

Vendor Representative Policy	
Effective Date: 08/2022	Replaced Policy(ies) LD-19; Vendor Representative Policy with Confidentiality Statement
	Policy Owner: Supply Chain

#### Introduction

This policy is intended to govern interactions and establish clear expectations regarding access, identification, conduct, and activities of a Vendor Representative ("VR") for any UCHealth or UCHealth affiliated site of care with UCHealth employees, patients, or providers.

## Scope

View the UCHealth Policy Scope Statement to see where this policy applies.

I. Covered products, equipment, and services include, but are not limited to, pharmaceuticals, medical and surgical supplies, devices/implants, nutritional products, medical equipment, clinical engineering, PAC s imaging service providers, Information Technology (IT), Radiopharmaceutical, and any vendors providing services to UCHealth. Vendors who do not have a contract with UCHealth may not access UCHealth facilities without express authorization from UCHealth Supply Chain.

### **Table of Contents**

I.	General Requirements For All VRs	1
II.	Value Analysis: Product Introduction, Evaluation, and Acceptance	6
	Capital and Purchased Services Evaluation and Acceptance	
	Donations	
	Recalled Medical Products and Implantable Devices	
	Area Specific Requirements	

## **Policy Details**

### I. General Requirements For All VRs

- **A.** Registration
  - **1.** Registration in RepTrax is required for all VRs
    - a. Prior to accessing a UCHealth or UCHealth affiliated site of care, all VRs who will have any on-site presence or could potentially have an on-site presence at a UCHealth facility are required to register as an approved UCHealth VR in RepTrax.

- **b.** All VRs are required to meet all credentialing requirements and are required to review and attest to all applicable policies and procedures as defined in RepTrax.
- c. All VRs are only allowed access to UCHealth or UCHealth-affiliated sites of care with an approved and prescheduled time, authorized by an appropriate UCHealth employee or medical staff member supporting UCHealth.
- **d.** All VRs are required to properly check-in through RepTrax on the day of their scheduled visit to a UCHealth or UCHealth-affiliated site of care either at a designated RepTrax kiosk or via mobile check-in.
- **e.** All VRs are required to agree to abide by this Vendor Representative policy and must attest to such agreement in RepTrax prior to completing the check-in process.

#### 2. Badging

- a. All VRs must have a date-specific printed RepTrax badge obtained from the RepTrax kiosk at each UCHealth or UCHealth-affiliated site of care, a current dated Go! E-badge, or proof of check-in through the RepTrax mobile check-in process while on site.
- **b.** Any VR not in possession of a current dated RepTrax validation will not be allowed to enter a UCHealth or UCHealth-affiliated site of care.
- **c.** All VRs must be able to show documentation of current dated RepTrax validation immediately upon request by any UCHealth employee or medical staff member.
- **d.** Any VRs not in possession of current dated RepTrax validation will be requested to leave the facility until such documentation can be provided.
- e. Instances in which VRs are found to be on-site without the proper RepTrax validation will be subject to VR sanctions – see Section L.2.a.

#### 3. Access

- **a.** VRs are not permitted in any patient care area, including waiting rooms, inpatient units, or faculty practice sites, unless otherwise defined in section VI of this policy or unless to provide in-service training on devices or other equipment and then, only by appointment and with the appropriate approval.
- **b.** VRs may not loiter in common hospital areas, such as lobbies, cafeterias, etc., for the purpose of initiating unsolicited contact with health care professionals. Under no circumstances may VRs initiate contact with house staff or medical students on UCHealth premises.

#### 4. Business Hours

**a.** All VR activities must be conducted within each UCHealth or UCHealth-affiliated site of care's normal business hours, unless approved in advance by appropriate UCHealth leadership.

### 5. Vendor Parking

- **a.** VRs shall park at vendor parking locations as outlined by sites.
- **b.** VRs may not park in patient parking areas or utilize valet or other patient parking services.
- **c.** Fines and/or VR Sanctions will be assessed for VRs found to be parking inappropriately.

## Vendor Representative Policy

#### B. Activities within UCHealth

- 1. VRs will not be allowed to visit any UCHealth or UCHealth-affiliated sites of care to include outpatient/medical clinics without a scheduled appointment. Meetings with physicians, care managers, patients/families, and UCHealth personnel must be prearranged with a scheduled appointment. Unscheduled visits are not permitted, including any marketing visits.
- 2. Medical students, pharmacy students, interns, residents, fellows, faculty, and UCHealth employees or medical staff shall not be contacted either in person or by telephone by VRs while they are on patient-care duty.
- 3. Unless approved in advance by UCHealth leadership, use of UCHealth facilities for the training of VR employees, non-UCHealth physicians VR 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. This prohibition exists regardless of whether or not anything of value is offered in return for the experience.
- 4. VRs will not have storage, office space, or workspace on site without express written permission from UCHealth leadership or a short-term lease to pay for space used. Exceptions to this in cases where the VR is under an active construction project and the space used is within the boundaries of the construction zone.

