

University of Colorado Hospital Policy and Procedure

Vendor Representative (VR) Policy

Related Policies and Procedures:

UCH Code of Conduct
Visitors to the Operating Room
Visitors and Observers in Hospital Facilities
Transplant and Implant Tissue Storage and Issuance

Approved by: Administrative Structure Subcommittee
Product Oversight Committee
Effective: 11/08

Description: This policy is intended to provide guidance as to appropriate activities and ethical principles of conduct for interactions between vendor representatives (VR) and University of Colorado Hospital (UCH) employees and its affiliates. Covered products and services include but are not limited to pharmaceuticals, medical and surgical supplies/devices/implants and nutritional products. VRs are defined as agents of manufacturers and suppliers who promote products and/or services and provide information to employees or agents of UCH. UCH buildings include Anschutz Inpatient Pavilion, Anschutz Outpatient Pavilion, Anschutz Cancer Pavilion, Rocky Mountain Lions Eye Institute, Lepirino Building and Purchasing Offices.

Accountability: All UCH employees, employees of affiliates doing business within UCH facilities, and vendor representatives are required to comply with the UCH Code of Conduct and are responsible for enforcing these policies.

Policies/Procedures: The UCH Product Oversight Committee has developed guidelines for VRs. The following guidelines will be enforced by UCH Products Oversight Committee assisted by related departments.

I. General Requirements - Apply to all VRs calling on UCH/University of Colorado at Denver personnel within UCH. *The VR must also check for area-specific policies (see section II below).*

A. Registration:

- Badging – UCH badging is not required. However **the VR must have his/her company-assigned identification card/nametag prominently displayed while in UCH facilities.** Area specific requirements may be more stringent – see below.
- Business Hours – pertaining to VRs, UCH business hours are considered to be 0600 – 1730, Monday through Friday exclusive of holidays; educational and detailing activities should not be conducted outside of these hours.

Vendor Representative (VR) Policy

- Parking – the southwest corner of the Visitors lot is to be used by all VRs. Outside catering is permissible provided that the meals are modest, occur in a venue and manner conducive to informational communication and provide scientific or educational value. "Takeout" meals or meals to be eaten without a company representative being present are not appropriate.

B. Activities within UCH:

1. Unless otherwise specifically permitted below, representatives' activities will be **confined to non patient care units** at all times.

Restricted areas are listed below.

- a. Patient room and nursing units/care team areas
 - b. All Intensive Care Units
 - c. Operating Rooms, Pre-op and Post Anesthesia Care Units
 - d. Emergency Department
 - e. Nurseries and Labor and Delivery area
 - f. Patient care areas in outpatient clinics
 - g. Pharmacy satellites
2. Meetings with physicians and UCH personnel must be prearranged with a scheduled **appointment. *Unscheduled visits are not permitted.*** Medical students, pharmacy students, interns, residents, and fellows shall not be contacted either in person or by telephone by representatives while on patient-care duty or during regular UCH business hours.
 3. Patient Confidentiality - Protected health information will not be discussed during any formal or informal conference/seminar when VRs are present. Individuals in charge of a conference should ask the VR to leave the room prior to discussing patient(s).
 4. Use of UCH facilities for VR training, "shadowing" or "vendor clinical preceptorships" i.e., situations where a VR spends contact time with a clinician in circumstances where patient information is typically presented and the vendor's product or a competing product may be discussed ***is not*** permitted whether or not an honorarium or anything of value is offered in return for the experience.
 5. Non-disclosure of UCH operations/policies – presence on our campus may lead to involuntary disclosure of our policies and/or operations. These are not to be further communicated. Violators are subject to sanctions at the Hospitals sole discretion.

C. Purchasing Authority – Only authorized UCH personnel representing the hospital and working in conjunction with their respective products oversight committee may authorize the purchase/rental of equipment, supplies, devices, medications, nutritional products or implants. Physicians are ***not*** authorized to approve purchases, engage in negotiations or approve product trialing on behalf of UCH. **UCH is not responsible for payment of products and/or services used at UCH without documented prior approval of authorized UCH personnel.**

D. Gifts/Money/Entertainment/Favors

1. Gifts Influencing Decision-making – VRs should not offer gifts, favors, services, entertainment, or other things of value that would influence the decisions or actions of a hospital employee or agent.

Vendor Representative (VR) Policy

2. Gifts From Existing Vendors - these are to be discouraged. *Cash/cash equivalents (e.g., gift cards) are never acceptable.* VR must never offer excessive gifts, meals, expensive entertainment, or other offers of goods or services which have more than a nominal value of \$50.
3. Vendor-sponsored entertainment - Occasional attendance at a local theater or sporting event, or similar entertainment at vendor expense may be offered.

