

Professional Integrity Handbook

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Part I: Professional Integrity: General Provisions

A. Scope and Applicability

Northwestern Memorial HealthCare and entities wholly-owned or wholly-controlled by Northwestern Memorial HealthCare (each individually referred to as an "NMHC-entity," and collectively referred to as "NMHC") are committed to the highest standards of honesty, integrity, and fairness and to conducting business in compliance with all applicable federal and state laws, regulations, the NMHC Integrated Code of Ethics, and all applicable organizational policies and procedures. Consistent with this commitment, this Handbook sets forth the "Rules of the Road" with respect to professional relationships with Vendors, Referral Recipients, and Referral Sources (defined below). This Handbook also explains how to handle gifts from patients.

This Handbook applies to you if you are NMHC personnel (including an employed physician); volunteer; corporate officer; director; Board committee member; student trainee; temporary agency staff or leased personnel; house staff; and medical staff member who (a) holds a paid or unpaid medical administrative position (e.g., Clinical Department Chair, Section and Division Chief, or special care unit director), (b) has procurement responsibility or the authority to recommend such procurement, or (c) participates on Boards or Board committees; or a person whose conduct is under the direct control of NMHC ("NMHC Personnel"). Please note that some provisions only apply to physicians. If so, this is clearly stated in the title of the section.

B. Definitions

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. ACCME: Accreditation Council for Continuing Medical Education.
- 2. Applicable Manufacturer: An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients. An Applicable Manufacturer would include, for example, a pharmaceutical or device company.
- **3. CCI:** NMHC's Office of Corporate Compliance and Integrity.
- 4. CMS: Centers for Medicare and Medicaid Services.
- **5. Clinical Department Chair**: Those individuals designated by NMHC as Department Chairs or equivalent physician leaders.
- **6. FDA:** United States Food and Drug Administration.
- 7. Feinberg: The Feinberg School of Medicine of Northwestern University.

- 8. Immediate Family Member: Unless otherwise defined, all references to "Immediate Family Member[s]" include your spouse/domestic partner/civil union partner and children. Immediate Family Members also include the following persons if they live with you, you manage their financial affairs, or you are aware without inquiry that they hold the interest or position in question: your parents, siblings, grandchildren, and their spouses/domestic partners/civil union partners; your spouse's/civil union partner's parents, siblings, children, grandchildren, and their spouses/domestic partner/civil union partners.
- **9. NMHC:** Northwestern Memorial HealthCare and entities wholly-owned or wholly-controlled by Northwestern Memorial HealthCare (individually referred to herein as an "NMHC-entity," and collectively referred to herein as "NMHC"). For purposes of this definition, "NMHC" and "NMHC-entity" shall also include those entities partially-controlled by NMHC (i.e. joint ventures) if, within a policy addressing joint ventures, the entities are expressly identified as being subject to this policy.
- 10. NMHC Personnel: NMHC personnel (including employed physicians); volunteers; corporate officers; directors; Board committee members; student trainees; temporary agency staff or leased personnel; house staff; or medical staff members who (a) hold a paid or unpaid medical administrative position (e.g., Clinical Department Chairs, Section and Division Chiefs, or special care unit directors), (b) have procurement responsibility or the authority to recommend such procurement, or (c) participate on Boards or Board committees; or persons whose conduct is under the direct control of NMHC.
- 11. OGC: NMHC's Office of General Counsel.
- 12. Ownership or Investment Interest: An Ownership or Investment Interest includes arrangements where you have (or plan to have) equity, debt, or other proprietary interests (including stock, stock options, profit sharing plans, LLC memberships, partnerships, and joint ventures) in any entity. An "indirect Ownership or Investment Interest" includes any equity, debt, or other proprietary interest held through a business investment or by an Immediate Family Member. For example, you have an indirect ownership interest in a nursing home if you are a shareholder in a company that is a shareholder of the nursing home. An interest comprised solely of publicly traded securities or mutual funds is considered an Ownership or Investment Interest only if such interest is five percent (5%) or more of any class of shares or other securities outstanding.
- **13. Outside Professional Activity(ies)**: Any paid or volunteer activity undertaken by you that is outside the scope of your regular NMHC 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 NMHC occupation or another occupation.
- **14. Referral Recipient:** 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 NMHC. 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.

- **15. Referral Source:** A person or entity, or an employee or representative of a person or entity, who or which refers or could potentially refer patients to NMHC. Referral Sources include, for example, community physicians who refer patients to NMHC for specialty services. **See explanatory note at the end of this section.**
- 16. Vendor or Industry: Any individual or entity that provides or could provide products or services of any type to NMHC or Feinberg. 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; 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.
- **17. You:** "You" refers to any person to whom this Handbook applies. Where appropriate we have indicated specific roles that may be affected by the Handbook provision.

