Introduction:
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 Health employees and its affiliates. Covered products, equipment and services include, but are not limited to: medical and surgical supplies/devices/implants, nutritional products and Post-Acute-Care (PAC) provider representative information/communication with access to Patient Care Areas. VRs are defined as facilities or agents of manufacturers and suppliers who promote products and/or services to employees or agents of UCHealth or representatives of Post-Acute Care (PAC) agencies who provide information to patients/families/care managers of UCHealth to facilitate a timely and efficient transition of care.

Scope:
This policy applies to entities identified in the UCHealth Policy Scope Statement.

Covered products, equipment and services include, but are not limited to, pharmaceuticals, medical and surgical supplies/devices/implants, nutritional products, and PAC provider representative information/communication. VRs are defined as agents of manufacturers, suppliers, and PAC provider facilities and agencies who promote products and/or services and provide information to employees or agents of UCHealth.

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Policy Details:
I. General Requirements – These requirements apply to all VRs calling on UCHealth personnel. The VR must also check for area-specific policies (see section II below).
   A. Registration:

The current version of this policy can be viewed on The Source. Printing is discouraged.
UCHealth
Vendor Representative

1. Badging – UCHealth badging is required in all departments. The VR must have his/her company-assigned identification card/nametag prominently displayed while in UCHealth facilities as well as a RepTrax badge which is obtained from the RepTrax kiosk at each facility. Area-specific requirements may be more stringent – see below.

2. Business Hours – pertaining to VRs, UCHealth 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. Exception: PAC provider representatives needing to access Patient Care areas 7 days a week during reasonable day or evening hours for evaluating or visiting prospective or current patients in preparation of a facility/agency discharge.

3. Vendor Parking – See attached map for each facility.

B. Activities within UCHealth:

1. Unless otherwise specifically permitted below, representatives’ activities will be confined to non-patient care units at all times. PAC provider representatives will be permitted to access Patient Care areas for evaluating or visiting prospective or current patients in preparation of a facility/agency discharge, otherwise these restricted areas apply:
   a. Patient rooms 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, care managers, patients/families and UCHealth personnel must be prearranged with a scheduled appointment with end-user. Unscheduled visits are not permitted, including any provider representative marketing visits. Medical students, pharmacy students, interns, residents, fellows shall not be contacted either in person or by telephone by representatives while on patient-care duty or during regular UCHealth 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 UCHealth 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 UCHealth 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

1. Only authorized UCHealth 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 UCHealth. UCHealth is not responsible for payment of products, equipment and/or services used at UCHealth without documented prior approval of authorized UCHealth personnel.

**D. Gifts/Money/Entertainment/Favors**

1. UCHealth team members will not give or accept business gifts or favors that represent, or could be thought to represent, unfair business incentives; violate laws, regulations or policies of UCHealth; or could cause embarrassment to or reflect negatively upon the reputation of UCHealth. Free vendor-sponsored training or education, including travel and lodging, may only be accepted when the business value to UCHealth outweighs the entertainment value of the training event. Staff must get the appropriate approvals from their Senior Manager and the Compliance Department before participating in such training or education.

2. UCHealth team members are prohibited from accepting cash or cash equivalents (including gift certificates and lottery tickets) from existing or potential vendors or referral sources.

**E. Business Associate**

1. A person or entity that receives Personal Health Information (PHI) from a covered entity in order to perform certain functions or activities on behalf of the covered entity or to perform certain services to or from the covered entity.

2. If a vendor receives PHI in order to perform services for UCHealth, they are considered a Business Associate and must sign the UCHealth Supply Chain Business Associate Agreement (BAA). Vendor is expected to contact Supply Chain office to obtain this form.

**F. Disclosure**

1. 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 UCHealth relationships will result in sanctions determined by UCHealth. Please see Supplier Ownership Certification (attached).

**G. 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 and in the Supply Chain offices.

**H. Legal Compliance**

1. UCHealth will not contract with any individual or company who has been convicted of a criminal offense related to health care items or services but has not yet been excluded, debarred or otherwise declared ineligible or who is listed by a Federal Agency as debarred, excluded or otherwise ineligible for participation in federally funded health care programs.

2. Additionally, pending the resolution of any criminal charges or proposed debarment or exclusion, individuals and companies with whom the System currently contracts who are charged with criminal offenses related to health care, or proposed for debarment or exclusion, must be removed from direct responsibility for or involvement in any federally-funded health care program. If resolution results in conviction, debarment or exclusion of the individual or company, the company must immediately cease contracting with that individual or company.
a. The GSA List and the OIG Sanction Report are located at, respectively:
   i.  http://epis.arnet.gov; and

b. All potential vendors are checked against both of these databases by Supply Chain before being set up as an approved vendor. If an individual or company appears on the report, UCHealth may not contract with that individual or company.

c. The Compliance Department will compare UCHealth’s Master Vendor List against the GSA List and the OIG Sanction Report on a monthly basis. If a match is confirmed and the contractor is an Ineligible Person on the GSA List and/or the OIG Sanction Report, UCHealth must terminate the contract and work with the Manager of Contracts and Reimbursement to address potential cost reporting issues.