E. Disclosure – the VR must complete the agreement as part of this document disclosing financial relationships that our physicians/staff may have with their company. Failure to disclose such relationships will result in sanctions determined by UCH.

F. Infractions and sanctions

1. Promotional activities of vendor representatives are a privilege which has been extended by UCH. The **Vendor Oversight Subcommittee** is responsible for enforcing this policy. Any individual observing infractions of these guidelines should contact the VOS at x82906.
2. The VOS will apply the following progressive sanctioning:
 - First Infraction -- Schedule a meeting with the representative and discuss the infraction with a letter of reprimand to immediate supervisor.
 - Second Infraction – banned from institution for three (3) months.
 - Third Infraction – privileges revoked immediately and permanently.
3. In the event that a vendor representative is found in a patient care area without authorization or requests or attempts to gain access to confidential information concerning patients or product use, privileges will be immediately and permanently revoked.

G. Risk Level/Encounter Types

High risk encounters, i.e., those encounters in patient care areas involving product/device installation and or training and requiring:

- a clinician's specific permission; and,
- documentation of a signed vendor agreement.

Areas including but not limited to OR/Perioperative Areas, Interventional Radiology/Catheterization Procedures Areas, GI Procedures Areas and Radiology Procedures Areas.

Standard encounters i.e., encounters in non-patient care areas only.

Areas including but not limited to Pharmacy, Nutrition, Laboratory, and Respiratory Care.

II. AREA-SPECIFIC

A. OR/PERIOPERATIVE AREAS

1. All new, replacement or trial products and/or equipment used in the OR must be approved by the OR products committee **prior** to use. Only UCH physicians may submit product requests to the OR products committee.
2. UCH requires that all products that contain tissue, including human, bovine, or porcine tissue, meet strict criteria regarding procurement and storage. By signing the vendor agreement, you are acknowledging that you have met and agree to all

Vendor Representative (VR) Policy

- requirements set by the UCH policy for Transplant and Implant Tissue Storage. You also agree that you have maintained all storage and handling requirements set by the product manufacturer.
3. Vendor Surgical Attire: all vendors must abide by the OR surgical attire policy which includes wearing of specific colored OR caps within the Perioperative environment. Backpacks and briefcases are NOT permitted within the OR restricted environment.
 4. Medical products vendors may access the OR/Perioperative areas on a case-by-case basis as determined by the surgeon. To minimize traffic within the sterile environment no more than three VRs are permitted in the surgical suite for a surgical case unless approved by surgeon.
 5. Vendors must wear the badge issued from the RepTrax kiosk. UCH card for UCH Perioperative areas may be obtained by select vendors to allow for scrub machine access only.
 6. Credentialing requirements for all vendor reps, sales reps, tissue/bone representatives, service technicians and distributor representatives are:
 - Proof of chicken pox
 - Proof of Hepatitis B vaccination
 - Proof of MMR-Measles, Mumps, and Rubella
 - Tuberculosis
 - Proof of Employer General Liability Coverage
 - Evidence of Employer Product/Service Competency
 - OR Protocol training
 - HIPAA Training
 - Blood Borne Pathogens training

B. PHARMACY/Pharmacy & Therapeutics Committee (P&T Committee)

1. Formularies – UCH maintains two closed drug formularies (UCH Inpatient /Clinics Formulary and Colorado Indigent Care Pharmacy Formulary) and both are under the purview of the UCH P & T Committee. The process for consideration of a product for formulary addition is for the VR to present information to representatives from the Pharmacy Department. Meetings with the Purchasing Lead Pharmacist and other departmental personnel are to be scheduled in advance (720-848-6869). Meeting times are scheduled biweekly.
 - Detailing a non-formulary product is considered a violation unless the person being detailed is informed that the product is non-formulary or restricted.
 - VRs are not permitted to participate in the UCH formulary processes (e.g., completing the P&T request).
 - VRs are not allowed to meet with members of the P & T Committee or any subcommittee members when their products are undergoing formulary consideration. Pharmacy personnel may contact a VR if additional information is required for formulary review.
2. Drug Samples
 - All representatives must comply with applicable laws and with Pharmaceutical Manufacturers Association (PMA) voluntary code regarding distribution of sample drugs.
 - Samples are to be left only when requested by the person licensed to prescribe

Vendor Representative (VR) Policy

or dispense medications.

