition, NMFF shall be guided by the following (as updated and supplemented by NMFF management from time to time): voluntary guidelines developed by the American Medical Association relating to gifts to physicians from industry; the Pharmaceutical Research and Manufacturers of America “Code on Interactions with Healthcare Professionals;” the Advanced Medical Technology Association’s “Code of Ethics on Interactions with Health Care Professionals;” and the Office of the Inspector General’s “Compliance Program Guidance for Pharmaceutical Manufacturers.”

Any exception to this Policy must be approved in advance by the Chief Compliance Officer and Legal Services. In addition, gifts or other arrangements with entities that provide and bill patients or payors for any of the following services should be discussed with the Chief Compliance Officer or Legal Services prior to entering into the arrangement: clinical laboratory services; physical and occupational therapy services; radiology and other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

Individual Departments may adopt additional policies (not inconsistent with this Policy) or policies more restrictive than this Policy.

An Employee who fails to comply with this Policy shall be subject to appropriate disciplinary and corrective action, including up to termination of employment or affiliation with NMFF.

PROCEDURE

I. Gifts from Vendors/Referral Recipients; Gifts to Referral Sources

The purpose of this Section is to ensure that no NMFF Employee accepts any gift from a Vendor/Referral Recipient that might inappropriately influence the NMFF Employee's clinical, purchasing or prescribing decisions or create the appearance of impropriety or influence over the physician-patient relationship. Similarly, this Policy is intended to ensure that no Employee provides any gift to a Referral Source that creates the appearance of impropriety or influence over referrals to NMFF. This Section addresses gifts such as money or other tangible items. Meals and other business courtesies are addressed in Section II (Meals and Other Business Courtesies).

1. Gifts from Vendors/Referral Recipients

a. **Permitted Gifts.** No Employee shall accept any gift from a Vendor/Referral Recipient other than the following:

- Items of minimal value that are primarily associated with the individual's professional practice, such as pens, notepads and other similar small reminder items with company or product logos
- Occasional gifts of items that primarily benefit patients and have a fair market value of less than \$100, provided that a medical textbook or an anatomical model used for educational purposes may have a value in excess of \$100
- Holiday gifts that are generally shared within the department or practice area, such as gift baskets, provided that the value of such gifts from a Vendor/Referral Recipient does not exceed \$100 per year from any one source. Gifts for personal holidays (e.g., birthdays, anniversaries) are not permitted

b. **Prohibited Gifts.** The following types of gifts should never be accepted:

- Cash or cash equivalents (e.g., gift certificates)
- Gifts for the individual recipient's personal benefit, including gifts in recognition of a personal life event (e.g., birthday, anniversary), such as floral arrangements, artwork, golf balls, sporting bags, or tickets to a sporting or other cultural events (except in the limited circumstances noted above)
- Samples given to a physician by a sales representative specifically for the physician's individual use (as opposed to being given to NMFF for patient/clinical use)
- Any gift, however small, that is in any way intended to influence the Employee's clinical decision-making, purchasing or prescribing decisions

- A gift to a spouse or other family member that could not be accepted directly by the Employee

2. Gifts to NMFF Referral Sources. NMFF does not make gifts to NMFF Referral Sources, and NMFF Employees, acting on behalf of NMFF or in the course of their employment, are prohibited from making any gift to an NMFF Referral Source. An NMFF Employee may not use his/her own funds to pay for gifts for the purpose of influencing referrals.

II. Meals and Other Business Courtesies

The purpose of this Section is to ensure that no NMFF Employee accepts any meals or other Business Courtesies from a Vendor/Referral Recipient that might inappropriately influence the NMFF Employee's clinical decision-making or give the appearance of any improper influence. Similarly, this Section is intended to ensure that no Employee provides any meals or other Business Courtesies to an NMFF Referral Source that creates the appearance of impropriety or influence over referrals to NMFF. "Business Courtesy" refers to a meal, entertainment or other hospitality or favor for which fair market value is not paid by the recipient.