3. The following language is to be included in all Request for Proposals (RFP) and Requests for Information (RFIs) submitted to potential contractors: “UCHC health seeks to comply with all Federal and state laws and regulations including the requirement not to contract with sanctioned individuals or companies. Has your company or any individual employed by your company been listed by a Federal Agency as debarred, excluded or otherwise ineligible for participation in federally funded health care programs?”

   a. An appropriate response to this question is mandatory before a supplier may be qualified to contract with UCHC health.

4. The following language is to be included in all agreements or attached to an addendum with contractors (the names of the parties listed in brackets should be changed to conform to the names used in the agreement and the brackets eliminated in the final document). Changes to this language may only be made as approved in advance by the Legal Department: “[Vendor] represents and warrants University of Colorado Health that [Vendor], its officers, directors and employees (i) are not currently excluded, debarred, or otherwise ineligible to participate in the federal health care programs as defined in 42 USC § 1320a-7b(f) (the “Federal Healthcare Programs”) or any state healthcare programs; (ii) have not been convicted of a criminal offense related to the provision of healthcare items or services but have not yet been excluded, debarred, or otherwise declared ineligible to participate in the Federal Healthcare Programs or any state healthcare programs; and (iii) are not, to the best of its knowledge, under investigation or otherwise aware of any circumstances which may result in [Vendor] being excluded from participation in the Federal Healthcare Programs or any state healthcare programs. This shall be an ongoing representation and warranty during the term of this Agreement and [Vendor] shall immediately notify University of Colorado Health of any change in the status of the representations and warranty set forth in this section. Any breach of this section shall give University of Colorado Health the right to terminate this Agreement immediately for cause.”

I. Infractions and sanctions

   1. Promotional activities of VRs are a privilege which has been extended by UCHC health. Supply Chain is responsible for enforcing this policy. Any individual observing infractions of these guidelines should contact the Director of Materials Management (DMM) in Supply Chain.

   2. The DMM will apply the following progressive sanctioning:
a. First Infraction -- Written and/or verbal communication to document infraction to VR as well as to immediate supervisor.
b. Second Infraction -- No access to UCHealth facilities for one (1) month.
c. Third Infraction -- No access to UCHealth facilities for six (6) months.
d. Forth Infraction -- No access to UCHealth facilities by any and all representatives of the offending Vendor for a period of one (1) year.

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.

4. Supply Chain may choose discipline dependent on issue not necessarily in suggested order.

J. Risk Level/Encounter Types

1. High risk encounters (i.e. those encounters in patient care areas involving product/device installation and/or training) require:
   a. a clinician's specific permission; and,
   b. documentation of a signed vendor agreement.
   c. These areas include, but are not limited to, OR/Perioperative Areas, Interventional Radiology/Catheterization Procedures Areas, GI Procedures Areas, Birthing Centers and Radiology Procedures Areas.

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

II. Value Analysis: Product Introduction, Evaluation and Acceptance

A. At NO time shall a vendor introduce new products to any UCHealth facility prior to meeting with Strategic Sourcing to obtain approval. Strategic Sourcing’s Value Analysis Teams (VATs) review and approve or deny staff or physician requests for new products and new and innovative technology. Requests will be considered for evaluation ONLY if, through analysis, it is proven that the product will ensure or improve patient safety, improve outcomes, reduce costs, improve contract penetration, or optimize utilization. Therefore, it is necessary for a vendor to work with the Strategic Sourcing Department to initiate this process:

1. UCHealth physicians or staff desiring to introduce new products for use at any UCHealth organization must complete a new product request in SupplyNET.

2. Vendors may not access UCHealth’s internal system to submit requests; only a staff member or physician can gain access to make a request.

