



TITLE Industry Representatives and Service Providers (Code of Conduct Addendum, Part 3 of 5)		IDENTIFICATION NUMBER A01-105	
ORGANIZATION(S) University of Kentucky / UK HealthCare	SITES AFFECTED <input checked="" type="checkbox"/> Enterprise <input type="checkbox"/> Chandler <input type="checkbox"/> Good Samaritan <input type="checkbox"/> KCH <input type="checkbox"/> Ambulatory	CATEGORY <input checked="" type="checkbox"/> Enterprise <input type="checkbox"/> Nursing <input type="checkbox"/> Department <input type="checkbox"/> Guideline <input type="checkbox"/> Protocol	REPLACES:
REVIEW CYCLE <input type="checkbox"/> 1 year <input checked="" type="checkbox"/> 3 years REVIEW DATES: 10/21/2019; 02/24/2020, 4/8/2022; 3/6/2023; 4/1/2024		EFFECTIVE DATE: 5/15/2024	

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. [42 CFR § 403.902](#).

PROCEDURES

Training, Orientation and Other Requirements for Industry Representatives

All industry representatives and service providers must register with UK HealthCare Supply Chain,. The industry representative shall register in the GHX Vendormate system and log in to this site prior to any visit to UK HealthCare. The Vendormate system will provide a vendor badge for the day that must be worn on upper torso for UK HealthCare members to see. The Vendormate system educates industry representatives on UK HealthCare policies, patient confidentiality, immunization and other clinical requirements, agreements stating that the industry representative or service provider shall adhere to [Behavioral Standards](#), as well as to the [American Medical Association Code of Medical Ethics Opinion 10.6 on Industry Representatives in Clinical Settings](#). Documentation of completed training and immunization requirements will be electronically maintained in/on the Vendormate site. The industry representative or service provider shall receive annual notification of updates needed for credentialing.

Clinical contractors shall also follow all UK HealthCare policies to ensure compliance with all regulatory requirements and contractual obligations.

Registration of Visits

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.**

Gifts and Meals

1. UK Healthcare Members may not accept gifts from industry representatives or service providers regardless of the nature or value.
2. 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 [A14-135, Medication Sample Management](#).
2. 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 FDA-approved or have Institutional Review Board (IRB) approval for clinical use. See [A07-115 \(Value Analysis Process\)](#).

Products left by an industry representative or service provider for patient use without a valid UK purchase order are considered gifts to the University of Kentucky.

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 operating room or other procedure areas to provide technical support.
 - a) The special consent signed by the patient pursuant to [A06-000, Consent to Treatment](#) shall include language that allows for the possible presence of an industry representative or service provider.
 - b) The industry representative or service provider shall read and sign the perioperative services orientation guide and sign-in.
 - c) Industry representatives and service providers shall wear RepScrub attire in the operating room and other procedure areas.
 - 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 UK HealthCare Supply Chain and appropriate operational leaders..

Violation of Policy

Industry representatives and service providers who violate the terms of this and/or any other UK HealthCare policy shall be issued a warning. Future violations may result in that representative being banned from the hospital. Non-compliance with the policy/guidelines may result in the loss of industry representatives' privileges. For any known or suspected violations contact the Office of Corporate Compliance.

Gifts, Gratuities, and Entertainment

Gifts, gratuities and entertainment offered by industry representatives shall be governed by [A01-155 \(UK HealthCare Members Interactions with Industry Representatives\)](#).

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. [A01-160, Annual Disclosures of Financial Conflict of Interest \(Code of Conduct Addendum, Part 5 of 5\)](#)

4. [AR 3:9, Consulting and Other Overload Employment Outside the University](#)
5. [American Medical Association Code of Medical Ethics Opinion 10.6 on Industry Representatives in Clinical Settings](#)
6. [42 CFR § 403.902](#)

APPROVAL

NAME AND CREDENTIALS: Noelle True TITLE: Assistant Chief Compliance Officer	NAME AND CREDENTIALS: Lorra Miracle TITLE: AVP, Health System Supply Chain
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