Note: Gifts are addressed in Section I of this Policy. Additional guidance relating to meals and Business Courtesies also may be found in the following Sections of this Policy: Consulting and Other Compensation Arrangements (relating to meals provided as part of or incident to a physician's compensated services to a Vendor/Referral Recipient); Third Party Medical Education Programs (relating to meals and receptions provided by a Vendor/Referral Recipient to program attendees, where permitted by the program sponsor); Educational Grants and Donations (relating to funding of meals provided in connection with programs conducted by NMFF); and Training Provided by Medical Device Manufacturers (where meals, travel and lodging are provided in connection with training provided by a manufacturer in order to facilitate safe and effective use of certain medical technology).

1. Meals and Business Courtesies Furnished by Vendors/Referral Recipients. NMFF Employees may accept meals from Vendors/Referral Recipients in connection with the following:

a. Business Meetings and Detailing/Marketing by Vendors/Referral Recipients. NMFF Employees may accept a Vendor/Referral Recipient's invitation to attend a lunchtime or dinnertime business meeting or discussion of *bona fide* business matters or learn more about the products or services of the Vendor/Referral Recipient. However, because receipt of meals or other Business Courtesies from a Vendor/Referral Recipient could inappropriately influence an Employee or could create the appearance of impropriety, NMFF Employees will comply with the following guidelines in connection with business meetings and detailing/marketing programs:

- NMFF Employees may attend "working" meals paid for by a Vendor/Referral Recipient only if they are modest in value and occur at venues appropriate for the exchange of information relating to the Vendor/Referral Recipient's goods and services or other business-related or educational discussion. Employees may not accept meals paid for but not attended by a Vendor/Referral

Recipient representative, even if for *bona fide* business or educational purposes (e.g., food dropped off by a Vendor/Referral Recipient representative or “dine and dash” programs).

- The expected value of the meal should be consistent with NMFF’s Business Expense Policy, i.e., Employees should not accept meals where the value or location would not be permitted if paid for by NMFF.
- No Employee may accept money or any other remuneration from a Vendor/Referral Recipient in exchange for attending any lunch, dinner or reception.
- No Employee may solicit or accept any Business Courtesy that is intended to influence the Employee’s clinical decision-making, purchasing or prescribing practices.
- Employees may not accept a Vendor’s/Referral Recipient’s invitations to attend entertainment events, such as plays, sporting events, or golf outings, even where some business may be discussed.
- Employees shall not, as a general matter, allow a Vendor/Referral Recipient to pay for a spouse or other guest who does not have an independent reason for meeting with the Vendor/Referral Recipient.

b. Vendor/Referral Recipient-Sponsored Educational/Training Meetings. NMFF Employees may attend meals and receptions in connection with Vendor/Referral Recipient-sponsored educational and training programs containing objective scientific and educational information that will benefit NMFF patients. However, it is NMFF policy that the educational and training programs sponsored by a Vendor/Referral Recipient and related meals or receptions be structured so as not to improperly influence purchasing or prescribing decisions. Accordingly, NMFF Employees will comply with the following guidelines when accepting meals and Business Courtesies in connection with Vendor/Referral Recipient-sponsored educational and training meetings:

- NMFF Employees’ purpose in attending the presentations, discussions and meals should be to further their knowledge on the subjects presented.
- NMFF Employees may attend modest receptions and meals provided by a Vendor/Referral Recipient in connection with educational training and meetings. The meals and receptions should be incidental and subordinate to the educational content of the meetings or training sessions with most time devoted to education. NMFF Employees may not “dine and dash,” i.e., take food provided by a Vendor/Referral Recipient without actually participating in any educational lecture or training program or accept a Vendor/Referral Recipient’s offer to provide a meal without providing educational content.

- Employees shall not, as a general matter, allow a Vendor/Referral Recipient to pay for a spouse or other guest who does not have an independent professional reason for participating in the educational/training program.

2. Meals Provided to NMFF Referral Sources. NMFF Employees are prohibited from providing any meal to an NMFF Referral Source that is inconsistent with the requirements set forth above relating to acceptance of meals from a Vendor/Referral Recipient. Other types of Business Courtesies are not permitted. Any meals provided pursuant to this Policy must be provided in accordance with NMFF's Business Expense Policy. An Employee may not use his/her own funds to pay for meals or other Business Courtesies that are otherwise prohibited by this Policy.

III. Consulting and Other Compensation Arrangements

The purpose of this Section is to ensure that all service arrangements between NMFF Employees and Vendors/Referral Recipients are memorialized in writing, reflect fair market value compensation for legitimate, reasonable and necessary services, and do not inappropriately influence Employees' clinical decision-making, prescribing or purchasing decisions.