### **C.** Confidentiality

- 1. Patient Confidentiality
  - **a.** Only the minimum necessary amount of Protected Health Information ("PHI") that is necessary for the VRs to perform their work for UCHealth should be disclosed to VRs during their visit to a UCHealth or UCHealth-affiliated site of care.
  - b. PHI should 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 before discussing patient(s).
  - **c.** VRs will be required to attest to abiding by UCHealth's patient confidentiality expectations in RepTrax. Any updates to these expectations will be cascaded to VRs through the RepTrax system.

### 2. UCHealth Operations/Policies

- a. Presence on a UCHealth or UCHealth-affiliated site of care may lead to voluntary or involuntary disclosure of our operations, employees, goals, priorities, policies, or other privileged information. These are not to be further communicated. Violators are subject to sanctions at UCHealth's sole discretion.
- b. VRs may be exposed incidentally to PHI during their visit to a UCHealth or UCHealth-affiliated site of care. Care should be taken to ensure any PHI the VR is exposed to is kept confidential and not further used or disclosed by the VR.

### **D.** Purchasing Authority

 Only authorized UCHealth Supply Chain personnel representing a UCHealth or UCHealth-affiliated site of care and working in conjunction with their respective oversight committees may authorize purchases, including but not limited to: the purchase/rental of equipment, supplies, devices, medications, nutritional products, services, or implants.

- 2. Non-supply chain employees are not authorized to approve purchases, engage in negotiations, or approve product trialing on behalf of UCHealth.
- **3.** UCHealth is not responsible for payment of products, equipment, and/or services used at UCHealth without documented prior approval of authorized UCHealth personnel.
- E. Vendor Gifts/Money/Entertainment/Favors
  - 1. See the UCHealth *Patient/Vendor Gift, Food, and Educational Offerings Policy* and the UCHealth *Conflicts of Interest Policy* for more guidance on business interactions with vendors or reach out to compliance@uchealth.org.
- F. Business Associate
  - 1. If a vendor maintains, creates, receives, or transmits PHI to perform services for UCHealth, it is considered a Business Associate ("Business Associate") and shall execute a Business Associate Agreement (BAA) with UCHealth.
  - 2. The vendor must have an executed BAA on file with UCHealth prior to a VR visiting a UCHealth or UCHealth-affiliated site of care. expected to
  - **3.** VRs must contact the Supply Chain office to obtain UCHealth's BAA Template form.
    - a. In certain situations, which must be approved by UCHealth Compliance and Privacy Department, UCHealth may agree to execute a BAA with a vendor using a non-UCHealth BAA template. In such a case, UCHealth Compliance and Privacy Department must review, and redline as applicable, any alternative to the UCHealth Template BAA.
    - **b.** See the UCHealth *Business Associates Policy* for more information.
- **G.** Colorado Consumer Data Security Law
  - 1. If a vendor maintains, creates, receives, or transmits Personal Identifying Information ("PII"), as defined under Colorado law, to perform services for UCHealth, it shall execute an *Agreement to Secure Protected Information* with UCHealth.
  - **2.** A Vendor that executes a BAA does not also need to execute an *Agreement to Secure Protected Information*.
- H. Physician Owned Entities and Distributorships
  - UCHealth does not do business with any Physician Owned Entities and/or Distributorships unless an exception or exemption exists and is documented and approved by UCHealth Supply Chain and Compliance and Privacy Departments.
    - **a.** See the UCHealth *Physician Owned Entities and Distributorships Policy* for more information.
- I. Code of Conduct
  - 1. While on any UCHealth property, Vendor representatives are expected to abide by the UCHealth Code of Conduct which is available on RepTrax, online, and in the Supply Chain offices.
    - a. See the UCHealth Code of Conduct for more information.
- **J.** Ineligible Persons or Entities
  - 1. Individuals and entities with whom UCHealth may or does engage in doing business are obligated to disclose:
    - **a.** Convictions of criminal offenses related to healthcare items or services.
    - **b.** State and/or federal exclusions.
    - **c.** Pending or final debarment actions.

