

Ohio State University Physician's Inc.
Vendor Interaction Policy
Policy effective July 1, 2009

Purpose

All healthcare professionals and institutions have an ethical obligation to provide safe, effective, patient-centered, timely, efficient, and high-quality care for their patients. In order to ensure that the care provided is always in the best interest of the patient, healthcare professionals and institutions should always strive to maintain the trust of their patients and to minimize any conflicts of interest in the delivery of care. The fiduciary nature of the relationship between patients and the healthcare professionals who treat them is based on an inequality of information about medicine and an imbalance of control between the parties. However, it is also based on an implicit understanding that a healthcare professional will make decisions that are in the best interest of the patient as opposed to the best interest of the professional.

Over the past twenty years, healthcare professionals have continued to redefine the appropriate ethical boundaries for relationships with vendor corporations and their representatives that have an interest in marketing products or services to professionals, institutions and patients. Since the early 1990's, a variety of professional and vendor organizations have developed broad statements of ethical principles related to this issue. In the last few years, a number of medical centers and medical schools have developed detailed policies that operationalize those ethical statements. These policies tend to include (but are often not limited to) a focus on the issues of gifts to healthcare professionals, payment to healthcare professionals for consulting or other advisory work, and payment to healthcare professionals who participate in speakers' bureaus or other educational programs.

The purpose of this policy is to outline a set of acceptable business practices and ethical principles that will guide the interactions of all staff of Ohio State University Physician's Inc. (OSUP) with vendor corporations and vendor representatives. The goal of this policy is not to completely or even materially limit the ability of vendor representatives to enter OSUP clinic sites/offices or to interact with individual OSUP staff. Ethical relationships between healthcare professionals, institutions, and vendor representatives can often be beneficial for all parties involved, including patients, in that these relationships may be the basis of advances in research, education and patient care. The goal of this policy is simply to place ethical boundaries on the actions of both parties.

Policy

1) Definitions:

- a) Scope: This policy applies to OSU Physician's Inc. and its wholly owned subsidiaries.
 - i) The OSU Health System, including all hospital business units, the Primary Care Network and the Specialty Care Network, the James Cancer Hospital and Solove Research Institute, the Office of Health Sciences, the College of Medicine, the Comprehensive Cancer Center, the Davis Heart Lung Research Institute, or other entities under the OSU Medical Center will operate under a vendor interaction policy with similar principles that will be adopted by the organization.
- b) OSU Physician's Inc.: The use of the term "OSU Physician's Inc." in this policy refers to an Ohio nonprofit medical practice corporation organized administratively into limited liability companies.
- c) OSUP Staff: The use of the term "OSUP Staff" in this policy applies to:
 - i) All members employed full-time by OSU Physicians, Inc., including physicians, clinical, administrative, clerical and other support staff members, working within OSUP and its wholly owned subsidiaries.
- d) Academic Department: The use of the term "Academic Department" in this policy refers to an identifiable administrative unit within the College of Medicine, including all clinical departments.
- e) Limited Liability Company (LLC): The use of the term "LLC" in this policy refers to the multi-specialty practice plans representing the physicians practicing at The Ohio State University Medical Center.
- f) Off-site and After-Hours Activities: For those individuals to whom this policy applies as defined in this section, this policy should be considered to apply equally to both on-campus activities as well as off-site, out of town, or after-hours (e.g., evening, weekend, etc.) activities.
- g) Vendor Corporation: This policy applies to those businesses, corporations or other entities that supply or wish to supply equipment, goods, services or other clinically related products to physicians, nurses, administrators or hospitals. This also includes organizations to which OSUP patients are referred for clinical services (e.g., extended care facilities, skilled nursing facilities, etc.).
- h) Vendor Representative: This policy applies to any individual who is employed by or who represents any entity defined in section 1.e who is not also an OSUP staff member. Vendor representatives are guests of OSUP and, as such, must provide their services in accordance with acceptable rules of conduct as determined by this policy and in a manner that provides the greatest benefit to OSUP and to our patients.
- i) Continuing Medical Education (CME) or Continuing Education: In this policy, the use of the terms "continuing medical education" and "continuing education" relate to a certified or accredited continuing professional education activity that provides credit toward maintenance of licensure for a healthcare professional. For example, CME in this document means a program that has been certified to provide Category 1 CME credit by an Accreditation Council for Continuing Medical Education (ACCME) accredited CME provider.

