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Part I: Professional Integrity

Introduction and Definitions

The following principles integrate provisions from the professional integrity and gift policies of Northwestern University Feinberg School of Medicine (“Feinberg”), Northwestern Memorial HealthCare (“NMHC”), and Northwestern Medical Faculty Foundation (“NMFF”). Please note that this Handbook does not replace the individual policies of Feinberg, NMHC, or NMFF. These policies remain in effect and can be accessed at http://www.feinberg.northwestern.edu/compliance/links/. The principles in this Handbook, however, navigate these policies by setting forth the most restrictive provision from the policies with respect to any topic. Hence, by following these guidelines, you can be assured that you will be acting in compliance with the policies of all three organizations.

This Handbook applies to you if you are a NMFF physician member, NMFF-employed physician, NMFF physician consultant, NMFF mid-level provider, or NMFF employee. This Handbook also includes NMHC requirements that are applicable to the extent that you are on the NMH medical staff and (a) hold a paid or unpaid NMH medical administrative position (e.g., NMH clinical Department Chairs, Section and Division Chiefs, or special care unit directors); (b) have NMH procurement responsibility or the authority to recommend such procurement; or (c) participate on boards or committees.

This Handbook summarizes rules that govern the relationships that you have with vendors, referral recipients, and referral sources. Definitions of these and other terms are set forth below.

1. **AAMC**: Association of American Medical Colleges
2. **ACCME**: Accreditation Council for Continuing Medical Education
3. **Conflict of Commitment**: A situation where an individual engages in outside activities, either paid or unpaid, that interferes with his primary obligation and commitment to NMFF.
4. **Department Chair**: Those individuals designated by NMFF as a Department Chair or an equivalent physician leader.
5. **FDA**: Food and Drug Administration
6. **Immediate Family Member**: Unless otherwise defined, all references to “Immediate Family Members” include your spouse, child, child’s spouse, and parent.
7. **MGMA**: Medical Group Management Association
8. **Outside Professional Activities**: An outside activity is any paid or volunteer activity undertaken by you that is outside the scope of your regular NMFF duties. Outside professional activities may include consulting, participation in civic or charitable organizations, working as a technical or professional advisor or practitioner, or holding a part-time job with another employer, whether working in one’s NMFF occupation or another.
9. **Referral Recipient:** A “Referral Recipient” refers to a person or entity, or an employee or representative of a person or entity, who or which receives or could potentially receive patient referrals from a Northwestern entity. For example, a Referral Recipient would include a hospital or nursing home to which a physician refers patients. **See explanatory note at the end of this section.**

10. **Referral Source:** A “Referral Source” refers to person or entity, or an employee or representative of a person or entity, who or which refers or could potentially refer patients to a Northwestern entity. Referral Sources include, for example, community physicians who refer patients to NMFF for specialty services. **See explanatory note at the end of this section.**

11. **Vendor or Industry:** “Vendor” or “Industry” includes any individual or entity that provides or could provide products or services of any type to Feinberg, NMHC, or NMFF. This includes, by way of example, providers of diagnostic, preventative, remedial and therapeutic services, such as doctors, nurses, hospitals and other private, public and voluntary organizations; medical device and equipment and pharmaceutical manufacturers and distributors; biotechnology firms; health insurance firms; and others that provide or could provide products and services directly related to the provision of health care and directly affecting the provision of health care; and other individuals and entities whose products or services are not necessarily limited to the health care industry (e.g., banks, law firms, information systems vendors, architects, and similar organizations). **See explanatory note at the end of this section.**

12. **You:** “You” refers to any person to whom this Handbook applies. Where appropriate we have indicated specific roles that may be affected the Handbook provision.

**NOTE:** “Vendor,” “Industry,” “Referral Recipient,” and “Referral Source” all refer to entities other than Feinberg, NMHC, NMFF, and their affiliates. While the relationships between the Northwestern entities must be carefully monitored, we have implemented processes to do so.

Not all scenarios that you may encounter may be addressed in the following pages. You are, therefore, strongly encouraged to contact the individuals listed in Part III with any questions or concerns.

**A. Gifts and Business Courtesies**

A gift or business courtesy includes any good, service, or other item of value given to a person without that person’s paying money or giving something of comparable or equal value for the good, service, or item. Gifts and business courtesies include, by way of example, the following: cash, checks, gift certificates, securities, property, favors, prizes, services, referrals, employment, food, attendance at plays, concerts, sporting events, golf outings, or any other entertainment events or hospitality.

Neither you nor your Immediate Family Members may accept gifts or business courtesies of any value from Vendors or from Referral Recipients. This prohibition includes, but is certainly not limited to,
acceptance of personal use of a Vendor or Referral Recipient’s facilities, equipment, or vacation home; personal trips, vacations, hotel or resort accommodations; de minimus office items (e.g., pens, notepads, mugs, calendars); birthday or anniversary gifts, floral arrangements, artwork, golf balls, or tickets to sporting, concert, or entertainment events; or any item that takes into account the volume or value of referrals, purchases, or other business generated. Any gift or business courtesy given to your Immediate Family Member is also prohibited if you could not accept the gift directly. The prohibition discussed in this paragraph does not apply to the following:

- if you pay for the gift or business courtesy. For example, you can go to a sports event with a Vendor if you pay for your own ticket;
- drug samples, as long as you abide by NMHC’s or NMFF’s guidelines for maintaining and dispensing drug samples;
- items otherwise expressly allowed in this Handbook (e.g., certain meals as set forth in Section G).