NOTE: "Vendor," "Industry," "Referral Recipient," and "Referral Source" all refer to entities other than NMHC-entities. While the relationships between NMHC-entities must be carefully monitored, we have implemented processes to do so.

C. Disclosure of External Professional Relationships to NMHC and Patients

1. Disclosures to NMHC

Fundamental to the mission of NMHC is the advancement of public health. This mission is critically dependent on the public's trust in the integrity of the patient care, research and educational activities performed within our institution. To that end, relationships with Vendors, Industry or other external entities, which often result in breakthroughs in medical research and promising new therapies, should be encouraged but also closely monitored to ensure that these relationships are not – or do not appear to be – influenced by factors other than the pursuit of knowledge and the best interests of the patient.

Accordingly, NMHC policy requires NMHC Personnel to disclose Vendor and Industry relationships, as well as other Outside Professional Activities in accordance with NMHC Administrative Policy: Conflict of Interest. This includes completion of the Annual Joint Disclosure Survey where applicable. Your disclosures are reviewed by CCI to determine if a conflict of interest might exist. If you also have a role at Feinberg, the Ann & Robert H. Lurie Children's Hospital of Chicago, or the Shirley Ryan AbilityLab, then representatives from those institutions

will also review your disclosures. If CCI determines that a conflict exists, a conflict management plan will be put in place. Research conflicts of interest are subject to separate processes. Further detailed information about the joint disclosure process is available at (http://www.feinberg.northwestern.edu/compliance/annual_disclosure_survey/index.html).

2. Disclosures to Patients: Physicians

NMHC requires that physicians disclose the following to patients receiving care at NMHC:

- Ownership or Investment Interests in entities involved in the manufacture, distribution, or sale of a product that you may use in treating a patient; and
- Royalties that you may receive on a product that you may use in treating a patient.

Although you must disclose any such interest, regardless of amount, you do not need to disclose specific amounts or values related to the Ownership or Investment Interest or royalties. Your disclosure should, however, be documented in the patient's record. The following talking points can guide you in making the disclosure (or in the event patients ask you directly about your relationships with Vendors and Industry):

- Tell the truth and acknowledge your relationship. In doing so, you may choose to emphasize the benefits to patients resulting from the relationship, as long as these are factual and evidence-based.
- Explain that NMHC has rules governing your relationships, that you are also required to report your relationships at least annually for review by NMHC and, as applicable, Feinberg.
- If the patient is concerned about your choice of a particular drug or device, take the time
 to explain why you made the choice that you did. Patients may be comforted by the fact
 that you are very familiar with a product that you may have helped develop or for which
 you provided consulting services.

Your disclosure should be documented in the patient's record. Contact CCI at compliance@nm.org or by calling (312) 926-4800 for specific instructions regarding such documentation.

D. Reporting of Potential Misconduct or Violations of this Handbook

Potential misconduct or violations of this Handbook should be reported. You may report to your supervisor or manager or to CCI at compliance@nm.org or by calling 312-926-4800. You may also report misconduct or violations through NMHC's confidential reporting system. The confidential hotline (844-339-6271) and web-based reporting portal (www.nm.ethicspoint.com) is administered by an outside (non-NMHC) company, so you may remain anonymous if you wish to do so. If you do not believe that the situation is being adequately addressed, you may discuss the situation with NMHC's Vice President, Integrity. Contact information is available on CCI's web site on NM Interactive.

NMHC policy prohibits retaliatory action against anyone for reporting or inquiring about potential breaches of NMHC policy or laws and regulations or for seeking guidance on how to handle suspected breaches.

E. Enforcement

Managers are responsible for ensuring that this Handbook is communicated to and understood by personnel and others in their respective areas and for enforcing the provisions of this Handbook. Violations of this Handbook are subject to disciplinary action in accordance with applicable NMHC policies.

F. Questions and Assistance

If you have questions about the items discussed in this Handbook, please contact CCI at compliance@nm.org or by calling 312-926-4800. For questions about professional integrity in research, please contact either the Northwestern University Office for Research or the NMHC Office of Research, as applicable.

Part II: Professional Integrity: Specific Applications

Not all scenarios that you may encounter may be addressed in the following pages. You should, therefore, contact the NMHC Office of Corporate Compliance & Integrity ("CCI") with any questions or concerns. **Note to Physicians:** Physicians and others with faculty appointments at Feinberg should also refer to Feinberg's Disclosure and Professional Integrity Policy, which is available at the following address:

http://www.feinberg.northwestern.edu/compliance/documents/2017 feinberg disc integ policy1.pdf.

A. Gifts and Business Courtesies

1. Gifts from or to Vendors, Referral Recipients, or Referral Sources

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; raffle items; services; personal travel; personal discounts; supplies; equipment; referrals; employment; food; attendance at plays, concerts, sporting events, golf outings; or any other entertainment events or hospitality.