Note - Compensation Arrangements Addressed Elsewhere: This Policy does not apply to service as an expert witness for an entity that is not a Vendor/Referral Recipient. Questions about such arrangements should be addressed to Legal Services. In addition, while the general principles set forth in this Policy apply to research arrangements, any arrangements involving research must comply with and be processed through the applicable policies and procedures of the Northwestern University ("NU") Office of Sponsored Research ("OSR"). Similarly, while the general principles set forth in this Policy apply to medical education programs sponsored by NU and other sponsors accredited by the Accreditation Council for Continuing Medical Education ("ACCME"), funding for such arrangements must comply with and be processed through the Feinberg School of Medicine Office of Continuing Medical Education.

1. Permitted Arrangements. This policy covers all consulting, medical director, product development, advisory committee, teaching/speaking, or other services that NMFF Employees provide to Vendors/Referral Recipients (collectively, "consulting arrangements"). NMFF Employees may be engaged by Vendors/Referral Recipients to perform such services only pursuant to a written contract that details the Employee's duties and that provides no more than reasonable fair market compensation for necessary services that are actually rendered. Under no circumstances should an Employee enter into a contract that is, or appears to be, motivated by any improper purpose, such as to induce the individual to change or maintain his or her purchasing or prescribing habits.

2. Contract Guidelines. Each consulting arrangement must meet the following guidelines:

- a. The consulting arrangement must be documented by a written contract, signed by the appropriate parties. Typically, the NMFF Employee will sign in an individual capacity, and not as an agent of NMFF. However, NMFF, rather than the individual Employee, is the appropriate contracting party for certain arrangements, such as facility medical director agreements, as well as arrangements involving an Employee's clinical services. Arrangements that are executed by NMFF (*e.g.*, for

medical director and other services provided to NMH) are subject to review and approval by Legal Services and the appropriate NMFF signatory. Departments are not separate legal entities, and therefore are not appropriate contracting parties. Any questions about the appropriate contracting party should be addressed to Legal Services.

- b.** The contract must specify the services to be provided, which must be legitimate, commercially reasonable services needed by the contracting party. An Employee may not enter into a contract that involves the provision of services or other terms that would restrict or interfere with the Employee's NMFF-related duties.
- c.** The payment amount or formula must be set in advance and must reflect fair market value for the services to be provided. When compensation is based on a royalty or similar arrangement, the payment amount should not take into account sales or use of products by NU, Northwestern Memorial Hospital ("NMH") or NMFF, or should include other measures to ensure that the payment does not inappropriately influence clinical decision-making.
- d.** The services must actually be performed and documented as a condition of payment.
- e.** The contract cannot involve or permit the use of NMFF's or NU's confidential or proprietary information. The contract must prohibit the use of the NMFF or NU name by any third party, except with written consent.
- f.** Meals, travel and other business courtesies provided in connection with performance of the services must be modest and incidental to the services being performed (*e.g.*, a meal in connection with an all day meeting is acceptable; a three hour meeting followed by golf or other entertainment is not).
- g.** Each Employee is responsible for determining that a proposed consulting arrangement complies with this Policy. However, Legal Services is available to answer questions on an as-needed basis. Employees may wish to use the contracting addendum (available from Legal Services) to facilitate compliance with this Section.

IV. Third Party Medical Education Programs

The purpose of this Section is to provide guidelines for Employees attending or participating in third party conferences, including continuing medical education events, professional society meetings, roundtables and other educational or scientific programs. NMFF permits Employees to attend bona fide third party conferences and to accept associated meals and receptions sponsored by Vendors/Referral Recipients at such conferences so long as they are modest and clearly subordinate to the conference goals of promoting objective scientific and educational activities and discourse.

Note – Medical Education Programs Sponsored by NMFF or NU: Educational programs provided by NMFF are addressed in Section V of this Policy. Funding for medical education programs sponsored by NU and other sponsors accredited by the Accreditation Council for Continuing Medical Education (“ACCME”) must comply with and be processed through the Feinberg School of Medicine Office of Continuing Medical Education.