As a general rule, if you receive a gift, you must return it. However, gifts such as holiday gift baskets or thank you gifts such as food baskets, flowers, or souvenirs may be donated, disposed of, or shared with your department where returning it is impractical. Prior to sharing, you must remove the name or other identification of the Vendor or Referral Recipient.

Similarly, neither you nor your Immediate Family Members may give gifts or business courtesies of any value to Referral Sources.

B. Consulting, Advisory Boards, Speaking Engagements, and Similar Compensated Activities

You may enter into arrangements to provide consulting, medical director, product development, advisory committee, teaching/speaking, or other services to Vendors or Referral Recipients for which compensation is received. However, all arrangements must be memorialized in writing; reflect fair market value compensation for legitimate, reasonable, and necessary services; and not inappropriately influence your research activities, clinical decision-making, prescribing or purchasing decisions.

1. Speakers’ Bureaus. With the exception of settings in which academic investigators are presenting results of their Industry-sponsored studies to peers and there is opportunity for critical discussion, you are strongly discouraged from participating in Industry-sponsored speakers’ bureaus. Should you choose to participate in a speakers’ bureau, the content and format of your presentation should be educational and independent of commercial influence and not for marketing purposes. You must adhere to all FDA requirements.

2. Ghost Writing. You may not author or co-author articles where your name or Northwestern’s name is used without your substantive contribution. If Vendor employees are co-authors, then this should be made known. There should be full disclosure of the role of each author.
3. **Contract Guidelines.** Each arrangement must meet the following guidelines:

   a) There must be a signed, written contract. Please understand that you sign in your individual capacity. **NOTE:** Certain arrangements, such as facility medical director agreements, as well as arrangements involving a physician’s clinical services, are executed by NMFF directly.

   b) The contract must specify the services to be provided, which must be legitimate, commercially reasonable services needed by the contracting party. You may not enter into a contract that involves the provision of services or other terms that would restrict or interfere with your job-related duties or create of Conflict of Commitment.

   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 be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. Specifically, the payment amount (i) must not be conditioned on a requirement that you or a Northwestern entity purchase, order, or recommend any product or medical technology or a requirement to market the product or medical technology upon commercialization; and (ii) must exclude from the calculation of royalties the number of units purchased, used, or ordered by you, members of your practice, or any Northwestern entity. Accordingly, for any agreement that does not comply, you should amend your royalty contract (either with the company or with an intermediary party which receives royalties from the company and then distributes a portion of such royalties to you) to exclude royalties for products purchased by any Northwestern entity. If doing so is not feasible, then contact the company to determine the amount of your royalties attributable to Northwestern purchases and reimburse the company (or intermediary party) that amount. As an alternative to reimbursement, you may donate the royalties to a charitable organization. Donations to a charitable organization shall be evidenced by a cancelled check in the same amount as the royalty payment. If you are unable to obtain the exact amount of your royalty payment attributable to purchases by any Northwestern entity, you may estimate such amounts. Be sure to document everything and retain that documentation.

   d) The services must actually be performed and documented as a condition of payment.

   e) The contract cannot involve or permit the use of a Northwestern entity’s confidential or proprietary information.

   f) 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). You may not accept invitations to entertainment events in conjunction with the performance of services.
g) You are responsible for negotiating your own terms and conditions. However, NMFF Legal Services is available to answer questions on an as-needed basis only with respect to compliance with these contract guidelines. Legal counsel must be contacted when a Northwestern entity may be affected by an arrangement (e.g., the arrangement involves ownership of intellectual property).

**NOTE:** Compensated arrangements may be subject to audit by any Northwestern entity and you are required to provide evidence of compliance (including copies of contracts, time reports, receipt of payment, reimbursements or contribution, etc.) to NMFF’s General Counsel upon request. In addition, if you enter into consulting or other agreements with parties outside of Northwestern University that require assignment of ownership rights in intellectual property, you should be aware that conflicts of interest may arise. For guidance in these matters, please refer to Northwestern University’s Policy on Faculty Conflict of Commitment and Conflict of Interest or the Policy on Staff Conflict of Interest. The inventor's dean or center director and the Technology Transfer Program must be notified of any patents or inventions arising from external consulting agreements.

The full policy is accessible here:


**C. Conflict of Commitment**

NMFF Department Chairs, and, if necessary, the Chief Compliance Officer, are responsible for reviewing activities on a case-by-case basis to determine if a Conflict of Commitment is present with respect to NMFF. Physicians should also refer to Feinberg’s Disclosure and Professional Integrity Policy. This policy is available at http://www.feinberg.northwestern.edu/compliance/links/.