Unless provided otherwise in this Handbook, you may not accept gifts or business courtesies of any value from Vendors/Industry or from Referral Recipients. This prohibition includes the items listed above, as well as acceptance of personal use of a Vendor's 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 other gifts in recognition of a life event, 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.

While personal discounts from a Vendor are prohibited, NMHC-wide discounts or promotions available to all personnel are not considered a gift or business courtesy (see Part II, Section J, Purchase Contracts and Discounts). In addition, the prohibition discussed in this paragraph does not apply to the following:

- if you pay for the gift or business courtesy (or reimburse the Vendor 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. The amount that you pay, however, should be consistent with the fair market value of the gift or business courtesy;
- drug samples, maintained and dispensed in accordance with NMHC operating guidelines applicable to your NMHC-entity;
- items otherwise expressly allowed in this Handbook (e.g., certain meals as set forth in Part II, Section E).

As a general rule, if you receive a gift, you must return it. However, if returning the gift is impractical, you may dispose of the item or donate it to Northwestern Memorial Foundation. Flowers, food, or other perishable items may be shared with your department. Prior to sharing, you must remove the name or other identification of the Vendor or Referral Recipient. Vendors and Industry representatives should be requested not to send gifts in the future.

Similarly, unless otherwise provided in this Handbook (see Part II, Section F) neither you nor your Immediate Family Members may give gifts or business courtesies of any value to Referral Sources.

2. Gifts from Patients

We ask that you use professional judgment in accepting gifts from patients. Flowers, food, or other modest perishable items may be shared with your department. Cash or cash equivalents (e.g., gift cards, tickets to events, etc.) should generally not be accepted. If a patient indicates a desire to give a monetary gift, please direct the patient to contact Northwestern Memorial Foundation so that an arrangement can be set up in accordance with the donor's intent.

3. Gifts to Patients

It is illegal to offer to a Medicare or Medicaid beneficiary any gift or other remuneration in order to influence the beneficiary's selection of NMHC as his or her provider of health care. This means that NMHC cannot waive, in whole or in part, a Medicare or Medicaid beneficiary's copayments and deductible amounts (except as part of NMHC's Financial Assistance Program) or provide meals or other gifts other than those of nominal value. The Office of Inspector General interprets

"nominal value" as any item having a retail value of no more than \$15 per item or \$75 in the aggregate per patient on an annual basis. The item, however, may not be cash or cash equivalents (e.g., gift cards). If your department or practice area is considering offering gifts to patients (including transportation), please contact CCI before doing so.

4. Gifts to Support Research and Education

Please contact CCI, prior to acceptance, about any gifts from Vendors or Referral Recipients to support clinical research as well as offers of scholarships and fellowships from Vendors. These matters must be coordinated with Northwestern Memorial Foundation and, if applicable, may need to comply with Feinberg requirements. 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.

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

Subject to the terms of your employment agreement, if any, you may enter into arrangements to provide consulting, medical directorship, product development, advisory committee, teaching/speaking, or other professional 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. Payment of compensation may not (i) be used to influence decision-making with respect to NMHC, (ii) induce referral of patients or the ordering of a service or supply, or (iii) take into account the volume or value of referrals, purchases, or business generated.

NOTE: This section addresses activities done in your personal capacity and outside of the scope of your NMHC duties. Accordingly, NMHC will not indemnify, defend, or provide legal counsel for any proceeding or cause of action arising from such activities. NMHC's insurance will not cover you. In conducting these activities, you should not hold yourself out as a representative of NMHC or in any way imply that your opinions are shared or endorsed by NMHC. For guidance in these matters, please contact OGC.

- 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 a physician choose to participate in a speakers' bureau, the content and format of the presentation should be educational and adhere to all FDA requirements.
- **2. Ghost Writing.** "Ghost writing" (i.e., authoring or co-authoring articles where your name or NMHC's or Feinberg's name is used without your substantive contribution) is prohibited. If Vendor employees are co-authors, then this should be made known to the reader. There should be full disclosure of the role of each author to the reader.

- 3. Medical-Legal Consulting Activities. If you review, consult and/or testify in any legal proceeding or medical malpractice claim where you are not involved as a party or treating physician, you are prohibited from using NM facilities, staff or other resources for any related activities. Employed providers must abide by the OGC's directives regarding the independent provision of Expert Witness Testimony. Any Expert Witness Testimony provided in your individual capacity must be disclosed to and approved by your Department Chair prior to you providing said Expert Witness Testimony. You may use the Expert Witness Consulting Notification form for said notification and approval.
- **4. Contract Guidelines.** Each arrangement must meet the following guidelines:
 - a) There must be a signed, written contract reflecting the terms and conditions of the arrangement. Please understand that you enter into and sign the contract in your *individual* capacity (i.e. not on behalf of NMHC). NOTE: Certain arrangements, such as facility medical director agreements, as well as arrangements involving the provision of clinical services, should be executed by an NMHC-entity directly. Such arrangements should be coordinated through OGC.
 - 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 includes other terms that would restrict or interfere with your job-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 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 NMHC purchase, order, recommend, or use 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 NMHC. 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 NMHC. If doing so is not feasible, then contact the company to determine the amount of your royalties attributable to NMHC 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 NMHC, 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 NMHC's or Feinberg's confidential or proprietary information. In addition, because you perform consulting in your individual capacity, you may not use NMHC or Feinberg letterhead in the performance of consulting activities.
- 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, CCI is available to answer questions on an as-needed basis with respect to compliance of the arrangement with these contract guidelines.

