

Administrative Manual

	Policy Name	Conflicts Of Interest: Interactions With Pharmaceutical And Other Vendors
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	Responsible for Content	Department of Pharmacy and Purchasing Department

I. Description

Procedures for interacting with vendors, including acceptance of funds, gifts and food from vendors.

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II. Rationale

The University of North Carolina Health Care System (UNC HCS), including UNC Hospitals (UNCH) and the clinical patient care programs of the University of North Carolina at Chapel Hill School of Medicine (“UNC SOM”), acknowledges that transactions and relationships with pharmaceutical and other vendors are important to UNC HCS and its patients, and may contribute to continued improvements in patient care. At the same time, it is the policy of UNC HCS to maintain compliance with regulatory requirements and to avoid any real or potential conflicts of interest with industry. Interactions with industry should support the missions of UNC HCS of service, education, and research, and should not compromise patient confidentiality, interfere with patient care or bias education of residents, students, patients or the public. Interactions should foster the appropriate use of equipment, supplies, and pharmaceuticals. No interactions with, or goods or services provided by, vendors should interfere with, or appear to interfere with, the independence of a healthcare professional’s prescribing or purchasing practices. This policy provides procedures for all faculty and staff of UNC HCS to interact with vendors of all types which conduct business with UNC HCS for patient care-related goods and services, including sales personnel or vendor representatives for medical/surgical supplies, durable medical equipment, and pharmaceutical sales representatives. This policy applies to all clinical patient care activities of the medical staff and other staff of UNC HCS for off-campus, as well as on-campus, clinical activities.

III. Policy

A. General

Generally, vendors may visit UNC HCS under controlled circumstances only and may have patient contact only if there is a legitimate health care need.

1. In general, vendors are allowed only by previously scheduled appointments to be in physicians' offices, department or division offices, administrative areas of Pharmacy and Purchasing departments, conference rooms or conference areas specified by each individual department or division. No "cold calling" will be allowed by vendors at any UNC HCS facilities under any circumstances. In addition, time limits on each authorized visit will be set by the applicable department. Vendors are not allowed in or adjacent to inpatient patient care areas, outpatient clinics, patient waiting areas, or conference or meeting rooms in patient care areas unless there is a specific educational or patient care need for the vendor to be present, and only then with the prior approval of the applicable department. Such exceptions include representatives required for implantation, operation, or programming of devices, setting up or training on new equipment or supplies, maintenance of equipment, replenishing of supplies, or individuals covered by the UNC HCS "Shadow Student or Visitor" policy.
2. The "Vendor Representative Policy and Visitation Guidelines", which apply to anyone representing or promoting products or pharmaceuticals that could be used by or sold to UNC HCS, provide specific requirements for vendors visiting UNC HCS. In addition, there are departmental guidelines that govern contact with specific departments. (Refer to specific departmental policies and procedures.) Among the requirements of the "Vendor Representative Policy and Visitation Guidelines" are the following:
 - a. UNCH, the Ambulatory Care Center, all community-based clinics and the Family Practice Center shall each designate a check-in location, and shall enforce the terms of this policy and those of the "Vendor Representative Policy and Visitation Guidelines".
 - b. Vendors are required to have an appointment to visit a UNC HCS facility.
 - c. Vendors are required to check in at the applicable UNC HCS facility upon arrival, and are required to wear identifying badges at all times while in a UNC HCS facility.
 - d. Only the Purchasing Department has the ability to contract with a vendor on behalf of UNC HCS. The Purchasing Department will also coordinate product evaluations.
3. Vendor companies which provide services on behalf of UNC HCS which involve the exchange of protected health information (PHI) may be considered "business associates" of UNC HCS under the Health Insurance Portability and Accountability Act of 1996 and its accompanying regulations ("HIPAA"), and will be required to sign and comply with a Business Associate Agreement. (See the UNC HCS policy entitled "Business Associates" for more specific information.)