- **d.** Any other matter that renders them ineligible for participation in federally funded healthcare programs.
- 2. Any individual or entity for whom such disclosure is made is considered Ineligible Persons or Entities ("Ineligible Persons or Entities"). UCHealth will not do business with or continue doing business with Ineligible Persons or Entities.
- **3.** All potential vendors are checked for exclusions in accordance with the UCHealth *Exclusion Monitoring and Licensure Exclusion Policy* prior to being set up as an approved vendor.
  - **a.** UCHealth will not contract individuals or companies who are excluded or otherwise ineligible to participate in federally funded healthcare programs.
- **4.** The Compliance and Privacy Department is responsible for conducting monthly exclusion monitoring of all active vendors.
  - a. If a match is discovered and confirmed, the Compliance and Privacy Department will proceed with necessary measures as outlined in the UCHealth Exclusion Monitoring and Licensure Verification Policy. Measures include working with Supply Chain stakeholders to investigate, determine, and address any potential issues.

# K. Infractions and Sanctions

- 1. Supply Chain is responsible for enforcing policy sanctions. Any individual observing infractions of these guidelines should immediately contact the Supply Chain Vendor Management Office at <a href="VendorManagement@uchealth.org">VendorManagement@uchealth.org</a> or the Supply Chain Director of Materials Management (DMM). Supply Chain may choose sanctions, at its discretion, dependent on the severity of the infraction and not necessarily in the order listed below.
- 2. At its sole discretion, Supply Chain will apply the following sanctioning:
  - **a.** First Infraction Written and/or verbal communication to document infraction to VR as well as to immediate supervisor and probationary period
  - Second Infraction No access to all UCHealth facilities for one (1) month
  - Third Infraction No access to all UCHealth facilities for six (6) months
  - **d.** Fourth Infraction –Up to a lifetime ban of access to all UCHealth facilities
- 3. If a VR 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 may be immediately and permanently revoked.
- **4.** If a UCHealth team member who is also a VR is found to be conducting vendor business during their UCHealth working hours, privileges may be immediately and permanently revoked.

### L. Conflict of Interest

- 1. Vendor should disclose any financial relationship with any UCHealth employee or medical staff member supporting UCHealth or UCHealth affiliated site of care.
- 2. Should a vendor disclose they have a relationship with a UCHealth a review of the COI should be conducted with Compliance to ensure appropriate

## Vendor Representative Policy

procurement process are being followed to avoid any potential conflict of interest.

Prior to accessing a UCHealth or UCHealth-affiliated site of care, a review of Conflict of Interest must be completed.

## II. Value Analysis: Product Introduction, Evaluation, and Acceptance

- **A.** New products requests (NPRs) must originate from a UCHealth clinician, staff member and/or provider. New product requests will not be considered unless the request meets one of the following exception criteria:
  - 1. New service line
  - 2. New procedure type, existing service line
  - 3. New physician performing new procedure type
  - 4. Safety concern
  - **5.** Quality concern
  - **6.** Technology Assessment Committee (TAC) request
  - **7.** Line extension (already approved product line, same vendor, same contract, different size
  - 8. Supplies items tied to capital purchase
- **B.** If the request meets the exception criteria, and it is proven that the product will ensure or improve patient safety, improve outcomes, reduce costs, improve contract compliance, or optimize utilization, the request will be presented for review to the appropriate regional Product Review Committee by Value Analysis (VA).
  - 1. New product approvals must follow the VA/Strategic Sourcing NPR process.
  - 2. Vendors may not access UCHealth's internal system to submit requests; only a UCHealth clinician, staff member and/or provider may gain access to make a request.
- **C.** If the Product Review Committee approves the product for further review, a full clinical and financial evaluation, which may or may not include a product trial at the sole discretion of the Product Review Committee, will be completed before final approval and/or denial of the product:
  - 1. All decisions made through the VA/Sourcing process will be effective for only the entities defined in the request. For example, a request approved in one region/facility will not necessarily apply to another.
  - 2. All committee members and committee decisions are confidential in nature.
  - **3.** Any decisions may or may not be communicated at the sole discretion of UCHealth.
  - **4.** Invoices for products brought into any UCHealth facility without VA approval will NOT be paid. The products will be considered a donation.

#### III. Capital and Purchased Services Evaluation and Acceptance

**A.** All equipment and purchased services require an authorized Purchase Order or executed contract issued by Supply Chain before delivery or use. Any equipment or purchased services provided without authorized Purchase Order or contract may be considered a donation and payment may be refused. This applies to loaners and/or trials. Exceptions may be research related.