NOTE: Compensated arrangements may be subject to audit by CCI and/or Internal Audit and you are required, upon request by CCI or Internal Audit, to provide evidence of compliance (including copies of contracts, time reports, receipt of payment, reimbursements or contribution, etc.). In addition, if you enter into consulting or other agreements with parties that require assignment of ownership rights in intellectual property, you should be aware that conflicts of interest may arise. Please refer to NMHC Administrative Policy: NMH ADM 01.0010, <u>Protection of Inventions, Discoveries, Trade Secrets and Publications</u>. For guidance in these matters, please contact CCI. Physicians with Feinberg faculty appointments should also notify the Northwestern University Technology Transfer Program of any patents or inventions arising from external consulting agreements.

C. Educational Conferences and Programs

You may attend educational conferences and programs as provided below. NOTE: Educational conferences and programs do not include meetings that deal solely with marketing of a Vendor's product or service. A Vendor may not pay for your registration fee, travel or lodging or provide other support for you to attend meetings that deal solely with marketing of the Vendor's products or services or where the purpose of the meeting is to view the Vendor's products or equipment that NMHC is considering purchasing (see Part II, Section F).

1. General Guidelines

a) Program Faculty. If you are a speaker, presenter, moderator, or otherwise provide a substantial educational role at a bona fide educational program, meeting or conference, you may accept a reasonable honorarium and reimbursement for travel, lodging, and meal expenses to attend the program, meeting or 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. NOTE: Absent your playing a substantial educational role at an educational program, Industry may not offer you an honorarium and/or reimburse your travel expenses to encourage your attendance as a "key opinion leader."

- b) Attendees. Unless you are a speaker, presenter, or moderator at an educational conference or meeting or unless you are receiving medical device manufacturer-sponsored training or education on a device or product currently in active use at NMHC (see Part II, Section D), a Vendor or Referral Recipient may not cover the cost of your attendance (i.e. registration fees, travel or lodging) at educational conferences or programs. Certain meals provided in connection with attendance at an educational conference, professional meeting or medical device training may be permitted under Part II, Section E.
- c) Conference-Related or Approved Meals and Receptions/Nominal Gifts. You may accept food only as allowed under Part II, Section E. You may accept a gift from a Vendor or Referral Source provided in connection with a paid educational conference or program as long as the gift is of nominal value and is generally available to all conference attendees. For example, you may accept a cloth bag given to all registrants to carry conference materials or a pen donated by a Vendor and made available to all attendees. You should not, however, use or display the gift at NMHC.
- **d) Attendance by Spouses 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.
- **e) 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.

2. Physician and Clinical Education Programs

Except as allowed under Part II, Section D, physicians should attend only those medical education programs that receive Industry funding if the program is (i) an ACCME-accredited program, (ii) if you have a Feinberg faculty appointment, a program sponsored by Feinberg or a Feinberg-affiliated institution and approved by the Feinberg Vice Dean for Regulatory Affairs, (iii) a professional society meeting that follows ACCME standards, or (iv) a non-ACCME-accredited program that you believe would advance the academic mission of your department or division, in which case you shall explain the basis for this and receive approval from your Department Chair, Division Chief, or Center/Institute Director and, if you have a Feinberg faculty appointment, the Feinberg Vice Dean for Regulatory Affairs prior to attendance. Similarly, except as allowed under Part II Section D, non-physician clinicians should attend only those medical education programs that receive Industry funding if the program is (i) an accredited program and/or offers continuing education units ("CEU"), (ii) a professional society meeting, or (iii) a program that you believe

would advance the academic mission of your department or division, in which case you shall explain the basis for this and receive approval from your supervisor, Department Chair, Division Chief, Center/Institute Director, or other person with authority. It is anticipated that attendance at non-accredited/non-CEU programs will be limited and relatively infrequent. Please note that an approval by your supervisor, Department Chair, Division Chief, or Center/Institute Director is for attendance only. You or your Department/Division must, except for meals (see Part II, Section E) or unless otherwise provided in this Handbook, independently pay for the program registration fee or other expenses of attending the program.