**D. Medical Educational Programs and Continuing Medical Education**

Except as allowed under Section F, you should attend only those medical education programs that receive Industry funding if the program is (i) an ACCME-accredited program, (ii) a program sponsored by a Feinberg-affiliated institution or Feinberg and approved by the Feinberg Vice Dean for Regulatory Affairs, (iii) a professional society meeting that follows ACCME standards, or (iv) a program that the you believe would advance the academic mission of your department or division, in which case the you shall explain the basis for this and receive approval from your Department Chair, Division Chief, or Center/Institute Director and the Feinberg Vice Dean for Regulatory Affairs prior to attendance. Partnering with either a for-profit or not-for-profit ACCME provider is permitted only with the approval of the relevant Chair and the Feinberg Vice Dean for Regulatory Affairs. **NOTE:** If you wish to use an ACCME provider other than the Feinberg Office of Continuing Medical Education (“Feinberg Office of CME”) to sponsor an educational event, you may do so only after receiving the approval of your Department Chair or Center/Institute Director and the Feinberg Vice Dean for Regulatory Affairs.

When attending educational programs, you shall abide by the following:
1. **Program Faculty.** Subject to compliance with Section B of this Handbook, you may serve as a faculty member for a third-party educational conference and may accept a reasonable honorarium and reimbursement for your own transportation, lodging, and meal expenses relating to the conference. Such compensation and reimbursement must be paid by the conference sponsor and not by Industry. You must ensure that no Industry representative influences the content of your presentation and that there is appropriate disclosure of any financial ties to Industry, consistent with the rules of the third-party sponsor and the ACCME.

2. **Attendees.** If you are attending a third-party conference only as an attendee (including as a key opinion leader) and not as a bona fide speaker of the conference, you may not accept reimbursement from Industry for the program registration fee, transportation, lodging, meals, or other expenses of attending the program or compensation for time spent at the event.

3. **Conference-Related or Approved Meals and Receptions.** You may participate in a meal or reception sponsored by Industry if the event complies with the guidelines of the ACCME. The meal or reception must be modest in value and conducive to discussion among those participating in the event. The amount of time at any such meals or receptions must 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 you accept reimbursement for transportation, lodging, or meals for the cost of your spouse or other guest(s) unless your spouse or guest(s) has a bona fide purpose for attending the program.

5. **Location.** Conferences must be held in locations that are conducive to the effective transmission of knowledge, which could include, but are not limited to, a hotel or other commercially available meeting facility, medical institution, laboratory, corporate office, or other training facility.

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**E. Vendor Support of Scholarships and Fellowships**

All offers of scholarships and fellowships from Vendors must be submitted to the Feinberg Vice Dean for Regulatory Affairs for prior approval. If approved, the relevant Department will have sole responsibility for determining the curriculum and selecting the recipient, with no involvement by the donor. There must be no *quid pro quo* for the acceptance of such funds.

Approval requests must be submitted to Feinberg Vice Dean for Regulatory Affairs via the Online Request for Approval Form available on the Policy Links page of the Office of Regulatory Affairs website at http://www.feinberg.northwestern.edu/compliance/links/.

**F. Training and Education Regarding Use of Medical Devices**

The Northwestern entities recognize that the FDA mandates training and education to facilitate the safe and effective use of certain medical technology. Additionally, 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 you may raise at least the appearance of impropriety. To ensure that you receive appropriate training free from inappropriate influences over your clinical decision-making, prescribing and purchasing decisions, you must adhere to the following guidelines regarding attendance at medical device manufacturer-sponsored training sessions:

1. You may attend medical device manufacturer-sponsored training and education programs in order to further your knowledge on the subject(s) presented. Such programs must contain objective scientific and educational information that will benefit 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. You may accept reimbursement for reasonable travel, lodging, and other expenses in connection with a training program at an appropriate location. NOTE: No reimbursement for travel, lodging, and meal expenses may be accepted if the purpose of the travel or meeting is to view equipment or products that you are considering purchasing but have not yet purchased.

4. You may only accept associated hospitality in the form of modest meals and receptions. Any meals and receptions provided in connection with the training program must be subordinate in time and focus to the educational/training purpose(s) of the program.

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

G. Meals

Vendor representatives are not permitted to provide food on-site at Feinberg, NMHC, or NMFF. Except as provided below, if you attend a meal to discuss business- or education-related matters with Vendor representatives, then you must pay for your own meal.

Food may be accepted from Vendors or Referral Recipients in the following limited circumstances:

1. Educational Conferences or Professional Society Meetings: You may attend meals and receptions provided by a Vendor or Referral Recipient in connection with an educational conference, training, or professional meeting. However, (i) the meals and receptions must be modest, incidental, and subordinate to the educational content or bona fide business purpose of the meeting, with most of the time dedicated to the educational or business purpose, and with respect to physician meetings, (ii) the Vendor or Referral Recipient must have given the support to the professional society or conference organizer, (iii) the support is disclosed, and (iv) Industry representatives do not participate in meetings and discussions. Meals, such as lunches,
refreshments, and receptions that are included in the conference fee and available for all attendees are appropriate.

2. **Medical Devices:** You may attend modest meals and receptions when attending Vendor-sponsored training and education regarding the use of medical devices.

3. **Services:** You may attend modest meals and receptions in connection with your performance of legitimate contractual services for Industry (e.g., consulting).

Under no circumstances may you accept or provide money, entertainment, or other business courtesy in exchange for attending the meal. In addition, you may not allow a Vendor or Referral Recipient to pay for meals for your spouse, other Immediate Family Member(s), or other guest(s) who do not have a bona fide professional interest in attending the meal.