- Pharmaceutical representatives are not allowed to solicit individuals to sign sample drug request forms. Refer to the Sample Drug Policy for more information.
3. Drug Literature
- If the VR distributes literature for non-formulary medications, they must indicate on the literature that the medication is 'Non-formulary.'
 - No detailing of drugs which have been denied admission to the hospital formulary or for which there is a therapeutic interchange in place.
 - Distribution of literature to patients or leaving in the clinic waiting areas is not permitted.
 - Preprinted prescription pads are NOT to be brought into or distributed in UCH. The Pharmacy department will not fill any prescription written on a preprinted pad.

C. INFORMATION SERVICES

Under specific circumstances, software and/or hardware vendors must be on UCH premises to perform services. Examples would be: installation of products, go-live support, user or IS team training. In these instances, the vendor may be required to be in clinical areas or HIGH-RISK AREAS without direct UCH employee supervision. The following criteria should be met under these circumstances:

1. UCH Project Manager or Management staff must be aware that vendor is on-site;
2. Manager/PM will notify the Director/Manager of the area the contractor is going to be working in without supervision;
3. Company assigned identification (i.e., name badge) must be worn at all times.

D. CLINICAL LABORATORY

1. All sales activities for laboratory tests or devices, whether for testing in the Clinical Laboratory or in a clinic/nursing unit (i.e. Point of Care testing) must be conducted with Clinical Laboratory staff.
2. Vendors may not contact physicians/ clinics/ nursing units for the sale of or to provide Information on laboratory tests or devices
 - a. The exception would only be if Laboratory staff, specifically instruct the vendor to provide pricing information to the clinic/ nursing unit for Point of Care testing devices.
3. Clinics/ nursing units which are contacted by vendors for lab testing must immediately refer the vendor to Clinical Laboratory Administration.

References:

1. The Joint Commission, Standard RI 2.130 Ethics, Rights and Responsibilities -Confidentiality
2. The Joint Commission, Standard MM 2.10 Medication Management - Selection and Procurement
3. The Joint Commission, Standard EC 2.10 Management of the Environment of Care - Security Risks
4. American Society of Hospital Pharmacists. ASHP Guidelines for Pharmacists on the

Vendor Representative (VR) Policy

Activities of Vendors' Representatives in Organized Health Care Systems. *Am J Hosp Pharm.* 1994; 51:520-1.

5. Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions With Healthcare Professionals, January 2004; PhRMA 1100 Fifteenth St., NW, Washington DC 20005.
6. Federal Anti-Kickback Statute, 42 U.S.C. 1320-a7(b)
7. Prescription Drug Marketing Act of 1987, 21 U.S.C. 353(c) (1)
8. Health Insurance Portability and Accountability Act of 1996
9. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, <http://vwww.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf> Accessed October 17, 2007
10. American Medical Association, Gifts to Physicians from Industry Accessed October 17, 2007 <http://www.ama-assn.org/go/ethicalgifts>.

CONFIDENTIALITY STATEMENT

University of Colorado Hospital (UCH) and University of Colorado Denver (UCD) employees and other persons, including but not limited to students, trainees, volunteers, contractors and vendors, who may from time to time, have access to confidential UCH information are required to keep the information confidential. Patient information, employee records, computer passwords, and proprietary business information are all examples of confidential information. Confidential information may not be removed from the facility and shall not be shared or disseminated to individuals who do not need the information in order to perform their jobs. Each individual must at all times act carefully, in good faith, in a manner which promotes the best interests of UCH and its patients and research subjects, and in a way which recognizes and promotes ethical considerations and the duty of loyalty that each individual owes to the UCH.

Patient information, employee records or proprietary business information may be disclosed only in accordance with UCH policies. If in doubt, you should act to preserve the confidence of the information requested until UCH policy(ies) can be verified. You should refrain from discussing or disclosing confidential information except as necessary to promote the legitimate business of UCH. Disclosing confidential information in violation of UCH policies or in violation of law may result in disciplinary action up to and including termination of employment or, for individuals who are not employed by UCH, termination of access to UCH's information systems and/or facilities. There are various federal and state laws which mandate that patient information be kept confidential and, in some instances, impose civil or criminal penalties for a breach of confidentiality.

No individual is permitted to realize any personal gain as a result of disclosing or using confidential information. This duty of nondisclosure and the obligation not to benefit from confidential information learned during the course of your employment or while you are working or studying at UCH continues indefinitely, even after your employment or arrangement with UCH ends.

a075n08