3. Sponsoring an Educational Event

Partnering with either a for-profit or not-for-profit ACCME provider (other than the Feinberg Office of Continuing Medical Education) to sponsor an educational event is permitted only with the approval of the relevant Chair and, if you have a Feinberg faculty appointment, the Feinberg Vice Dean for Regulatory Affairs. If CME credit will be awarded for an educational program, please contact the following the Feinberg Office of Continuing Medical Education to ensure compliance with accreditation guidelines.

D. Training and Education Regarding Use of Medical Devices or Other Products in Use at NMHC

NMHC recognizes that the FDA mandates training and education to facilitate the safe and effective use of certain medical technology used at NMHC. Manufacturers of or other entities providing products in use at NMHC (e.g., software Vendors, equipment Vendors, etc.) may also offer training or educational programs with respect to the use of such products. Attendees often participate on committees or user groups for these Vendors. While attendance at the above-described manufacturer-sponsored training and education may be necessary and valuable, the activities surrounding training and education provided to you, however, may raise at least the appearance of impropriety. To ensure that you receive appropriate training and education free from inappropriate influences over your clinical prescribing and purchasing decisions, you must adhere to the following guidelines regarding attendance at manufacturer-sponsored training and education sessions:

- You may attend 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 NMHC and its patients. In advance of the trip, you should inform your supervisor that you plan to attend the manufacturer-sponsored training and education.
- 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, meals, and other expenses in connection with a training and education 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 and education 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 or other manufacturer 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 and education program.

E. Meals

Vendor representatives are not permitted to provide food on-site at NMHC. 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. If a working lunch with a Vendor is necessary on-site at NMHC, NMHC should provide the lunch.

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, the meals and receptions must be (i) 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 (ii) generally available to all attendees. For example, meals, such as lunches, refreshments, and receptions that are included in the conference fee and available for all attendees are appropriate. If you have a Feinberg faculty appointment, the event must also comply with the guidelines of the ACCME.
- 2. Non-Accredited Programs. If you are a physician or other clinician attending a non-accredited/non-CEU program for which you have received approval pursuant to Part II, Section C, you may accept a meal or attend a reception in connection with the program as long as the meal or reception is (i) modest, incidental, and subordinate to the educational purpose of the meeting, with most of the time dedicated to the educational purpose, and (ii) generally available to all attendees.
- **3. Manufacturer-Sponsored Training and Education.** In accordance with Part II, Section D, you may attend modest meals and receptions when attending Vendor-sponsored training and education regarding the use of medical devices or other products used at NMHC.

- **4. Services**. In accordance with Part II, Section B, you may attend modest meals and receptions in connection with your performance of legitimate contractual services for Industry (e.g., consulting).
- **5. Networking Events.** Food provided at networking events may be accepted in accordance with Part II, Section G.
- **6. Vendor Open Houses.** You may accept modest food at a Vendor open house that is open to the professional community.

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. 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 Part II, Section F.

F. Marketing and Promotional Activities

As it is the goal of NMHC to consistently demonstrate our commitment to transparency in all that we do, we must minimize the appearance of conflicts of interest. This includes carefully managing promotional interactions with our Vendors/Industry, Referral Recipients, and Referral Sources. For this reason, CCI must review all requests to engage in public relations and sales and marketing activities on behalf of NMHC or on behalf of a Vendor/Industry or Referral Source. This includes contractual agreements that call for promotional activities, verbal requests for participation in promotional activities, and use of any NMHC logo(s), formal name(s) or branding identity whether institutional, departmental or service line in nature.

Activities in question include, but are not limited to, providing service testimonials and product endorsements, engaging in collateral promotions like joint press releases, or providing our premises for video shoots. For example, a drug company may request our permission to use the Northwestern Medicine name and logo in an online ad that promotes the availability of its products at an NMHC hospital or outpatient location. Another example may involve the mutual interest of an NMG physician and a device maker with which he or she works to co-sponsor a patient seminar that promotes a procedure or clinical service. In another instance, one of our preferred MRI facilities may want to develop a video using NMHC clinicians touting the benefits of its services such that the video can be posted on its website. Regardless, any and all proposed promotional arrangements involving the public dissemination of an NMHC affiliated name or logo, including job titles and clinical department names, must be reviewed and approved by CCI.

NMHC reviews and monitors these activities to ensure that the NMHC name is used only by appropriate parties and in appropriate circumstances. NMHC also wants to ensure that all applicable policies are followed and to determine whether it is appropriate to use NMHC's or a physician's name in connection

with the arrangement; whether NMHC may accept any funding with respect to the arrangement; and whether NMHC should pay a share of funding for the proposed activity or event.