4. Promotion of drugs must be consistent with institutional guidelines established by the Pharmacy and the Pharmacy and Therapeutics Committee. When discussing specific drugs with UNC HCS staff, vendor representatives are required to state whether these drugs or devices are on the UNC HCS formulary and acknowledge any institutional restrictions in their use. Vendor marketing representatives are not allowed to discuss with UNC HCS staff off-label uses of any particular drug (however, information regarding off-label uses may be solicited through the Medical Affairs Division of the vendor).
5. Vendors may make unrestricted general contributions to UNC HCS, The Medical Foundation of North Carolina on behalf of individual units, or individual units of UNCH. UNC HCS or the respective UNCH unit will determine how such funds are used. Such contributions shall be reviewed in advance by legal counsel for either UNC HCS or UNC SOM.

B. Educational Activities

Vendors may sponsor legitimate educational programs and provide educational materials, but may not speak at or dictate the content of these programs.

1. UNC HCS adopts the American Medical Association's Council on Ethical and Judicial Affairs definition of a legitimate "conference" or "meeting" as "any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made."
2. The policies and procedures of the UNC SOM Continuing Medical Education Office govern interactions with vendors in those instances when a vendor, funds or provides in-kind support for, educational programs that provide AMA PRA category 1 credit. These procedures require a written agreement between the commercial supporter and the accredited provider (UNC SOM CME) documenting the funding or in-kind support. They also require all funds and expenses associated with the event to be handled by the UNC SOM CME Office. In no case may a vendor directly purchase and provide food or other supplies for a program that offers category 1 credit. For other legitimate educational programs for UNC HCS staff, vendors may provide support with the approval of the Department Chair, Division Chief, Residency Program Director, or other administrator of the sponsoring department or unit by submitting funding to the educational program coordinator. Each Department will be allowed to determine the specific arrangements for its educational programs. It is recommended that an educational fund be established to receive vendor educational funding, that no specific items be purchased by the vendor, and that the Department make all of the arrangements for programs; however, vendors may be allowed to bring in or directly pay for lunches or other food. No cash or reimbursement of expenses, including travel and meals, should be paid by a vendor to any individual attending such program (other than the speaker). In all cases, the selection of speakers, topic, educational materials and assurance of

the educational integrity of the program is the responsibility of the applicable program chair. Sponsorship may be acknowledged, but vendors are not allowed to speak at any educational presentation or to actively market products before, during or after the educational presentation. Vendors may have a display of products outside the actual meeting area as long as the product display is not located in patient care areas.

3. Multidisciplinary and Interdisciplinary Patient Conferences (including grand rounds, quality improvement, morbidity and mortality conferences): Vendors may not be present for discussions of PHI regarding patients for whom their presence provides no specific educational or clinical purpose, except as otherwise allowed by this policy or the UNC HCS "Shadow Students or Visitors" policy. Vendors may provide education and training regarding their product or equipment outside of the conference setting, or provide specific information with respect to a particular patient who may benefit from their product or equipment; however such vendors may only be present for discussions regarding a specific patient for whom they are consulting. At the conclusion of the discussion regarding patients who are using or could benefit from the vendor's product, the vendor should be asked to leave the conference. Each vendor representative participating in such a conference must have signed the UNC HCS Confidentiality Statement, and the applicable vendor company must have signed a Business Associate Agreement.
4. Educational materials, such as textbooks or medical journals which benefit patients, may be provided by a vendor to UNC HCS if such materials serve a genuine educational function. No promotional material or product information from the vendor may be attached to any such item; however, it is acceptable identify the source of the item. In addition, a vendor may provide scholarships to educational conferences to permit UNC HCS staff to attend, however, the selection of individuals who will receive the scholarships must be made by the applicable department.
5. Vendors may provide grants for named research or educational positions with UNCH departments as long as the selection of the attending physician, resident or other provider and the specific requirements of the position are made by the applicable department or an independent reviewing body, and there is no input by the vendor.
6. See Section III below regarding provision of food for educational programs.

C. Promotional Activities, Gifts and Food

UNC HCS personnel are strictly prohibited from receiving gifts or other incentives that have no educational benefit from vendors.