2) **Gifts to Individuals**

- a) Individual OSUP staff is prohibited from accepting any gifts from vendor representatives or vendor corporations regardless of the value of the gift. This includes items of minimal value like pens, mugs, notepads, etc. that have been commonly distributed by vendors in the past.
- b) Individual OSUP staff may receive marketing, instructional, warning or other educational information from a vendor about the vendor's products at any time.
- c) Any gifts that are delivered directly to an individual OSUP staff member at any site must be either:
 - i) Returned directly by the OSUP staff member to the vendor, or
 - ii) Forwarded to the OSUP Compliance Department (700 Ackerman Road, Ste. 600) which will return the gift to the vendor.
 - iii) In either case, a standard letter will be prepared by the Compliance Department that should accompany the returned gift that explains that individuals can no longer accept any gifts from vendors.
 - iv) The one exception to this rule is if a gift is a perishable item (i.e., fruit basket) and returning the gift is unpractical, the gift may be given to a charitable organization in lieu of returning the gift to the vendor.

3) **Gifts to OSUP or the LLCs**

- a) OSUP or the LLCs may accept cash donations, gifts or other items of value that support the clinical mission of OSUP or the LLC from a vendor corporation in accordance with this policy.
- b) Any donations or gifts accepted by OSUP or an LLC should remain the property of OSUP or the applicable LLC.
- c) When working with vendors who would like to provide a donation, gift, or other item of value to an Academic Department, the LLC leadership must work with Medical Center development to ensure that the gift is appropriately processed and that the vendor gets appropriate recognition with the University for the gift. When possible, Medical Center development should be contacted before the plans for the gift are finalized to ensure that appropriate processes are followed.
 - i) If the gift is for another purpose beyond those listed above, the Academic Department accepting the gift must work with the appropriate University or Medical Center administrative oversight entities to coordinate the gift based on the gift's purpose.
- d) All donations and gifts from vendors to OSUP or an LLC should be documented in writing. Although no specific form is required, at a minimum, this documentation should include:
 - i) the total amount of the gift,
 - ii) the timeframe over which the gift will be given (e.g., lump sum, quarterly, annually, etc.), and

iii) the intended use of the funds or the gift.

e) All gifts to OSUP or an LLC of greater than \$10,000 (either in individual or cumulative gifts from one vendor over the course of a fiscal year) must be reviewed by OSUP's External Legal Counsel to ensure that they are being documented and managed appropriately.

4) **Meals**

a) Vendors are prohibited from directly supplying meals, food, snacks or other food items to OSUP staff. The exceptions to this rule are:

i) a modest meal as part of an event that grants CME or other continuing education credit when the event is sponsored by the vendor.

ii) a meal in conjunction with an individual's role as an advisor or consultant to a vendor corporation.

5) **Vendor Sponsored Events**

a) OSUP staff is permitted to attend, participate in and/or lead any off-site event that offers CME or other continuing education credit regardless of the sponsor of the event.

b) Individual OSUP staff may attend any non-CME/CE dinners or other events sponsored by a vendor only if the staff member pays for their own meal, beverages, etc. Documentation of payment by the individual should be maintained and must be produced upon request by a supervisor.

c) Individual OSUP staff is prohibited from receiving payment or gifts in exchange for attendance as an audience member at any event.

d) An individual OSUP staff member is permitted to accept an item with a vendor logo on it in conjunction with an educational conference (e.g., a tote bag, a water bottle, etc.) if:

i) the item has the name of the conference or sponsoring organization on it,

ii) the item is provided by the educational conference, and

iii) the item is provided to all conference attendees.

e) Meetings with vendors regarding the potential purchase, lease or rental of equipment or services from the vendor and any meals provided at such a meeting must be in accordance with the policies of OSUP and the respective Limited Liability Company working with OSUP and the laws of the State of Ohio. In general, all costs for meals, travel, lodging, etc. for these meetings should be covered by OSUP or the LLC and not by the vendor unless explicitly approved by a member of the OSUP Board or Executive Leadership.