3. The VAT consisting of Value Analysts and clinicians or director-appointed staff will review the request and recommend one or more of the following:
   a. Clinical Evaluation
   b. Approved for VAT discussion
   c. Denial of the request
   d. Request for additional information/data

4. The VAT reviews agenda items for the committee’s approval/denial only after ALL considerations and evaluations are complete.
   a. All decision made through the Value Analysis process will be effective for the company or region that made the request. A request approved in one region will not necessarily apply to another.
   b. If a product is deemed unacceptable the product may NOT be purchased by UCHealth. All decisions made by the VAT are final for
one year. The VAT will not review additional requests for the same item during the one year period.

c. All equipment supplies and loaner supplies for evaluation must be assigned a purchase order (PO) number by Supply Chain. Goods found in areas without a proper purchase order authorization will be destroyed or donated to charity as appropriate. Evaluations done with product brought in without a purchase order will not be valid.

d. Invoices for products brought in to any UCHealth facility without VAT 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 prior to 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. AREA SPECIFIC - These areas include, but are not limited to, Pharmacy, Nutrition, Laboratory, Birthing Center, Cardiovascular and Respiratory Care.

A. OR/Perioperative Areas

1. All new, replacement or trial products used in the OR must be approved by the OR products committee prior to use. Only UCHealth staff and physicians may submit product requests to the OR products committee.

2. All new, replacement or trial of equipment must be preapproved and authorized according to the Capital Approval process. No equipment will be brought into UCHealth facilities without preauthorization and a purchase order. Product or equipment that is delivered without a purchase order will be considered a donation to UCHealth, or may be picked up at VR’s expense. All equipment must be checked by Biomed prior to use.

3. UCHealth 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 requirements set by the UCHealth policy for Transplant and Implant Tissue Storage. You also agree that you have maintained all storage and handling requirements set by the product manufacturer. All new, replacement or trial of products must be preapproved and authorized according to the Value Analysis process. No product will be brought into UCHealth facilities without preauthorization and a purchase order.

4. All vendors are required to provide two (2) hard copies of invoices, signed and approved by a UCHealth RN stakeholder in the room at the end of the case; the hardcopies must be present for real time documentation. The copies will document a complete list of implant tray contents and supplies used during the surgical case. Invoices must be received within 24 hours of service or next business day, unless regional policy dictates otherwise. If invoice is not received within the stated terms, vendor will not be reimbursed.

5. 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.
6. Medical product 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 (3) VRs are permitted in the surgical suite for a surgical case unless approved by surgeon. In addition, VRs may only be present for surgical cases pertaining to the role or product that they provide; VRs are not allowed to “observe” cases. Vendors must wear the badge issued from the RepTrax kiosk in all areas including Perioperative and Cardiovascular areas.

7. Credentialing requirements for all vendor reps, sales reps, tissue/bone representatives, service technicians and distributor representatives are available on RepTrax and as follows:
   a. Proof of chicken pox
   b. Proof of Hepatitis B vaccination
   c. Proof of seasonal Flu vaccination
   d. Proof of MMR- Measles, Mumps, and Rubella
   e. Yearly Tuberculosis testing
   f. Proof of Employer General Liability Coverage
   g. Evidence of Employer Product/Service Competency
   h. OR Protocol training
   i. HIPAA Training
   j. Blood Borne Pathogens training

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

1. Formularies – Each hospital maintains a closed drug formulary for inpatient and clinic administered drugs. Central also maintains a closed drug retail formulary for the Colorado Indigent Care program. All formularies are under the purview of each hospital’s respective P&T Committee. Requests for formulary additions can only be made by a UCHealth Employee or a member of the Medical Staff. VR meetings with hospital and Medical Staff must be scheduled in advance.
   a. Detailing a non-formulary product is considered a violation unless the person being detailed is informed that the product is non-formulary or restricted.
   b. VRs are not permitted to participate in the UCHealth formulary processes (e.g., completing the P&T request).
   c. 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
   a. All representatives must comply with applicable laws and with Pharmaceutical Manufacturers Association (PMA) voluntary code regarding distribution of sample drugs.
   b. Samples are to be left only when requested by the person licensed to prescribe or dispense medications and can only be left at locations approved by each facility.
   c. 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
   a. If the VR distributes literature for non-formulary medications, they must indicate on the literature that the medication is 'Non-formulary'.
b. No detailing of drugs which have been denied admission to the hospital formulary or for which there is a therapeutic interchange in place.

c. Distribution of literature to patients or leaving in the clinic waiting areas is not permitted.

d. Preprinted prescription pads are NOT to be brought into or distributed in UCHealth.

e. The Pharmacy department will not fill any prescription written on a preprinted pad.

C. Information Services

1. Under specific circumstances, software and/or hardware vendors must be on UCHealth premises to perform services. Examples would be: 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 or HIGH-RISK AREAS without direct UCHealth employee supervision. The following criteria should be met under these circumstances:
   a. UCHealth Project Manager or Management staff must be aware that vendor is on-site;
   b. Manager/PM will notify the Director/Manager of the area the contractor is going to be working in without supervision;
   c. Company assigned identification (i.e., name badge) must be worn at all times.
   d. All products, equipment and services must be preauthorized and a purchase order must be obtained prior to installation and use.