### **IV. Donations**

**A.** Any supplies or equipment given to UCHealth staff members by a VR without solicitation must be immediately reported to Supply Chain. A review for potential conflict of interest must be completed and documented.

## Vendor Representative Policy

**B.** UCHealth team members are not permitted to accept samples – samples may be permitted if approved by the Director of Pharmacy or other authorized party.

## V. Recalled Medical Products and Implantable Devices

- **A.** Approved UCHealth staff must accompany manufacturer or supplier representative if present during the physical removal of supplies from UCHealth facilities. Such removals must be scheduled in advance and authorized by approved UCHealth staff.
  - 1. Approved UCHealth staff may include recall manager, recall coordinator, Supply Chain personnel, or IT manager or director if hardware/software.
- **B.** VRs are not authorized to remove supplies from UCHealth facilities without providing a return authorization.

# VI. Area Specific Requirements

- A. Procedural Areas
  - 1. All new, replacement, or trial products used in any UCHealth or UCHealth affiliated site of care must be approved in advance before use through Value Analysis. Only UCHealth staff and physicians may submit new product requests. Products that are used without approval by Value Analysis will be considered a donation to UCHealth and may result in VR sanctions.
  - 2. All new, replacement, or trial of equipment used at any UCHealth or UCHealth affiliated site of care must be preapproved and authorized according to the capital approval process. No equipment will be brought into UCHealth facilities without preauthorization and purchase orders. Product or equipment that is delivered without a purchase order will be considered a donation to UCHealth and may result in VR sanctions or may be picked up at VR's expense. All equipment must be checked and approved by Biomed/Clinical Engineering before use.
  - 3. All VRs must abide by the facility OR surgical attire -expectations which may include wearing specific colored OR caps or facility VR designated scrubs within the Perioperative environment. Backpacks and briefcases are NOT permitted within the OR restricted environment.
  - 4. Medical product VRs may access the OR/Perioperative areas on a case-by-case basis as determined by the surgeon and contingent upon meeting the required credentials in RepTrax in advance of the VR coming on-site. If the surgeon is not a UCHealth team member, review and notification must be given to the specialty leader or COO of the UCHealth or UCHealth-affiliated site of care.
    - a. To minimize traffic within the sterile environment, no more than two (2) VRs are permitted in the surgical suite. In addition, VRs may only be present for surgical cases in relation to the role or product that they provide; VRs are not allowed to "observe" cases for their training requirements.
  - **5.** Credentialing requirements for all VRs, sales reps, tissue/bone representatives, service technicians, and distributer representatives are available on RepTrax.
- **B.** Pharmacy/Pharmacy & Therapeutics Committee (P&T Committee)
  - 1. New drugs for consideration by the P&T Committee shall only be discussed with the Director of Pharmacy Services or designee. The Director of Pharmacy may schedule a discussion of the new drug and its potential addition onto formulary on a P&T Committee meeting agenda.

- **2.** VRs are not permitted to participate in the UCHealth formulary processes (e.g., completing the P&T request).
  - **a.** Requests for formulary additions can only be made by a UCHealth Employee or a member of the Medical Staff.
  - **b.** 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.
  - **c.** VR meetings with hospital and Medical Staff must be scheduled in advance.
  - **d.** Detailing a non-formulary product is considered a violation unless the person being detailed is informed that the product is non-formulary or restricted.
  - **e.** All requests are required to complete the P&T Committee Formulary Request Form.

## 3. Drug Samples

- **a.** Drug samples can only be accepted by the authorized provider or pharmacist that have requested the samples in writing prior to acceptance or delivery.
- **b.** Only an authorized provider with prescriptive authority or a pharmacist may dispense sample medications. Only those given authorization will be permitted to access or dispense sample medications. See the UCHealth *Sample Medications Policy* for additional guidance.

### **4.** Drug Literature

- **a.** If the VR distributes literature for non-formulary medications, they must indicate on the literature that the medication is 'Non-formulary'.
- **b.** Distribution of literature to patients or leaving in the clinic waiting areas is not permitted.
- **c.** All promotional literature and materials shall first be provided to and approved by the Pharmacy Department.