6) **Consulting, Speakers' Bureaus and Other Business Arrangements**

a) Individual OSUP staff may serve as paid consultants or advisors to vendor corporations in accordance with this and other applicable OSUP policies on work outside of OSUP (please see OSUP's Conflict of Interest Policy).

- i) OSUP staff may receive complimentary meals from a vendor only in direct relation to their work for the vendor as a paid consultant or advisor (e.g., a lunch or dinner at an advisory committee meeting). This does not include meals or gifts from a vendor not in conjunction with their work as an advisor or consultant (e.g., one-on-one lunch with a vendor representative unrelated to their paid position).
- ii) Any paid consulting relationship with a vendor corporation must be disclosed through the annual OSUP disclosure process and should be discussed directly with the individual's Chairman or Practice Administrator.
- iii) Consulting or advisory relationships should be entered into by OSUP staff members carefully. The work that will be done for the vendor corporation must be:
 - (1) generally commensurate with the amount of compensation provided by the vendor and,
 - (2) the compensation must approximate fair market value.
- iv) There should be a signed agreement that outlines, at a minimum, the work to be done for the vendor corporation and the compensation to be provided by the vendor.
 - (1) If this agreement is between the vendor and the individual, all aspects of OSUP's Conflict of Interest policy still apply.
 - (a) The agreement with the vendor must be produced by the individual staff member if requested by the OSUP Executive Committee or the LLC Chairman.
 - (b) The individual must report to the University if any intellectual property will be created as a part of this activity.
 - v) Staff serving as a paid consultant, advisor, etc. for a vendor should comply with OSUP HR policies regarding the requirement to use appropriate leave time for these activities when required.
- b) Speakers' Bureau and Educational Events
 - i) OSUP staff are permitted to participate in a vendor-sponsored speakers' bureau or other educational event only:
 - (1) when the presentation is to be made in an academic setting (e.g., grand rounds, visiting professor, guest lecturer etc. at an academic medical center or other teaching hospital), or
 - (2) at any event granting CME/CE credit regardless of the location, or
 - (3) when the presentation is an educational or training activity for a vendor's employees.
 - ii) When presenting at a vendor-sponsored speakers' bureau or other educational event, any slides and other information presented by the OSUP staff member must have been prepared by the OSUP staff member. Use of slides or other vendor-prepared educational materials by the OSUP staff member is not permitted with the exception of FDA-approved slides that are mandated for use when discussing a specific product.

- iii) OSUP staff may receive an honorarium or speaker fee for lecturing in a permitted vendor sponsored or supported educational event as defined in this policy.
 - (1) If the event occurs in an academic setting (i.e., an academic medical center, teaching hospital, etc.), the honorarium or speaker fee must be from the academic institution.
 - (2) If the event occurs as a part of a CME/CE event, the honorarium or speaker fee must be from the organization sponsoring the CME/CE event.
- iv) OSUP staff are prohibited from receiving a retainer or other similar payments simply for being a member of a speakers' bureau. Any payments for involvement with a speakers' bureau must be in relation to actually performing a service as a speaker, lecturer, etc.
- v) OSUP staff are prohibited from participating in and receiving an honorarium for a vendor sponsored "speakers' bureau" event when the goal of the activity is marketing of the vendor's products.
- c) "Token consulting" arrangements are strictly forbidden.
 - i) "Token consulting" arrangements are agreements to pay an OSUP staff member for consulting or advising a vendor corporation when either:
 - (1) No substantive work is done on behalf of the vendor, or
 - (2) The work done for the vendor is not commensurate with the amount of compensation provided by the vendor, or
 - (3) When the compensation is not at fair market value as determined by acceptable benchmarks (e.g., AAMC faculty or MGMA practicing physician salary benchmarks).
 - (4) If there are any concerns that a consulting arrangement could be considered "token consulting," please consult OSUP's External Legal Counsel for further review.