- 1. Program Faculty.** Subject to compliance with Section III of this Policy (Consulting Arrangements), an Employee may serve as a faculty member for a third party educational conference and may accept a reasonable honorarium and reimbursement for his or her own transportation, lodging and meals expenses relating to the conference. Such compensation and reimbursement must be paid by the conference sponsor and not by Vendors/Referral Recipients. In such circumstances, the Employee must ensure that no Vendor/Referral Recipient influences the content of the presentation made by the Employee, and that there is appropriate disclosure of any financial ties to any Vendors/Referral Recipients, consistent with the rules of the third party sponsor and the body accrediting the program, if any (e.g., ACCME).
- 2. Attendees.** If an Employee is attending a third party conference only as an attendee (including as a key opinion leader) and not as a bona fide faculty member of the conference, the individual may not accept reimbursement from any Vendor/Referral Recipient for the program registration fee, transportation, lodging, meals or other expenses of attending the program.
- 3. Conference-Related or Approved Meals and Receptions.** An Employee may participate in a meal or reception sponsored by a Vendor/Referral Recipient at a third party conference if the event complies with the guidelines of the organization sponsoring the conference. The meal or reception should be modest in value and conducive to discussion among those participating in the event. The amount of time at any such meals or receptions should be clearly subordinate to the amount of time spent at the conference’s educational activities.
- 4. Attendance by Spouse or Guests.** Under no circumstances may an Employee accept reimbursement for transportation, lodging or meals for the cost of his or her spouse or other guest(s).
- 5. Attendance by Healthcare Professionals in Training.** At times, Vendors/Referral Recipients may wish to offer financial assistance to allow medical students, residents, fellows and other healthcare professionals in training to attend educational conferences. Any such arrangements must be made through NU. NMFF does not accept funding for such purposes.

V. Educational Grants and Donations

While most educational funding will be given to NU, NMFF may, from time-to-time receive from Vendors/Referral Recipients funding for educational programs. The purpose of this Section is to ensure that NMFF accepts such grants and donations only where such grants and donations directly benefit NMFF patients or serve an educational purpose. NMFF will not accept funding that is offered in connection with the purchase or sale of goods or services. The provision of funding by Vendors/Referral Recipients should never influence clinical decision-making, purchasing or prescribing decisions, or the awarding of contracts.

Note – Grants and Donations for Research or Accredited Medical Education Programs: Grants to fund research (including clinical research) must comply with and be processed through the applicable policies and procedures of the NU OSR. Grants to fund medical education programs sponsored by NU and other sponsors accredited by the ACCME must comply with and be processed through the Feinberg School of Medicine Office of Continuing Medical Education.

- 1. In General.** All educational grants received from Vendors/Referral Recipients must be documented in a writing, approved by Legal Services and the Chief Compliance Officer, signed by all applicable parties and must not be made for any improper purpose, such as in exchange for changing (or maintaining) any purchasing, prescribing or other clinical decisions or practices. Permitted support includes: funding for educational programs conducted by NMFF and related meals in compliance with Section II of this Policy (Meals and Other Business Courtesies), funding for textbooks or other educational materials, and funding of outside speakers.
- 2. Management of Grant Funds.** NMFF will maintain a separate bank account for the receipt, management and dispensing of grant monies. The Department conducting the educational activity must independently develop a budget for any such project, and must ensure that donated funds are applied toward the applicable educational program. Any funds remaining after completion of the educational program shall be used for educational purposes, or as otherwise required by the funding agreement. Funds from other sources will not be commingled with grant monies. No donated funds may inure to the benefit of any NMFF Employee.
- 3. Program Requirements.** Vendors/Referral Recipients may direct grants to a specific Department and indicate the general topic of the program to be funded. However, Vendors/Referral Recipients are not permitted to specify or preapprove the program content or speakers. Program speakers must disclose any financial relationships with the Vendor/Referral Recipient providing a grant and any other relevant financial relationships. Any program support by a Vendor/Referral Recipient shall be disclosed to program attendees and any recipients of program materials.
- 4. Prohibited Arrangements.** Neither NMFF nor an NMFF Employee may accept from a Vendor/Referral Recipient either (1) tickets to a fundraising or other event, or (2) funds intended to be used to purchase tickets to a fundraising or other event of another organization. In addition, educational grants may not be used to provide meals or entertainment to persons who do not have a bona fide reason to attend the educational event, including spouses or guests of attendees.