### **C.** Information Services (IS)

- Software and/or hardware vendors are required to wear a UCHealth badge or be accompanied by a UCHealth employee at all times while on site at a UCHealth or UCHealth affiliated site of care.
- 2. Under specific circumstances, software and/or hardware vendors must be on UCHealth premises to perform services. Examples would be the installation of products, go-live support, and user or IS team training. In these instances, the vendor may be required to be in clinical areas without direct UCHealth employee supervision. These situations are allowed only if the following criteria is met:
  - **a.** UCHealth Project Manager (PM) or an IS Manager or Director must have approved, in advance, vendor to be on-site.
  - **b.** Vendor is required to wear a UCHealth badge at all times.
  - **c.** Manager/PM will notify the Director/Manager of the area the contractor is going to be working in without supervision.

#### **D.** Clinical Laboratory

- 1. All sales activities for laboratory tests or devices, whether for testing in the Clinical Laboratory or 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. The only exception would

# Vendor Representative Policy

- be if Laboratory staff specifically instructs the vendor to provide pricing information to the clinic/nursing unit for Point of Care testing devices.
- **3.** Clinics/nursing units that are contacted by vendors for lab testing must immediately refer the vendor to Clinical Laboratory Administration.
- **4.** All products, equipment, and services must be preauthorized, and a purchase order must be obtained before installation and use.
- **5.** All equipment must be checked and approved by Biomed/Clinical Engineering before use.
- E. Construction/Building Maintenance/Engineering
  - 1. VRs are required to have a UCHealth temporary badge issued by the UCHealth Facilities, Design, and Construction department at all times while on site at a UCHealth or UCHealth affiliated site of care.

#### **Related Policies:**

Business Associates Policy
Code of Conduct
Conflict of Interest Policy
Exclusion Monitoring and Licensure Verification Policy
Identification Badges Policy
Patient/Vendor Gift, Food, and Educational Offerings Policy
Physician-Owned Entities and Distributorships Policy
Sample Medications Policy

#### **Definitions:**

**Business Associate:** A person or entity that performs certain functions or activities that involve the use or disclosure of PHI on behalf of, or provides services to, a Covered Entity. A Workforce Member of a Covered Entity is not a Business Associate. A Covered Entity can be a Business Associate of another Covered Entity. Business Associate functions and activities include: claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; billing; benefit management; practice management; and repricing. Business Associate services include: legal; actuarial; accounting; consulting; data aggregation; management; administrative; accreditation; and financial.

Ineligible Persons or Entities: Any individual or entity that: (i) is currently excluded, suspended, debarred, or otherwise ineligible to participate in Federal health care programs; (ii) has been convicted of a criminal offense related to the provision of health care items or services but has not yet been excluded, debarred, or otherwise declared ineligible; or (iii) is currently excluded on a state exclusion list.

**Personal Identifying Information (PII):** As defined by the Colorado Data Privacy Laws set forth at Colo. Rev. Stat. §§ 6-1-713, 6-1-713.5 and 6-1-716, PII includes Social Security numbers; personal identification numbers; passwords; pass codes; official state or government-issued driver's license or identification card numbers; government passport numbers; biometric information; employer, student, or military identification numbers; and financial transaction devices, including financial account numbers.

**Protected Health Information (PHI):** Health information protected under the HIPAA privacy standards' use and disclosure provisions. PHI includes individually identifiable health information created, received, maintained, or transmitted by a Covered Entity or Business Associate (as both terms are defined in HIPAA), that is transmitted or maintained in any form or medium, including electronic, paper, or oral.

**Vendor Representative (VR):** Facilities or agents of manufacturers and suppliers who promote products and/or services to employees or agents of UCHealth or representatives of

# Vendor Representative Policy

PAC agencies who provide information to patients/families/care managers of UCHealth to facilitate a timely and efficient transition of care.

#### References:

The Joint Commission, Standard RI 2.130Ethics, Rights and Responsibilities -Confidentiality The Joint Commission, Standard MM 2.10 Medication Management - Selection and Procurement

The Joint Commission, Standard EC 2.10 Management of the Environment of Care - Security Risks

American Society of Hospital Pharmacists. ASHP Guidelines for Pharmacists on the Activities of Vendors' Representatives in Organized Health Care Systems. *Am J Hosp Pharm.* 1994; 51:520-1.

Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions With Healthcare Professionals, January 2004; PhRMA 1100 Fifteenth St., NW, Washington DC 20005.

Federal Anti-Kickback Statute, 42 U.S.C. 1320-a7(b)

Prescription Drug Marketing Act of 1987, 21 U.S.C. 353(c) (1)

Health Insurance Portability and Accountability Act of 1996

OIG Compliance Program Guidance for Pharmaceutical Manufacturers,

http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf Accessed October 17, 2007

American Medical Association, Gifts to Physicians from Industry Accessed October 17, 2007, http://www.ama-assn.org/go/ethicalgifts