When marketing NMHC program services or product lines to potential or current customers, you may provide modest meals or food items if doing so is necessary in order to secure a face-to-face meeting for purposes of discussing NMHC program services or product lines. You may also provide low value items (e.g., pens, mugs, umbrellas, etc., with the NM logo) for purposes of reminding the potential customer about NMHC program services or product lines. A low value token of appreciation may be provided to customers no more than once per year (e.g., during the holiday season). NMHC Property Operations may provide more frequent tenant appreciation activities (e.g., seasonal food). The value of the item provided should not reflect the volume or value of business from any particular customer. Notwithstanding the foregoing, you should check with the customer to make sure that the provision of meals, food, or items as described above is permissible under the customer's own policies and procedures. NOTE: If you provide a meal, food, or item as described above to a physician Referral Source, you must track and log these items. Please refer to the policy addressing "non-monetary compensation" applicable to your NMHC-entity or contact CCI.

NOTE: A Vendor may not pay for your registration fee, travel or lodging or provide other support for you to attend meetings that deal solely with marketing of the Vendor's products or services or where the purpose of the meeting is to view the Vendor's products or equipment that NMHC is considering purchasing.

G. Networking Events

NMHC recognizes that networking events hosted by Vendors may provide an opportunity to stay relevant in an Industry and to develop and maintain important professional relationships that benefit NMHC. However, such events may raise at least the appearance of impropriety. In order to minimize inappropriate influences over your ability to make decisions for NMHC and its patients, you must adhere to the following guidelines:

- 1. Networking events do not include meetings that deal solely with marketing of a Vendor's product or service.
- 2. Other than modest receptions or meals, you should pay for the event. For example, if you are invited to a reception followed by attendance at a Blackhawks game, you may attend the reception, but you should pay for your own ticket to the game. Similarly, if a law firm sponsors a cooking class and invites in-house counsel from multiple institutions, you may attend but should pay for your own cooking class. If paying for your ticket is not feasible, you should not go.
- 3. The event itself should focus on allowing attendees to interact. For example, if a Vendor provides tickets to the opera (i.e., an event that would not allow for significant interaction of the attendees), then you should not attend (or should pay for your own ticket). If the Vendor offers a reception in conjunction with the opera, you may attend the reception, but should pay for your own opera ticket; if paying for your ticket is not feasible, you should not go;

- **4.** If the event is offered in conjunction with a professional conference, it should be subordinate to and not interfere with the educational portion of the conference. For example, attendance at a Vendor-sponsored wine and cheese reception following the conference day is fine. NOTE: If the professional conference sponsor provides a networking activity (i.e., the event is not provided solely by a Vendor) as part of a conference, you may participate in the event;
- **5.** The event should be an "open event" (i.e., to all attendees at a conference, to multiple customers or clients). It should not be limited to NM alone;
- **6.** The environment should be conducive to interaction. For example, attendance at a sporting event where it is difficult to mingle or hear conversation is not an appropriate networking event. You may attend, but should buy your own ticket.

NMHC expects that you will apply professional judgment in attending networking events. When in doubt, you must take a conservative approach and look for another way to network. NMHC seeks to minimize even the appearance of impropriety.

H. Health Fairs

In reference to health fairs, the following standards will apply to any Vendor which participates in or contributes to a health fair hosted by an NMHC entity:

- 1. All contributions shall support NMHC's charitable mission and values and, consistent with this mission, support outreach to the community.
- 2. Vendor contributions must be separate and independent of all NMHC clinical decision-making or purchasing decisions—health fair support is never an appropriate exchange for business favors.
- **3.** NMHC shall not accept contributions that are offered in connection with the purchase or sale of goods or services.
- **4.** NMHC shall use monetary contributions to cover the expenses of the health fair, and NMHC shall be solely responsible for determining how the contributions will be spent. If monetary contributions exceed health fair expenses, excess amounts shall be used to support NMHC's academic, educational, and charitable purposes.
- **5.** Sponsor names shall be disclosed at the health fair and in promotional materials. As appropriate, health fair speakers shall disclose any relationship between NMHC and the Sponsor.
- **6.** NMHC shall not endorse any Sponsor.
- 7. Sponsors and other Vendors may also participate in a health fair by hosting a table or other display. Any information displayed or distributed to health fair attendees must relate to health care (i.e. condition-specific information, treatment, healthy lifestyles, etc.) and not focus on sales of a particular product.

8. Sponsors and other Vendors participating in a health fair are prohibited from soliciting business during the event but may distribute token items to attendees. Additionally, if such participants provide a health screening, the screening results shall be sent to the individual attendee's provider of choice (i.e. the participant should not use this as an opportunity to obtain/solicit business).

I. Vendor Fairs

1. Attendance at Vendor Fairs

NMHC recognizes that Vendor fairs can be an efficient way to obtain information about Vendor products and services. Because there are typically many Vendors at a fair, the potential for any one Vendor to impact one's clinical, prescribing, and/or purchasing decisions is minimized. However, to avoid actual or the appearance of impropriety, you must adhere to the following guidelines:

- You may attend Vendor fairs for the purposes of gathering information about Vendor services relevant to your position at NMHC;
- You may accept only token gifts (e.g., candy, pens, etc.) from the Vendors that are being handed out to all attendees. You should not participate in raffles where the value of the gift is more than token (e.g., gift baskets, tv's, etc.);
- The use or display of the gifts at NMHC is discouraged. If possible, remove the Vendor name.