1. The payment of cash or other incentives or rebates by a vendor to UNC HCS or its staff, and the receipt of any such incentive by UNC HCS or its staff, is strictly prohibited. Incentives include any tangible enticement, whether in cash, extra goods, services, or gifts, which are offered by a vendor to encourage the use or purchase of the vendor's product.

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2. Vendors are not permitted to provide monetary or in-kind support of any activities, including meals, except in connection with educational events and as otherwise permitted under this policy.
3. UNC HCS personnel may not receive personal gifts of any nature and of any value from Vendors. Even items of a relatively trivial value that incorporate a product or company logo--such as pens, notepads, or desk items—provide an inappropriate opportunity for the company to market to UNC HCS personnel, to patients and to other members of the public. This prohibition includes gifts to the families of UNC HCS personnel and to legal entities, such as limited liability companies, through which UNC HCS personnel engage in consulting activities. UNC HCS personnel may not accept company reimbursement for travel or lodging for family members in conjunction with attendance at meetings, conferences, etc.
4. Vendors are not permitted to distribute, post or leave any type of printed or handwritten material, advertisements, signs or other such promotional materials anywhere at UNC HCS unless specifically requested by faculty or staff.
5. Vendors may leave educational materials regarding their goods or services that may be useful to patients with the applicable department administration, but may not distribute them directly to patients. All such educational information should be reviewed by and distributed by the appropriate department.
6. All use of drug samples will be accomplished in compliance with the Prescription Drug Marketing Act of 1987 and the UNC HCS Pharmacy policies and procedures. Individual departments will develop policies and procedures for use of samples within their clinics, and will appoint one contact person for acceptance of samples. Vendors will be required to communicate only with the appointed contact person with respect to permission to distribute drug samples.
7. Vendors may contribute funding to UNC HCS that may be used for meals for educational programs, including seminars, conferences and grand rounds presentations. The guidelines provided above in Section II should be followed. Any meals provided should be modest and be conducive to discussion among faculty and attendees, and the amount of time allotted for meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the program.
8. Generally, UNC HCS personnel may only accept reimbursement for travel and expenses for site visits to evaluate a product or service in accordance with this policy. Visits to vendor sites for training are acceptable if the cost of such training visits is included and itemized in the quotation and included in the signed final contract. In addition, UNC HCS personnel may take site visits to evaluate a product or service at the vendor's expense as follows:
 - a. All arrangements related to site visits, including selection of participants, duration of the visit, selection of travel method and accommodations, will be made by the applicable department.
 - b. Site visits at the expense of the vendor may only include travel, housing and food expenses specifically related to the evaluation of the product or service,

and may not include any extra expenses which are personal in nature or unrelated to the evaluation. All expenses must be incurred in accordance with departmental policies regarding the appropriateness of business expenses and within spending guidelines for expenses, including per diem payments, business class travel, and hotel accommodations.

- c. All expenses will be determined and paid by the applicable department, with an invoice for appropriate expenses sent to the vendor for reimbursement.

D. Contracting with Vendors

Contracting with vendors on behalf of UNC HCS should be accomplished through the applicable Purchasing Department. Contracting with vendors on an individual's behalf is subject to scrutiny under "fraud and abuse" regulations.

1. Individuals who directly contract with a vendor for services such as consulting or speaking engagements are still subject to regulatory requirements. Such arrangements can be subject to scrutiny under fraud and abuse regulations, and legal review is suggested. UNC HCS staff members who wish to enter into such contracts with a vendor should follow applicable departmental guidelines, including completion and submission of the "External Professional Activities for Pay" form, and obtain the approval of the applicable department chair.
2. No departments or clinical staff are permitted to contract directly with a vendor on behalf of UNC HCS, although departments and staff may participate in the contract negotiations along with Purchasing Department. All contracting with vendors will be accomplished through the applicable Purchasing Department. (See the UNC HCS "Vendor Representative Policy and Visitation Guidelines".)
3. UNC HCS staff are generally prohibited from participating in the negotiations with any vendor with whom such staff have a personal interest, including a financial interest or personal or family relationship, and should disclose any such conflict of interest in accordance with applicable policies. The staff may, however, provide professional advice to the selection team regarding specific goods and services.