You may only provide meals to Referral Sources if doing so is part of a bona fide business purpose (e.g., as part of an information presentation to educate community physicians about Northwestern capabilities). However, the meals must be modest in value and occur at venues appropriate for the exchange of information. If the primary purpose of the meeting is marketing and promotion, see Section H below.

### H. Marketing and Promotional Activities

In some cases, funding from a health care Vendor or an entity that could receive patient referrals from a Northwestern entity could be characterized, in whole or in part, as support of the Northwestern entity’s marketing or promotional activities. For example, a drug company might offer to pay for a magazine advertisement that references certain services (which involve use of the Vendor’s product) being available at NMH or NMFF. Another example might occur if NMH or NMFF and a medical device company decide to jointly sponsor a patient seminar to promote a procedure, which utilizes a new device. Examples of such arrangements might also include a MRI facility’s website reference to the Northwestern entity or its physicians. Any proposed arrangement that involves marketing of a Northwestern entity or physician services and also involves Industry funding must be reviewed and approved by the Feinberg Vice Dean for Regulatory Affairs and other appropriate personnel from the affected Northwestern entity. This includes attorneys from Feinberg or NMFF or the NMHC Vice President, Public Relations, Marketing and Physician Services. They will determine whether it is appropriate for the Northwestern entity’s or physician’s name to be used in connection with the arrangement, whether the Northwestern entity may accept such funding, and whether the Northwestern entity should pay a share of funding for the proposed activity or event.

### I. Vendor Provision of Demonstration Products and Other Services

Some Vendors offer various kinds of assistance to providers at no charge. For example, a drug company may provide assistance in securing insurance coverage for a new drug. Similarly, a Vendor might provide a product, piece of equipment, or technology to a physician at no charge for evaluation or demonstration purposes. If structured properly, these types of arrangements can be very beneficial to
physicians and their patients. However, the arrangements may be subject to special billing rules, could be seen as kickbacks, or may raise other regulatory concerns. Accordingly, you must, prior to entering into the arrangement, contact appropriate personnel from the affected Northwestern entity. This includes attorneys from Feinberg or NMFF or the Director of Strategic Sourcing and Procurement at NMHC.

**J. Purchase Contracts and Discounts**

All contracts to purchase goods or services on behalf of a Northwestern entity are subject to that entity’s standard procurement processes. 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 a physician’s personal use as part of a package of discounted products sold to a Northwestern entity). Because discounting and pricing raise complex legal issues, any discounting or pricing arrangement that involves a discount (other than a straightforward discounted price reflected on the seller’s invoice) must be reviewed by purchasing personnel or attorneys in the affected Northwestern entity.

**K. Vendor Access to Premises**

Unless required for training or treatment purposes, access by Vendor representatives shall be restricted to non-patient care areas and nonpublic areas and should take place only by appointment or invitation of the physician or department management. Involvement of students or trainees in such meetings should occur only for educational purposes and only under the supervision of the physician. Vendor access to NMH operating suites must comply with NMH policies.

**L. Fundraising**

If you are considering a fundraising activity on behalf of a Northwestern entity, it is important you follow the rules of the entity on whose behalf you are raising money. Contact the individuals listed at the end of this Handbook for further guidance.

**M. Charitable Events**

You may not accept from a Vendor, Referral Recipient, or Referral Source either tickets to a fundraising or other charitable event, or funds intended to be used to purchase tickets to a fundraising or other charitable event of another organization.

**N. Human Subjects Research**

Physicians should refer to Feinberg’s Disclosure and Professional Integrity Policy with respect rules governing the conduct of research. This policy is available at http://www.feinberg.northwestern.edu/compliance/links/.
O. Faculty Use of Students/Trainees in Outside Professional Activities

Physicians should refer to Feinberg’s Disclosure and Professional Integrity Policy with respect to the use of students/trainees in Outside Professional Activities. This policy is available at http://www.feinberg.northwestern.edu/compliance/links/.

P. Arrangements Requiring Legal Review

Any financial arrangements that you or an Immediate Family Member might have with non-Northwestern entities that perform or bill for “designated health services” must be discussed with NMFF Legal Services prior to your entering into the arrangement. “Designated health services” include 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. For purposes of this Section (Section P) only, an “Immediate Family Member” includes the following: husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Q. Patient Referrals to Family Members or to Entities in which You or Your Family Member has an Investment Interest or Financial Relationship

NMFF recognizes that, for a variety of reasons (including convenience, geographical proximity, or personal preference), patients may wish to seek care from providers other than Northwestern-affiliated providers (i.e. NMFF, NMH, NMPG, Children’s Memorial, and RIC). You must comply with the following safeguards to ensure that referrals to non-Northwestern entities are made in accordance with law and ethical standards. Examples of allowable and prohibited referrals are provided at the end of this Section (Section Q).

1. Referrals for services and products outside of Northwestern-affiliated providers should be made on the basis of what is best for the patient and never made in exchange for remuneration (whether monetary or in-kind), benefits, or favors of any kind from the recipient of the referrals.