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. The only exception would 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 which 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 prior to installation and use.

5. All equipment must be checked by Biomed prior to use.

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.

1. Approved UCHealth staff may include recall domain manager, coordinator, responder, or Supply Chain personnel.

B. Manufacturer or supplier representatives are not authorized to remove supplies from UCHealth facilities without providing a return authorization.

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

The current version of this policy can be viewed on The Source. Printing is discouraged.
The Joint Commission, Standard EC 2.10 Management of the Environment of Care - Security Risks
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
CONFIDENTIALITY STATEMENT

University of Colorado Health (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 health 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 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 policies 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 a UCH facility continues indefinitely, even after your employment or arrangement with UCH ends.
SUPPLIER OWNERSHIP CERTIFICATION

Date: __________________________ Address: __________________________

Supplier (“Company”): __________________________ City: __________________________

Product Type(s): __________________________ State/Zip: __________________________

1. Organizational form:
   □ Corporation   □ Partnership   □ Sole
   □ LLC         □ LLP          □ Other

2. Choose one of the following:
   □ a. Supplier is a publicly held company with its stock publicly traded, and no physician nor an immediate family member of a physician\(^1\) individually owns, or physicians collectively own, a controlling interest.
   □ b. Supplier is a privately held entity, and no physician or an immediate family member of a physician\(^1\) individually owns, directly or indirectly, any ownership interest.
   □ c. Supplier is a publicly held company with its stock publicly traded, and stockholder’s equity of at least $75 million dollars for the last fiscal year (please attach statement).
   □ d. Supplier is a privately held entity, with one or more physicians, directly or indirectly having an ownership interest; or Company is a physician. If this option is checked, please list the names of the physician owners on next page.
   □ e. Supplier is a publicly traded company with less than $75 million dollars in stockholder’s equity or is not traded on an exchange, and a physician or an immediate family member(s) of a physician individually owns, or physicians collectively own, a controlling interest. If this option is checked, please list the names of the physician owners on the next page.

3. Does Supplier have a current compensation arrangement with a physician or immediate family member of a physician who refers patients, tests or services to a UCH-affiliated facility?
   □ Yes □ No If "yes", please list names of the referring physician on Continuing Page.

\(^1\) An immediate family member means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-

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law, daughter-in-law, brother-in-law or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.
The representative signing below on behalf of the Company makes the following representations:

- I hereby certify that the information provided above is true and accurate
- I agree to promptly notify University of Colorado Health of any changes in the above as soon as such changes are known to the Company

"COMPANY"

Acknowledged by:

Signature: ___________________________ Date: ___________________________

Name: ___________________________ Phone: ___________________________

Title: ___________________________

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Driving/Parking Map:

From downtown Denver
- East on Colfax to Quenant St.
- Left on Quenant St. to 16th Ave.
- Right on 16th Ave to the stop sign

From the south (via I-225)
- West on Colfax to Aurora Court
- Right on Aurora Court to 15th Ave.
- Left on 15th Ave to the stop sign

From the north
- South on Pecos to Colfax
- East on Colfax
- Left on Quentin St. to 16th Ave.
- Right on 16th Ave.

Street Addresses For Our Buildings:

- Larimore Building
  12401 E. 17th Ave.
  Aurora, CO 80045
- Anschutz Inpatient
  Pavilion 2
  12505 E. 16th Ave.
  Aurora, CO 80045
- Anschutz Inpatient
  Pavilion
  12615 E. 16th Ave.
  Aurora, CO 80045
- Anschutz Outpatient
  Pavilion
  1635 Aurora Ct.
  Aurora, CO 80045
- Anschutz Cancer
  Pavilion
  1665 Aurora Court
  Aurora, CO 80045
- Rocky Mountain Lions Eye Institute
  1675 Aurora Court
  Aurora, CO 80045

Find Your Way

The “Find Your Way” icons (located on the first floor wall) indicate that you are on the main hospital pathway. Follow them in either direction to help find an elevator, 1st floor destination, or exit.

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Memorial Hospital Central

1400 E. Boulder Street, Colorado Springs, CO 80909

VALIANT

Valet parking is available at the emergency department entrance, north entrance (near the parking garage), and the main entrance/Boulder Street. The emergency department and main entrance valet stations are open 24 hours a day 7 days a week.

You may drop off/pick up your car at any of the three entrances.

Meeting Room Location Map
- Meeting rooms in Main Building (basement, 2nd and 3rd floors)
- East Tower (2nd, 3rd and 6th floors)
- North Tower (7th floor)

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