2. Sponsoring Vendor Fairs

NM-sponsored vendor fairs should be consistent with the rules from Part II Section I for attendance at vendor fairs. In addition, if your department is planning to sponsor a Vendor fair, please adhere to the following guidelines:

- Prior approval should be obtained from CCI. If the same event is held multiple times, approval need only be obtained the first time;
- The fair should be informational and relevant to healthcare;
- The selection of vendors to exhibit at the fair shall support the informational purpose of the fair and shall not influence the selection of vendors for NM business purposes;
- The fair should be open to the community;
- Vendors shall provide informational literature and may offer token gifts or food items to all participants (e.g., pen, cookie, etc.). Vendors do not need to remove their logos;

 Vendors shall not offer big raffle items such as TV or gift cards or prizes that participants can win.

There may be other requirements or limitations based on the space being used.

NOTE: Vendor support for purely educational events is addressed in Part 2 Section O.

J. Purchase Contracts and Discounts

All contracts to purchase goods or services on behalf of NMHC are subject to NMHC's standard procurement processes. Please refer to NMHC Materials Management Policy: MM 01.7001, Contracting—Authorization, Administering and Market Evaluation. 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 NMHC). Because pricing discounts and incentives from vendors may raise complex issues, vendor arrangements which involve incentives and discounts (other than a discounted price disclosed on an invoice), demonstration equipment usage, use of NMHC as a beta site, or similar arrangements must be reviewed by OGC or the Director, Sourcing and Procurement, or his or her designee, and may require review by CCI and/or OGC.

K. Fundraising

Vendors may be solicited for funds or gifts-in-kind where:

- **1.** The solicitation is made in the name of NMHC to support and advance NMHC's mission, values, programs, and related needs;
- **2.** The solicitation clearly indicates that the Vendor's response is voluntary and that an affirmative or negative response will not factor into the Vendor selection determination;
- **3.** The solicitation is organized or otherwise overseen and sponsored by Northwestern Memorial Foundation; and
- **4.** The solicitation clearly indicates that there will be no link or relationship with or between the contribution from a Vendor and the volume of business with a Vendor.

Referral Recipients should not be solicited for funds or gifts-in-kind.

L. Charitable Events

You may accept invitations to *local* charitable or fundraising events (e.g., charity auctions, benefit dinners, and golf outings) from Vendors or Referral Recipients where *all* of the following conditions are met:

 Acceptance may not be used to influence decision-making, to induce referral of patients or the ordering of a service or supply, and cannot take into account the volume or value of referrals, purchases, or business generated;

- **2.** The event is solely for the benefit of NMHC or another bona fide charitable entity whose mission is related to, complementary to, or otherwise compatible with NMHC's mission;
- 3. In advance of the charitable event, you inform your supervisor that you plan to attend the event;
- **4.** You limit your acceptance of such invitations to one (1) event from any single Vendor or Referral Recipient per year.

If the Vendor or Referral Recipient also offers a gift (in additional to any meal or other event program), you should decline the gift.

M. Arrangements Requiring Legal Review: Physicians

If you are a physician employed by an NMHC entity, any financial arrangements that you or an Immediate Family Member might have with entities that perform or bill for "designated health services" must be discussed with OGC prior to your entering into the arrangement. "Designated health services" include clinical laboratory services; physical and occupational therapy services; outpatient speech-language pathology 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 M 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.

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

NMHC recognizes that, for a variety of reasons (including convenience, geographical proximity, or personal preference), patients may wish to seek care from providers other than NMHC-entities. You must comply with the following safeguards to ensure that referrals to non-NMHC-entities are made in accordance with legal and ethical standards. Examples of allowable and prohibited referrals are provided at the end of this Section N. In any case of referrals, patients should always be told that they are free to select the provider of their choice.

NOTE: In this section, the term "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.

- 1. Referrals for services and products outside of NMHC-entities should be made on the basis of what is best for the patient and never made in exchange for remuneration (whether monetary or inkind), benefits, or favors of any kind from the recipient of the referrals.
- 2. Unless an exception has been granted by OGC, no referrals for any 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 N.2, an "investment interest" does not include an investment interest in certain "publicly traded entities." Contact CCI for more information about what constitutes a "publicly traded entity."
- **3.** Unless an exception is approved by OGC, 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). For purposes of subsections N.3 and N.4 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 always 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 N 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 as set forth above.
- 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.
- 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 NMHC policy.

