

TITLE Industry Representatives and Service Providers (Code of Conduct Addendum, Part 3 of 5)			IDENTIFICATION NUMBER A01-105
ORGANIZATION(S)	SITES AFFECTED	CATEGORY	REPLACES:
University of Kentucky / UK HealthCare	X Enterprise	X Enterprise	
	Chandler	Nursing	
	Good Samaritan	Department	
	☐KCH	Guideline	
	Ambulatory	Protocol	
REVIEW CYCLE 1 year X 3 years		EFFECTIVE DATE: 4/15/2023	
Review Dates: 10/21/2019; 02/24/2020, 4/8/2022; 3/6/2023			

POLICY STATEMENT

Interactions with industry and service providers occur in a variety of on-campus and off-campus circumstances, including marketing of new products, training of new purchases, research support, educational support for trainees and continuing medical education programs. Many aspects of these interactions are very positive and important for promoting the educational, clinical and research missions of UK HealthCare. However, these interactions must be ethical and cannot create conflicts of interest, real or perceived, that could endanger patient safety, data integrity, the integrity of our education and training programs or the reputation of our members and our institution.

PURPOSE

The purpose of this policy is to act as guidance for industry representatives and service providers in their interactions with UK HealthCare Members. It also sets expectations for behavior when an industry representative or service provider is on the premises of any UK HealthCare facility.

SCOPE

This policy applies to all industry representatives and service providers in their interactions with UK HealthCare Members.

DEFINITIONS

UK HealthCare Members

"UK HealthCare Members" is defined as University of Kentucky Trustees, UK HealthCare employees, trainees, students, volunteers and representatives acting on behalf of the University involved in healthcare delivery and to all faculty, staff and trainees in the academic programs of the University of Kentucky Colleges of Medicine, Dentistry, Nursing, Pharmacy, Health Sciences and Public Health whether or not those individuals engage in clinical care.

Industry Representatives and Service Providers

For the purpose of this policy, "industry representatives and service providers" means any "manufacturer(s)" or "group purchasing organization(s)" as those terms are defined below. It also includes other outside entities and individuals who provide services (for example, IT services) to UK HealthCare.

Manufacturer

A "manufacturer" is an outside entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, or any entity under common ownership with a manufacturer. 42 CFR 403.902.

Group Purchasing Organization

A "group purchasing organization" means an entity that purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of other individuals or entities. <u>42 CFR § 403.902</u>.

PROCEDURES

Training, Orientation and Other Requirements for Industry Representatives

Before their first visit or appointment, all pharmaceutical industry representatives must register with UK HealthCare Pharmacy Services Administration. All other industry representatives and service providers must register with UK HealthCare Purchasing. When registering, the industry representative or service provider shall complete a computer-based module orientation session and receive a packet of information. The computer training and the packet will include UK HealthCare policies, University of Kentucky purchasing information, information regarding patient confidentiality and current immunization requirements, and agreements stating that the industry representative or service provider shall adhere to <u>Behavioral Standards</u>, as well as to American Medical Association and Research & Manufacturers of America guidelines. Documentation of completed training will be electronically maintained with Pharmacy or with Purchasing, as appropriate. The industry representative or service provider shall also provide Purchasing or Pharmacy with electronic documentation of annual TB screening, Hepatitis B, MMR, and varicella immunizations.

Clinical contractors shall also follow all UK HealthCare policies to ensure compliance with all regulatory requirements and contractual obligations. In addition to the requirements listed above, industry representatives and clinical contractors are required to abide by <u>Policy A03-125 (COVID 19)</u>.

Registration of Visits

Industry representatives and service providers must sign in on-line with Pharmacy or Purchasing at least 24 hours prior to their scheduled visit. Sign-in information shall include their destination, the individuals with whom they are meeting and the time of each meeting. Failure to sign in will be considered a violation of this policy.

UK HealthCare Issued Name Badges

All industry representatives and service providers shall be issued an identification badge for appropriate access. The badge shall include the individual's name and company. Any falsification of this information will be considered a violation of this policy. The badge must be worn on the upper front torso and be visible at all times while the representative is in a UK HealthCare facility.

