

University of Louisville (UofL) Health Care Policy on Vendors
Approved, UofL Medical Council on July 23, 2008, Effective this date

This policy is intended to improve the educational environment at UofL Health Care (i.e., University Hospital, the James Graham Brown Cancer Center, the Kentucky Lions Eye Center and University Physicians Associates) for the faculty, staff, and students, as well as the clinical care of their patients by reducing actual and perceived conflicts of interest on their selection of treatment. This policy applies to all hospital and office settings owned, operated by, or rented by UofL Health Care where UofL medical students, residents, and fellows work, practice medicine, conduct research, or are educated by University of Louisville-salaried faculty. This policy reinforces and does not infringe on the existing function and structures of the participation in clinical trials, clinical committees, or policies at the University, including the Product Review Committee, the Pharmacy and Therapeutics Committee, and the Conflict of Interest Policies: (<http://research.louisville.edu/policies/conflictinterest.html> and <http://www.louisville.edu/admin/humanr/policies/conflict.htm>), which require the disclosure and recusal of any person with any financial interest in a vendor's services. This policy has no standing at other hospitals not part of the University of Louisville except as noted in Sections 2 and 8.

Vendors are defined as pharmaceutical company and medical equipment representatives, as well as including equipment and service providers.

1. Gifting: Vendors may not make any form of gifts (whether cash or an item of *any value*) at *UofL Health Care*, the School of Medicine, and all other clinical, administrative, educational, and research venues and activities.

2. Detailing and Marketing: Vendors may not product or brand detail (i.e., in-person marketing visits by vendors), or market, at *UofL Health Care*, the School of Medicine, and all other clinical, administrative, educational, and research venues and activities. Vendors may *not* give any form of food, cash, or material gifts between them (or their companies) and University of Louisville-salaried faculty, staff, residents, fellows, and health care students in person, by phone, email, mail or any other means at *UofL Health Care* premises or at any UofL affiliated educational sites. Displays of products, cash incentive programs for prescribing,

product pamphlets, pre-printed prescription pads with product names, and other materials are prohibited. Detailing and marketing at hospitals and facilities outside of UofL HealthCare and the School of Medicine will be governed by the policies and procedures of the individual institutions.

3. Visits to faculty by appointment: This policy does allow for visits by appointment (as set forth by protocols approved by individual administrative units — i.e., Departments, Divisions, etc.) for updates on new products, education regarding existing products, discussions of support for unrestricted education grants, and supply of pharmaceutical samples, competitive selection by clinical committees for new products, services, or devices, and in-service training for products to faculty and staff that have been duly deliberated upon and selected for use at UofL Health Care. Vendors, who each must be credentialed with UofL Pharmacy or Operating Room, as applicable, will register with the inpatient pharmacy or the operating room scheduler's desk prior to all UofL visits and will be issued an appropriate ID badge.

4. Educational Grants: This policy does allow for unrestricted educational *topic-focused or general* grants from vendors for Continuing Medical Education (CME) and Graduate Medical Education (GME) activities. Unrestricted educational grants from pharmaceutical companies and medical equipment companies are allowed for the purchase of educational needs as warranted for patient and medical education and patient care, either in an open (unspecified) manner or with acknowledgement that it is focused on a specific area of educational focus. Additionally, these grants can be used for educational related expenses (e.g., staff, resident, faculty lunch-based presentations). These CME symposia may not involve marketing, detailing, or advertising of brand names or products, and the granting companies may not select paid lecturers or require the inclusion or exclusion of medications purchased for patient care. These symposia will comply with all CME regulations. CME symposia (i.e., ACGME accredited and in compliance with ACGME guidelines) may provide food purchased with these grants. Vendors may restrict the educational grant to cover specific educational topics (e.g., breast cancer or heart disease) so long as the above listed requirements are met. Recognition of these grants may consist of attribution (e.g., in brochures for conferences, graduation event agenda, acknowledgement slides in presentations, and wall plaques of thanks) for contributions received.