2. Unless an exception has been granted by your Department Chair, NMFF’s CEO and NMFF’s General Counsel, and in accordance with applicable law and NMFF policy, no referrals for health care services may be made to entities in which you have or an Immediate Family Member has an investment interest. For purposes of this subsection, an “investment interest” does not include an investment interest in certain “publicly traded entities.” Contact NMFF Legal Services if you want more information about what constitutes a “publicly traded entity.”

3. Unless an exception is approved by your Department Chair, NMFF’s CEO, and NMFF’s General Counsel, and in accordance with applicable law and NMFF policy, no referrals may be made for Medicare patients for “designated health care services” to entities with which you or your
Immediate Family Member has a financial relationship (e.g., investment interest, compensation arrangement, or other). “Designated health services” include the following items or services: clinical laboratory services; physical therapy services; occupational therapy services; outpatient speech-language pathology services; radiology and certain 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; inpatient and outpatient hospital services. For purposes of this Section (Section Q.3) only, an “Immediate Family Member” includes the following: husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

4. If you refer a patient to an Immediate Family Member (or the Immediate Family Member’s facility, group, etc.) for health care services, you should always (i) disclose the relationship to the patient, and (ii) provide names of reasonably available alternative providers, if possible. Patients should be told that they may select the provider of their choice.

5. If you refer a patient for products to an entity in which you or an Immediate Family Member have an investment interest (such as a retail store offering health care products), you should always (i) disclose the relationship to the patient, and (ii) provide names of reasonably available alternative providers, if possible. Patients should be told that they may select the provider of their choice.

6. You should document disclosures required under this Section (Section Q) in the patient’s medical record.

7. EXAMPLES:

   ❖ Your father is part owner of an ambulatory surgery center. You should not refer a patient to the center unless you have been granted an exception to do so in accordance with law and NMFF policy. If granted an exception, you would need to practice at the center and be involved in providing care to your patient.

   ❖ Your wife is an owner (member) of A-B-C, LLC, a home health agency. Your wife is entitled to distributions pursuant to the LLC’s Member Agreement. You should not refer patients to A-B-C. NOTE: The referral is not allowed not only because of your wife’s ownership interest, but also for Medicare patients because home health services qualify as “designated health services.”

   ❖ Your adult child is employed as a physical therapist at a sports clinic in a suburb where your Medicare-eligible patient resides. Physical therapy services qualify as “designated health care services.” Therefore, you may not, absent an exception, refer the patient to your adult child, to another physical therapist at the clinic, or to the clinic generally.
Your husband is a specialist with a private medical practice (organized as a medical corporation) located in downtown Chicago. Your husband is employed by the practice but is not a shareholder. You may refer a patient to your spouse as long as you disclose your relationship, provide other alternatives, and emphasize that the patient is free to go to whom they please. Your conversation should be documented in the record. NOTE: This referral for physician services is not a referral for designated health care service. Nor would the referral be prohibited due to an investment interest by your husband. If, however, your husband were a shareholder, then you would not be allowed to make the referral unless you have been granted an exception to do so in accordance with law and NMFF policy.

R. Educational Grants and Donations

NMFF’s acceptance of grants and donations from Vendors must directly benefit NMFF patients or serve an educational purpose (e.g. a symposium with broad attendance). The provision of funding by Vendors should never influence clinical decision-making, purchasing or prescribing decisions, or the awarding of contracts. Accordingly, NMFF will not accept funding that is offered in connection with the purchase or sale of goods or services.

In order to achieve the above, you (and your department or division) must comply with the following safeguards:

For ACCME-accredited educational programs:

Grants and donations from Industry must directly benefit patients or serve an educational purpose (e.g., a symposium with broad attendance). The provision of funding by Industry should never influence clinical decision-making, prescribing, or purchasing decisions, or the awarding of contracts. Accordingly, Feinberg will not accept funding that is offered in connection with the purchase or sale of goods or services.

In order to achieve the above, faculty (and their department or division) must comply with the following safeguards:

For ACCME-accredited educational programs:

1. Permitted support includes funding for ACCME-accredited educational programs conducted by Feinberg to offset the cost of the CME program, such as catering, textbooks, educational materials, and outside speakers’ expenses. The distribution of the funds must be in compliance with Standard 3 of the ACCME’s Standards for Commercial Support including but not limited to:

   (a) All support must be given with full knowledge of the Feinberg Office of CME;
   (b) Support must be used to pay all or part of the cost of the CME activity, including the services of the institution in the production and distribution of the activity; and,
(c) The distribution of the funds must be outlined prior to the activity and the total amount of the grant is to be listed in the signed letter of agreement (LOA). The LOA must be signed by the Industry sponsor and the appropriate parties at Feinberg.

For non-ACCME-accredited educational programs and other purposes:

1. All educational grants or donations offered by Industry sponsors may be used for non-ACCME accredited educational programs and other purposes if, prior to acceptance, they are reported to and approved by the Feinberg Vice Dean for Regulatory Affairs. Approval requests must be submitted to the Feinberg Vice Dean for Regulatory Affairs via the online Request for Approval Form available on the Policy Links page of the Office for Regulatory Affairs website http://www.feinberg.northwestern.edu/compliance/links/.