Failure to wear an identification badge will be considered a violation of this policy.

Industry Representative and Service Provider Access to UK Healthcare Members

 Industry representatives and service providers are required to make an appointment in order to meet with a UKHealthCare Member. These appointments must be in non-patient, non-care areas (unless as set forth below) and shall be between the hours of 6:00 am and 5:00 pm, Monday through Friday. 2. Industry representatives and service providers may not interact directly with students or house officers unless supervised by a UK HealthCare Member.

Gifts and Meals

- 1. UK Healthcare Members may not accept gifts from industry representatives or service providers regardless of the nature or value.
- Industry sponsored meals or snacks are not allowed unless the meal or snack is in conjunction with an accredited continuing education program and it is offered to all attendees.

Samples

- 1. For polices regarding pharmaceutical samples, see <u>A14-135, Medication</u> <u>Sample Management</u>.
- All non-drug samples used in a patient care setting shall be registered with and approved by the overseeing committee before use. A valid no charge purchase order number shall be issued by Purchasing. All such products and equipment shall be FDAapproved or have Institutional Review Board (IRB) approval for clinical use. See <u>A07-115 (Value Analysis Process)</u>.

Industry Representatives and Service Providers in Patient Care Areas

- 1. At the request of the attending physician, an industry representative or service provider may be allowed in a patient care area. The attending physician assumes responsibility for the representative and must be present with the representative at all times. The interaction with the patient must be guided by UK HealthCare policies governing patient privacy and confidentiality,informed consent and quality patient care.
- 2. At the request of a surgeon, an industry representative or service provider may be allowed in an operatingroom or other procedure areas to provide technical support.
 - a) The special consent signed by the patient pursuant to <u>A06-000</u>, <u>Consent to</u> <u>Treatment</u>, shall include language that allows for the possible presence of an industryrepresentative or service provider.
 - b) The industry representative or service provider shall read and sign the perioperative services orientationguide and sign-in.
 - c) Industry representatives and service providers shall wear proper attire in the operating room and otherprocedure areas, which includes a red bouffant cap.
 - d) Industry representatives and service providers shall remain with the designated patient at all times and shall not visit other physicians within the operating room or procedure area.
 - e) Industry representatives and service providers shall not provide medical or patient care directly or indirectly. They shall not scrub in for the surgical/procedural case and, in general, they shall not open sterile supplies onto the field or touch the patient. Industry representatives/service providers in the patient area to program implantable medical devices may open supplies or touch the patient only if necessary to program the implantable device.
 - f) Industry representatives and service providers shall only be present in the operating room/procedure area during the period of time in which the product is in use.
 - g) Any problems related to industry representatives or service providers shall be reported to Purchasing and Operating Room Enterprise Administration.

Violation of Policy

Industry representatives and service providers who violate the terms of this or any other UK HealthCare policy shall be issued a first warning. This warning will be sent to the product sales representative's supervisor. A second violation may result in that representative being banned from the hospital. For any known or suspected violations contact the Office of Corporate Compliance.

Gifts, Gratuities, and Entertainment

Gifts, gratuities and entertainment offered by product sales representatives shall be governed by <u>A01-155 (UK HealthCare Members Interactions with Industry Representatives)</u>.

Questions

Any questions regarding this policy should be directed to the Office of Corporate Compliance.

REFERENCES

- 1. A01-005, Code of Ethics (Code of Conduct Addendum, Part 1 of 5)
- 2. A01-030, Conflicts of Interest (Code of Conduct Addendum, Part 2 of 5)
- 3. <u>A01-160, Annual Disclosures of Financial Conflict of Interest (Code of Conduct Addendum,</u> <u>Part 5 of 5)</u>
- 4. <u>AR 3:9, Consulting and Other Overload Employment Outside the University</u>
- 5. <u>A03-125, COVID-19</u>
- 6. <u>42 CFR § 403.902</u>

APPROVAL

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