- a. Funds designated to specific units will be kept in designated unit accounts through the Assistant Vice President for Finance, UofL Executive Vice President for Health Affairs (EVPHA) office,** with these funds channeled through a central administrative account, but with separate accounts kept for each unit. Individual Departments of the School of Medicine will administer these grants and will be responsible for their collection and expenditure. Annual reporting of the receipt of such grants and their expenditure will be provided to the Dean of the School of Medicine, Dentistry, or Nursing as appropriate. Any perceived violation of the conditions outlined above will be reported to the appropriate Dean.
- b. General grants (i.e., non-unit or topic specific) will be placed in trust within the Assistant Vice President for Finance, UofL EVPHA office,** and administered as deemed appropriate under the supervision of a Faculty Oversight Committee elected from the Executive Faculty.

5. Pharmaceutical Samples: This policy does allow for pharmaceutical samples to be given to UofL Health Care clinical sites. Acceptable sample medications will be articulated in a formulary in each department as approved by each in consultation with UofL Pharmacy Services. Delivery of sample medications may not be accompanied by any form of detailing or gifting. UofL Health Care is dedicated to soon implementing a voucher plan with area pharmacies to mitigate the need for sample medications.

6. Vendors are *not* allowed into the following locations: patient care areas, operating rooms, delivery rooms, emergency rooms, medical student and resident lounges, and staff elevators except only to provide in-service training or assistance on devices and equipment, for example, in the operating room. In such cases, there must be prior disclosure to and consent by the patient or surrogate (if the patient is incapacitated) whenever possible, i.e., if it is known ahead of time that a vendor will be involved. However, in such cases that crisis or emergency treatment with devices, equipment, etc. from a vendor is required during an operation or procedure in order to provide the best care for the patient, and if the patient is incapacitated and no surrogate is available, the requirement for consent will be waived.

7. Education programs for students, trainees, staff, and faculty should be developed and implemented by UofL-HSC schools and by individual departments on vendor marketing, as well as the subtle influences that such promotion has on physician decisions. If desired, one educational option is to have a vendor provide an interpretation of educational material on products, which would then be discussed and critiqued by a faculty member. Students may interact with vendors only in educational forums, and only when accompanied by faculty supervision.

8. Off-Campus Vendor Relationships: While *UofL*-salaried faculty, staff, residents, fellows, and health care students are personally prohibited from accepting any form of gifts, food, or products (of any type or value) from vendors or their companies, at *UofL Health Care* Kentuckiana locations, other forms of professional interaction, employment, and consulting do exist. Although this policy does not call for institutional policing of off-site activities (i.e., vendor gifting in person, or by phone, e-mail, mail or any other means at any time outside the *UofL* premises to faculty, staff, residents, fellows, and health care students), adherence to the principles outlined in this policy is not reserved for duty hours.

a. Off campus, non-*UofL* endeavors (such as paid lectureships) are strongly discouraged. Research relationships by *UofL* personnel are covered by this policy, as well as by the *UofL* policy on Conflict of Interest. *UofL* personnel who are hired speakers for Vendors as well as all researchers funded by any Vendor will fully disclose any potential commercial bias at all presentations and interactions, will not allow their own relationship to bias the content of the lecture, and will not accept payments from Vendors for their services above fair market value.

b. Travel funds may not be directly given to any *UofL* faculty, residents, or students, except in the cases of legitimate reimbursement or contractual services to those Vendors. Travel funds for educational purposes must be otherwise handled per Section 4.

c. It is recognized that **members of the faculty may, in the course of their leadership roles in non-profit professional and scientific organizations, be expected to participate in programs, meetings, and events that involve Vendor relationships.**

Vendor interaction of UofL faculty members in the course of representing legitimate professional organizations will be governed by the policies and procedures of the specific organization.

9. UofL faculty, residents, or students are prohibited from engaging in any form of ‘ghostwriting’ of any presentations, publications, or other forms of media product (i.e., the provision of materials by a Vendor or intermediary that is officially credited to someone other than the writer(s) of the material).

10. Implementation and monitoring of this policy will be made at the administrative unit level (such that surveillance and remediation of minor violations be managed on this basis). Major violations (as determined by the unit administrative head) would be the purview of the appropriate Dean or his/her appointed designee for action.