2. The grant/donation must be memorialized in a written funding agreement with the Industry sponsor.

3. Industry sponsors may direct grants to a specific department and indicate the therapeutic area of the program to be funded. Industry sponsors, however, are not permitted to specify or pre-approve program content or speakers. Prior to the start of the presentation, program organizers must announce the sponsoring organization(s), and all program speakers must disclose any financial relationships with the Industry sponsors providing the grant, and any other relevant financial relationships.

4. Materials advertising non-ACCME accredited educational programs must list the names of the sponsoring organization(s) and must be submitted to the Feinberg Vice Dean for Regulatory Affairs for approval prior to display or distribution. Program support by an Industry sponsor shall be disclosed to all recipients of program materials.

5. 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. No donated funds may inure to the benefit of any Feinberg faculty, staff, or student/trainee.

S. Disclosure of External Professional Relationships

All physicians, management and staff members involved in procurement are required to disclose annually their Vendor relationships and other Outside Professional Activities. In addition, these individuals are required to update their listing of relationships and activities between annual surveys. Disclosures are made electronically (http://jointsurvey.feinberg.northwestern.edu), and information is shared among Feinberg, NMHC, and NMFF as appropriate. The disclosures are reviewed by representatives of Feinberg, NMHC, and NMFF to determine if a conflict of interest might exist. If so, a conflict management plan will be put in place. In addition, physician disclosures are made available to
the general public through publication on the Feinberg web site (http://fsmweb.northwestern.edu/faculty/).

Further detailed information about the joint disclosure process is available at http://www.feinberg.northwestern.edu/compliance/annual_disclosure_survey/index.html. Contact the Joint Survey Administration Team contact person listed in Part III if you have any questions about the joint disclosure survey process or reporting requirements.

**T. Reporting of Potential Misconduct or Violations of this Handbook**

Potential misconduct or violations of this Handbook may be reported on an anonymous basis at www.nmff.ethicspoint.com or by calling 1-877-228-5417. Alternatively, you may contact the individuals listed at the end of this Handbook. If you do not believe that the situation is being adequately addressed, you may discuss the situation with a member of NMFF’s Compliance and Audit Committee or a member of NMFF’s Board of Directors. Contact information is available from NMFF’s Legal Services (312-695-9166).

NMFF policy prohibits the taking of retaliatory action against anyone for reporting or inquiring about potential breaches of NMFF policy or for seeking guidance on how to handle suspected breaches.
Part II: Frequently Asked Questions

Gifts and Business Courtesies

Q: A drug company sales representative sent me flowers with a thank you note for trying a new product? Is this a permitted gift?
A: No. You may not accept gifts as a “thank you” for prescribing, purchasing, or ordering products. The flowers should be donated (with identifying information removed), and the sales representative should be requested not to send gifts in the future.

Q: How do I handle unsolicited gifts?
A: Do not accept the gift. If returning the gift is not feasible, then donate the gift or, in the case of a holiday food basket, share the gift with the department or practice area. Identifying information should be removed prior to sharing. Industry representatives and Referral Recipients should be requested not to send gifts in the future.

Q: May I provide a small gift to a community physician as a thank you for his referrals?
A: No. You may not provide gifts as a “thank you” for referrals.

Q: My brother-in-law works for a drug company. Am I prohibited from accepting holiday gifts from him?
A: Gifts given by family members and by friends who are your friends independent of the business relationship (e.g., a college friend who happens to be a sales rep) are not prohibited. However, the types of gifts accepted should be appropriate to the relationship. A lavish gift from a distant relative would raise the question of whether the gift really arose from the family relationship, or was influenced by your status at a Northwestern entity.

Q: My best friend is a primary care physician who sometimes makes referrals to NMFF. Am I prohibited from giving her a birthday gift?
A: Gifts to friends and relatives are not prohibited. However, the size and frequency of any such gift must be appropriate to the personal relationship, and it must be clear that the gift is not given in your capacity as a physician at a Northwestern entity, and is not for the purpose of influencing or rewarding referrals.

Q: I was given a gift certificate for attending a presentation on a new medical device. Is this appropriate?
A: No. Gifts—no matter how small—are not permitted.

Q: A sales rep provides samples of a certain drug that he knows my spouse uses for his medical condition. Is this permitted?
A: No. Samples should be provided for patient use, and handled according to NMHC’s or NMFF’s guidelines for maintaining and dispensing drug samples.

Q: Do I have to get rid of pens, coffee mugs, posters, anatomical models, and similar items with Industry logos that my department received under the previous policy (when de minimus items were allowed)?
A: No. However, you may not accept any new item.

Q: Is it appropriate for a drug company or a medical device manufacturer from whom my NMFF department or NMHC makes purchases to provide educational funding for fellows?
A: Possibly. All offers of scholarships and fellowships from Vendors must be submitted to the Feinberg Office for Regulatory Affairs for prior approval. The Feinberg Vice Dean for Regulatory Affairs, after consultation with the appropriate Department Chair when relevant, will evaluate and select uses and the
recipient of such funds with no involvement by the donor. There must be no *quid pro quo* for the acceptance of such funds.