O. Educational Grants and Donations to Underwrite Educational Conferences at NMHC Facilities or Otherwise Sponsored by NMHC

An offer from a Vendor or Referral Recipient to underwrite the costs of an educational conference or a professional meeting may be accepted only where:

- 1. The subsidy is provided in the form of a restricted donation to NMF for the applicable specified educational purposes;
- **2.** NMHC retains responsibility for and control over the selection of content, faculty, education methods and ownership of the materials;
- **3.** Program speakers are required to disclose any financial relationships with the Vendor or Referral Recipient providing the gift or any other relevant financial relationships; and
- **4.** Any program support by the Vendor or Referral Recipient is disclosed to the program attendees and any recipients of program materials.

In no event should a subsidy ever be paid directly to an individual involved with the conference or meeting. The provision of funding by Vendors or Referral Recipients should never influence clinical decision-making, purchasing or prescribing decisions, or the awarding of contracts. Accordingly, NMHC will not accept funding that is offered in connection with the purchase or sale of goods or services.

P. Relationships with the Investment Community

You should be aware of the risks associated with participating in expert advice panels hosted by the investment community, such as investment firms and hedge funds. Participating in an expert advice panel and potentially disclosing information that is not publicly available may put you at risk for insider trading liability. The safest course of action is to avoid participating in expert advice panels entirely. If you choose to participate in expert advice panels, you can reduce risk by ensuring that (i) the advice being sought is legitimately related to your area of expertise, (ii) your compensation reflects the fair market value, and (iii) the information you provide is publicly available.

Q. Sunshine Act: Physicians

The Physician Payments Sunshine Act is a transparency initiative that requires that Applicable Manufacturers and group purchasing organizations to provide CMS with the details of any direct or indirect payments made to physicians (limited to doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors) and teaching hospitals. The initiative requires that information about payments and other transfers of value to physicians and teaching hospitals worth \$10.00 or greater be made available to the general public. Such payments or transfers of value include, among other things, consulting fees, compensation from speaking or other activities, travel, food, entertainment, gifts, honoraria, royalties, education, research, current and prospective ownership or investment interests, and the use of trial equipment beyond the trial period (see Part II, Section I, "Vendor Provision of Demonstration Products and Other Services"). Applicable Manufacturers, such as pharmaceutical and device companies, are required to collect this information and provide it to CMS who will, in turn, post the information on a publicly available website. This information may be reviewed in conjunction with the Joint Affiliate Annual Disclosure of External Professional Relationships Survey.

The American Medical Association ("AMA") created a website as an educational resource available to physicians (Physician financial transparency reports (Sunshine Act)). Notably, the AMA recommends that physicians, upon a patient's request, discuss his or her financial interactions with Applicable Manufacturers and communicate how such interactions may result in medical innovations and improved outcomes for patients. Additionally, the AMA website provides information on how physicians can review reports submitted by Applicable Manufacturers and the process to challenge reports that may be false, misleading or inaccurate.

R. Physician-Owned Distributorships: Physicians

According to the Office of the Inspector General (OIG), a physician-owned distributorship or "POD" is "any physician-owned entity that derives revenue from selling, or arranging for the sale of, implantable medical devices and includes physician-owned entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation." While the legality of a particular POD will depend upon the surrounding facts and circumstances, the OIG views PODs as inherently suspect under the Anti-Kickback statute. Furthermore, the OIG does not believe that disclosure to a patient of a physician's financial interest in a POD addresses these concerns. As a physician's relationship with a POD can impact NMHC, if you have, or are considering acquiring, a relationship with a POD – either directly or indirectly – you should promptly contact CCI. For more information, please refer to the U.S. Department of Health and Human Services Office of Inspector General ("OIG") March 2013 Special Fraud Alert; the October 2013 OIG study on prevalence and use of POD devices; and the Sunshine Act reporting requirements (see Part II, Section Q).

S. Foreign Corrupt Practices Act (FCPA)

The Foreign Corrupt Practices Act of 1977 ("FCPA") prohibits United States companies, their directors, officers, employees and agents from the payment or authorization of the payment of any money, or the giving or authorization of the giving of anything of value, directly or indirectly, to a foreign official or to an

entity that's an instrumentality of a foreign government, for the purpose of influencing any act or decision of such foreign official, or inducing such foreign official to use his influence to assist the NMHC in obtaining or retaining business for or with, or directing business to, any person. The FCPA covers not only the actual payment of money but also an offer, promise or authorization of the payment of money and an offer, gift, promise or authorization of the giving of anything of value. NMHC strictly prohibits all improper or unethical payments or gifts to foreign government officials or instrumentalities in any of its business operations. No NMHC officer, personnel or agent has authority to make or offer payments to a foreign official to induce that official to affect any government act or decision in a manner that will assist the NMHC or any of its subsidiaries or affiliates to obtain or retain patients or provide services.