7) Promotional materials

- a) Vendor corporations and vendor representatives are prohibited from directly placing any promotional materials or educational materials in any OSUP patient care area or waiting area.
- b) OSUP staff are permitted to distribute or display high-quality patient education materials produced by a vendor corporation in patient care areas or waiting rooms of any outpatient site provided that the materials are unbiased and are not product-specific.
- c) Promotional materials that are product-specific or that directly market a vendor's products may be distributed to patients:
 - i) only after they have been reviewed specifically by the LLC to ensure that they are generally complete and accurate regarding the vendor's product, and
 - ii) only after it is determined that the patient needs or potentially needs to use the product or medication covered in the promotional material, and

iii) preferably by OSUP staff and not directly by a vendor representative.

d) This policy should not be construed in any way to limit the distribution of accurate and complete instructions for use or safety warnings for any product or medication regardless of the source of the information after an item has been ordered or prescribed for use by a patient.

8) **Samples**

a) In order to ensure patient safety and the appropriate storage and distribution of medication samples, the distribution of medication samples will be prohibited except as noted under Section 8.b below.

i) In an attempt to minimize the need for samples:

(1) vendors are encouraged to provide vouchers to OSUP clinics that may be distributed to patients. These vouchers, in addition to a valid prescription, will allow a patient to receive free or discounted medications at a retail pharmacy.

(2) prescribers are encouraged to prescribe generic medications for those patients who cannot easily afford prescription medications and in those clinical situations when a generic medication is appropriate for the patient's condition.

b) If members believe that their clinical practice requires the continued use of medication samples for a specific medication or for a special patient population, they may apply to the Health System Pharmacy and Therapeutics Committee for an exception to this rule. As a part of that approval, the clinic will be required to annually report the following to the Pharmacy and Therapeutics Committee:

i) The medication samples that are routinely stocked in the clinic,

ii) The process for ensuring the proper storage, security and distribution for samples,

iii) The process for monitoring the expiration dates on medication samples, and

iv) The process for the documentation of distribution to patients.

c) For non-medication product samples, the clinic should ensure that any samples provided to patients are appropriately packaged, in good condition and have not expired.

9) **Conflict of Interest in Purchasing Decisions**

a) Any OSUP staff member who is involved in the evaluation of a product, selection of a vendor, negotiation with a vendor, or the decision to purchase a product must fully disclose any equity positions, consulting agreements, or other compensation relationships between him/herself or a member of his/her family with a vendor under consideration.

b) This conflict of interest should be disclosed in writing to the OSUP staff member's direct supervisor as well as to the applicable staff from the respective department assigned to the purchase.

i) Both the individual's supervisor as well as the respective purchasing department staff member is required to review the conflict of interest with the OSUP staff member. If the

conflict of interest is significant or cannot be managed appropriately in the opinion of the supervisor or the department representative, the individual must remove themselves from the process.

- ii) If additional assistance is needed to evaluate the conflict of interest, OSUP's External Legal Counsel, the Compliance Department and the Chief Executive Officer are additional resources that can be utilized.
- c) If an individual OSUP staff member is in any position to materially benefit from the relationship with the vendor or if the conflict is deemed too significant by either the LLC or the individual's supervisor to be managed appropriately, the individual must immediately remove him/herself from any further discussions, meetings or negotiations.
- d) Any OSUP staff member who is involved in the evaluation of a product, selection of a vendor, negotiation with a vendor, or the decision to purchase a product should be generally familiar with all OSUP policies regarding their role in the process.
- e) Communication between OSUP staff members and vendor representatives related to selection of a vendor, negotiation with a vendor or a decision to purchase a product should occur only in accordance with OSUP policies.
- f) All costs related to meals, travel, lodging, etc. for meetings, site visits, or other activities related to a purchasing decision must be covered by OSUP or the LLC and not the vendor unless explicitly approved by a member of OSUP's Board, Executive Leadership or other senior administrator.