**Q. Is it appropriate for medical device manufacturer from whom my NMFF department or NMHC makes purchases to provide a research grant to my Feinberg department?**

**A.** The receipt of benefits in exchange for purchases raises possible ethical issues as well as legal issues under the Stark Law and Anti-Kickback Statute. Even if a purchase contract is silent as to the exchange or expressly states that the purchase is made independently of any other exchange between the parties, the facts and circumstances may still be problematic. If this situation arises, contact NMFF or NMHC attorneys as appropriate.

**Q: May I accept patient education literature from a Vendor for distribution to patients?**

**A: Yes.**

**Physician Consulting, Advisory Boards, Speaking Engagements, and Similar Compensated Activities**

**Q:** I perform consulting services on my own time. Why is this any of Feinberg's, NMHC's, or NMFF’s business?

**A:** Your activities can reflect on Northwestern University, NMHC, and NMFF as well as you. The guidelines relating to consulting and other compensation arrangements are intended to protect you and the Northwestern entities from arrangements that could be viewed as improperly affecting purchasing, prescribing, or other patient care decisions.

**Q:** Will Legal Services review and approve a proposed contract?

**A:** You enter into consulting agreements on an individual basis. Accordingly, you are responsible for negotiating the agreement’s terms and conditions. However, NMFF Legal Services is available to answer questions with respect to whether or not the agreement complies with the contracting guidelines set forth in this Handbook. In addition, legal counsel should be consulted when a Northwestern entity may be affected by the arrangement (e.g., intellectual property rights).

**Q:** Am I covered by the insurance policies of any Northwestern entity when I do my consulting work?

**A:** No.

**Q:** What kind of payment mechanisms are ok? How do I know if the payment is ‘fair market value’?

**A:** As an initial matter, payment amounts or mechanisms need to be set in advance. Payment for services on an hourly basis is fine (as long as the amount paid per hour reflects fair market value). If payment is structured on this basis, it is very important that your services be documented (i.e. date, amount of time spent, description of activity) in order to justify the payment. We recognize that many arrangements may pay a per diem. This is fine as long the hours spent in the activity, when divided into the per diem, equals an hourly rate that reflects fair market value. Physicians should avoid retainer arrangements where amounts are paid prior to and without regard to the performance of services. It is better to document time spent and submit this to the Vendor for payment at rates that are not excessive. Fair market value can be established by looking at independent benchmarks (e.g., MGMA and AAMC compensation data).
Q: How should I handle royalty payments?
A: When compensation is based on a royalty or similar arrangement, the payment amount should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. Specifically, the payment amount (i) must not be conditioned on a requirement that you or a Northwestern entity purchase, order, or recommend any product or medical technology or a requirement to market the product or medical technology upon commercialization; and (ii) should exclude from the calculation of royalties the number of units purchased, used, or ordered by you, members of your practice, or any Northwestern entity. Accordingly, for any agreement that does not comply, you should amend your royalty contract to exclude royalties for products purchased by any Northwestern entity. If doing so is not feasible, then contact the company to determine the amount of your royalties attributable to Northwestern purchases and reimburse the company that amount. Be sure to document everything and retain that documentation.

Educational Programs and Continuing Medical Education

Q: I am a member of the scientific advisory board for a device company. A meeting of the scientific advisory board is scheduled for the day after a major medical conference in my specialty that I would like to attend. May I use the round trip ticket provided to attend the advisory board to attend the meeting as well?
A: If the scientific advisory board meeting is a bona fide meeting of the advisory board, and the timing and location in connection with the conference make the advisory board meeting more convenient and likely to be attended by advisory board members, then the round trip ticket may be used to attend the conference. However, advisory board meetings should not be scheduled before or after medical conferences as a pretext for funding attendance at the conference. In addition, conference registration fees, hotel expenses, and meals during the conference should not be paid by the advisory board sponsor.

Q: A medical device company proposes to pay for me to attend a medical conference and report back to the company on the proceedings. Is this appropriate?
A: No. This appears to be a pretext for paying for the expenses of attending a medical conference.

Q: My Department is considering the purchase of a major piece of equipment. The equipment will be displayed and demonstrated at a medical conference. The manufacturer has offered to pay for two members of the Department to attend the conference to view the equipment. Is this permitted?
A: No.

Q: Why am I prohibited from accepting payment from a manufacturer for attending a third-party medical conference, but am allowed to do so to attend training on a manufacturer’s products?
A: There are similarities between the two types of programs. However, medical device companies have an obligation to ensure that their devices are used properly. Although training programs involving a manufacturer’s products may include general medical, scientific, and technical information, the primary focus is on the use of products. Such programs do not have independent value to physicians, but rather are provided to ensure that the products are used safely and effectively. Subsidizing attendance at third-party educational events, on the other hand, potentially provides value to physicians and a Northwestern entity by reducing or eliminating the cost of Continuing Medical Education (CME) or the amount that
otherwise would be spent to attend educational programs. Therefore, manufacturers should provide
funding to the conference sponsor rather than individual attendees. Such funding may reduce the costs
for all attendees, as opposed to being targeted to specific customers of the manufacturer.

Q: There is a reception at a medical conference sponsored by a drug manufacturer that is open to spouses
of attendees. Is this permitted?
A: The sponsor of a medical conference sets the rules for conference-related activities that may be
supported by Industry. If the reception is not lavish, is subordinate to and does not interfere with the
educational portion of the conference, and is open to all attendees, it is probably fine. However, a
conference that includes extensive entertainment for attendees and spouses as opposed to focusing
primarily on educational and scientific topic should be viewed with suspicion. Contact the Feinberg
contact person listed in Part III if you have any question about conference activities.