E. Patient Confidentiality

Vendor representatives are only permitted to participate in discussions involving PHI if the representative serves a legitimate educational or clinical purpose, and the representative must have signed a UNC HCS Confidentiality Statement

1. Multidisciplinary and Interdisciplinary Patient Conferences: Vendors may be present for discussions of PHI regarding patients only if their presence provides a specific educational or clinical purpose, the vendor company has signed a Business Associate Agreement (BAA), which has been reviewed and approved by UNC HCS Legal Department prior to execution by either party, and the vendor representative has signed a UNC HCS Confidentiality Statement. See discussion of "Educational Activities" above.
2. Training Regarding a Product: Vendor representatives who come to UNC HCS to provide training on the vendors' products in patient care areas, including procedure rooms and surgical suites, but will not be involved with specific

patients, will be required to sign the UNC HCS Confidentiality Statement, and the vendor company is required to sign a BAA prepared by UNC HCS Legal Department and executed by both parties prior to training date. The department that sponsors the training is responsible for ensuring that the Confidentiality Statement has been signed. Admission to procedure rooms and surgical suites depends on the applicable departmental policies and procedures.

3. **Involvement in Patient Care:** Vendor representatives who come to UNC HCS to provide training on the vendor's products in patient care areas, including procedure rooms and surgical suites, and will be involved with specific patients, will be required to comply with all requirements of business associates of UNC HCS, which includes execution by the vendor representative of the UNC HCS Confidentiality Statement and execution by the vendor company of the BAA. The department that has requested the involvement of the vendor in patient care is responsible for compliance with the Business Associate Policy, which includes ensuring that the Confidentiality Statement has been signed. If it has been determined, based on the Business Associate Policy, that a vendor is not a business associate of UNC HCS, the affected patient must sign a HIPAA-compliant Authorization Form allowing the participation, and all other applicable departmental policies and procedures must be followed, including admission to procedure rooms and surgical suites.

F. Research activities

All research activities, including but not limited to the use of investigational drugs, must be conducted pursuant to UNC SOM policies and procedures. Promotional activities by vendors may not be performed under the guise of research.

1. Investigational drug supplies are managed by the Department of Pharmacy's Investigational Drug Service and guided by the related policies and procedures of the UNC Institutional Review Board (IRB) and the Department of Pharmacy.
2. Investigational devices utilized in clinical practice settings must also be approved by the IRB. Documentation of such approval must be provided to the Purchasing Department prior to procurement.
3. Any IRB-approved projects should identify legitimate research questions, and any reimbursement of faculty and staff should be commensurate with effort and expertise required. It is not acceptable to disguise promotional activities for a vendor as research.

G. Enforcement

Violators of this policy will be subject to disciplinary action, and in some instances, prohibited actions may also violate applicable laws.

1. All UNC HCS staff members who are aware of potential violations of this policy by UNC HCS staff members should report such potential violations to the UNCH Corporate Compliance Officer or the UNC SOM Office of University Counsel . All incidents will be fully and vigorously investigated. Reports can be made in person or to the applicable Corporate Compliance Hotline.

2. If a UNC HCS or UNC SOM staff member witnesses a violation of these guidelines by a UNC HCS or a UNC SOM staff member or witnesses a violation of the UNC HCS Vendor Representative Policy and Visitation Guidelines by a vendor, the UNC HCS or UNC SOM staff member should contact the Purchasing Manager or the Director of Pharmacy.
3. Actions taken by UNC HCS as a result of infractions by a vendor representative to these guidelines will be dependent on the severity of the offense. These actions shall include, but not be limited to a verbal or written reprimand, suspension, or expulsion from the account.
4. Deliberate violation of this policy by UNC HCS staff will be handled in accordance with UNC HCS Code of Conduct and applicable Human Resources Policies.
5. Some actions taken in violation of this policy may violate applicable federal and state laws and may subject the violator to regulatory investigation.