- 5. Grants vs. Marketing/Promotional Activities.** In some cases, funding from Vendors/Referral Recipients could be characterized, in whole or in part, as support of NMFF marketing or promotional activities rather than support of an educational program. Examples of such arrangements include website or other media references to NMFF or its Employees and support of NMFF outreach to NMFF Referral Sources. Any proposed arrangement that involves marketing of NMFF or Employee services, even in an educational context, must be reviewed by Legal Services. Legal Services will determine whether it is appropriate for NMFF's or an NMFF Employee's name to be used in connection with the arrangement, whether NMFF may accept such funding consistent with this Policy, and whether NMFF should pay a share of funding for the proposed activity or event.
- 6. Solicitation of Support.** To ensure that contributions from Vendors/Referral Recipients do not inappropriately influence NMFF's or an NMFF Employee's purchasing, prescribing or contracting decisions, NMFF and its Employees should not solicit or accept contributions from the marketing or sales department of a Vendor/Referral Recipient.

VI. Training and Education Regarding Use of Medical Devices

The purpose of this Section is to ensure that NMFF Employees receive appropriate training regarding medical devices free from any inappropriate influence, or the appearance of any improper influence, which might interfere with the physician-patient relationship or improperly influence clinical, prescribing, or purchasing decisions.

NMFF recognizes that the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain medical technology. NMFF further recognizes that proper training in and awareness of new and innovative medical technology may contribute to better and/or more cost-effective patient care. However, the activities surrounding training provided to physicians and others may raise at least the appearance of impropriety. To ensure that NMFF Employees receive appropriate training free from inappropriate influences over their clinical decision-making, prescribing and purchasing decisions, the following guidelines shall be followed regarding attendance at medical device manufacturer-sponsored training sessions:

- 1.** NMFF Employees may attend medical device manufacturer-sponsored training and education programs in order to further their knowledge on the subject(s) presented. Such programs must contain objective scientific and educational information that will benefit NMFF patients.
- 2.** Training and education programs must be conducted in settings that are conducive to the effective transmission of knowledge, such as hotel or other commercially available meeting facilities, medical institutions, laboratories or other training facilities.
- 3.** NMFF Employees may accept reimbursement for reasonable travel, lodging and other expenses in connection with a training program at an appropriate location. Reimbursed expenses should be consistent with the types of expenses permitted under NMFF's Business Expense Policy.
- 4.** NMFF Employees attending training programs should only accept associated hospitality in the form of modest meals and receptions. Any meals and receptions provided in connection

with the training program should be subordinate in time and focus to the educational/training purpose(s) of the program.

5. NMFF Employees may not allow a medical device company to pay for meals, hospitality, travel or other expenses for their spouses or other guests who do not have a *bona fide* professional interest in the information being provided at the training program.

VII. Purchase Contracts; Discounts and Other Reductions in Price

The purpose of this Section is to ensure that contracts for the purchase of goods and services on behalf of NMFF are negotiated and entered into by authorized persons, and that any discounts, free samples or other reductions in price from Vendors/Referral Recipients meet applicable legal requirements.

1. **Purchase Contracts.** All contracts to purchase goods or services on behalf of NMFF must be reviewed by Financial Services and Legal Services, and executed by authorized signatories. No one else is authorized to bind NMFF to purchase goods or services.
2. **Discounts and other Reductions in Price.** Discounts or other reductions in price that reduce the cost of patient care and are appropriately structured and reported are permissible and beneficial. However, certain arrangements characterized as discounts may be viewed as kickbacks (e.g., providing a free item for an NMFF Employee's personal use as part of a package of discounted products sold to NMFF). Because discounting and pricing raise complex legal issues, any discounting or pricing arrangement that involves other than a straightforward discounted price reflected on the seller's invoice must be reviewed by Legal Services. The following are some additional guidelines regarding discounts.
 - a. NMFF may only accept a discount that is made at the time it purchases the goods or services or where the terms of any rebate are fixed and set forth in writing at the time of the initial sale of a good or service.
 - b. Any invoice, coupon or statement provided by the supplier must accurately reflect the discounted price.
 - c. NMFF must retain documentation of any discount received from a supplier for items or services billed to federal or state health care programs so that such documentation is readily accessible should it be requested by a federal or state health agency.
 - d. Samples are governed by NMFF's Guidelines for Maintaining and Dispensing Drug Samples.