Vendor Support of Scholarships and Fellowships
Q: My Department is a very good customer of a certain drug company. Can I use information about our
purchases in an application for a research grant?
A: No. Grants may not be solicited or accepted in return for or as a reward for purchasing or prescribing a
Vendor’s products. To avoid even the appearance of impropriety, discussions of grants should be
completely separate from any discussions of purchasing. Many Vendors have separated their sales and
marketing functions from their grant-making functions. You should report to contact person of the
affected entity (see Part III) any Vendor that attempts to link purchases and grants or donations.

Meals
Q: A drug sales rep brings in lunch occasionally and provides information about the company’s products.
Is this okay?
A: No. Sales representatives are no longer permitted to bring food on-site.

Q. What if the sales rep asked me to join him for lunch or dinner at a restaurant to learn more about the
products and services offered by the company?
A. You can go to lunch or dinner, but the sales rep cannot pay for your food. You (or your NMFF
department) would need to buy the meal.

Q: May I accept tickets to a charity benefit dinner or charity golf event, or funds to purchase tickets to a
charity benefit or charity golf event, from a Vendor such as a drug company?
A: No. A Vendor may make a donation for such an event directly to the charity. If the Vendor chooses not to
use all of the tickets to the dinner or golf event, the Vendor should let the charity choose persons to use
the tickets.

Q: I can provide much more information about NMFF programs to a potential Referral Source if I have his
attention for several hours on the golf course than if I have him just for a lunch or dinner. Why is golf
prohibited?
A: While it is possible to conduct legitimate business on the golf course, golf is inherently recreational, and
providing recreational activities for Referral Sources could create the appearance that a purpose is to
generate business.
Vendor Provision of Demonstration Products and Other Services

Q: Can my department bill for services provided using demonstration equipment?
A: Occasionally Vendors of medical equipment and supplies offer a department free items or free trial use of equipment in order for the department to evaluate whether to purchase the items or equipment. While such free trials are appropriate and useful in many circumstances, it is important to ensure that these arrangements are properly documented, to ensure that they cannot be characterized as improper incentives to use or purchase a particular Vendor’s products. The following are guidelines to keep in mind:

- Free trial use of equipment and/or free items should be limited to no more time than what is reasonably necessary to evaluate the products.
- If a free item is separately reimbursable by payors, the department should not bill for the item.
- In the case of free trial use of equipment, contact legal counsel for NMFF or NMHC, as appropriate, to determine whether any billing is appropriate. It may be appropriate to bill for the associated professional component of the service. It is generally not appropriate for a department to bill for use of the equipment (i.e. the technical component) if the equipment is provided as part of a free trial.
- There should be a written agreement between the Northwestern entity and the Vendor, describing the terms of the free trial.

Contact legal counsel for NMHC or NMFF, as appropriate, for review of all free trial arrangements.

Purchase Contracts and Discounts

Q: My Department is a very good customer of a certain manufacturer. Can our contract to purchase the manufacturer’s products include a requirement that the company provide research funding to NU?
A: No. Donations may not be solicited in connection with purchase contracts. While a discount on items purchased is completely legitimate, a grant in exchange for purchases may be viewed as a kickback or improper hidden discount. The legal issues raised by purchase arrangements can be complex and are not always obvious. For this reason, contracts must be reviewed by appropriate personnel in the affected Northwestern entity and executed by authorized signatories. Negotiations for purchases should never be mixed with discussions of research or educational grants.

Vendor Access to Premises

Q: I understand that, as a physician, I can no longer accept meals brought in by a pharmaceutical representative to be eaten during her presentation on new drugs. However, my staff works really hard and these occasional lunches are something they always enjoy. Is it really that big of a deal for the staff? They don’t make purchasing decisions.
A: Yes, it is a big deal. A physician should not do indirectly what he cannot do directly. This position also eliminates the appearance of impropriety.
Part III: Contacts Referenced in this Handbook

Feinberg

- Robert M. Rosa, MD, Vice Dean for Regulatory Affairs; rrosa@northwestern.edu; 312-908-8491
- Stephanie Graham, Deputy General Counsel; smg@northwestern.edu; 847-491-3503

NMHC

- Carol M. Lind, Senior Vice President, Senior Counsel; clind@nmh.org; 312-926-4505
- Jennifer Wooten, Chief Integrity Executive; jwooton@nmh.org; 312-926-8320
- Holli I. Salls, Vice President, Public Relations and Marketing; hsalls@nmh.org; 312-926-2121
- Nancy E. Hensley, Director of Sourcing and Procurement; nhensley@nmh.org; 312-926-0056

NMFF

- Robert M. Rosa, MD, Chief Compliance Officer; rrosa@northwestern.edu; 312-908-8491
- Laurel Fleming, Assistant General Counsel; lfleming@nmff.org; 312-695-9452

Joint Survey Administration Team

- Bridget B. Chamberlain, Director Compliance and Joint Survey Administrator; bridget-chamberlain@northwestern.edu; 312-503-2855