10) Non-compliance

- a) The OSUP Board, Administrators and Executive Leadership are charged with ensuring that all OSUP staff members in their practices are educated about this policy.
- b) If a potentially non-compliant act or event is brought to the attention of any OSUP Board member, Administrator or Executive Leadership, that person must either directly investigate the issue or refer the issue to the OSUP Compliance Department for further investigation.
- c) Reporting of potential non-compliance with this policy may be done through a variety of mechanisms.
 - i) Report entered in the Ethics Point compliance reporting system
 - (1) Web URL: http://www.osup.medctr.ohiostate.edu/osup_compliance_anonymous.htm, then select "Make an Anonymous Report."
 - (2) Toll Free number: 1-800-559-5217
 - ii) Report directly to the OSUP Compliance Department
 - iii) Report to an appropriate Corporate or LLC Administrator
- d) Determination of non-compliance and disciplinary action: Determination of noncompliance by a vendor representative or OSUP staff member and the determination of any disciplinary action will be done with the cooperation of the applicable LLC leadership where the alleged issue(s) occurred. For physicians, this should also include the Department Chair for the individual involved. Additional assistance in any investigation, determination of non-compliance with this policy, or determination of disciplinary action can also be provided by the OSUP Chairman of the Board, the Chief Compliance Officer, OSUP External Legal Counsel, the OSUP President, or the Chief Executive Officer.

- e) Vendor non-compliance: Each issue of non-compliance with this policy will be dealt with on an individualized basis taking into account the actual events that occurred and any previous non-compliance with OSUP policies. Non-compliance may result in actions including, but not limited to,
 - i) a warning,
 - ii) a temporary suspension of access to OSUP clinic sites,
 - iii) permanent revocation of the individual vendor representative's access to OSUP clinic sites, or
 - iv) complete termination of business with the vendor corporation.
- f) Staff non-compliance: Each issue of non-compliance with this policy will be dealt with on an individualized basis taking into account the actual events that occurred, any previous non-compliance with OSUP policies, and the individual's overall applicable employment record. Any disciplinary action will be consistent with regard to existing disciplinary policies that apply to the individual in question. Non-compliance may result in disciplinary action, including but not limited to,
 - i) a warning,
 - ii) probation,
 - iii) suspension
 - iv) removal from a position whose duties include vendor interaction, or
 - v) termination.
 - vi) Any disciplinary action may be appealed in accordance with applicable OSUP HR policies.

11) References

- 1) *OSU Physician's, Inc. "Conflict of Interest Policy."*
- 2) *Report of the AAMC Task Force on Industry Funding of Medical Education, Association of American Medical Colleges, 2008.*
- 3) *The Scientific Basis of Influence and Reciprocity: A Symposium, Association of American Medical Colleges, 2007.*
- 4) *Chapter 2921 of the Ohio Revised Code.*
- 5) *PhRMA Code on Interactions with Healthcare Professionals, PhRMA, April 2002.*
- 6) *OIG Compliance Program Guidance for Pharmaceuticals Manufacturers, April, 2003.*
- 7) *American Medical Association Council on Ethical and Judicial Affairs (CEJA) Ethics Opinion E-8.061 — Gifts to Physicians from Industry.*
- 8) *American Medical Association Council on Ethical and Judicial Affairs (CEJA) Ethics Opinion E-9.01 1 — Continuing Medical Education.*
- 9) *White Paper on the Relationship of GME and Industry, Accreditation Council on Graduate Medical Education (ACGME), 2002.*
- 10) *Resident Physician and Medical Industry Interactions: Guiding Principle, Association of American Medical Colleges, 2003.*