

SC-4 – Vendor Visitation and Control Program

Key Points

- University Hospital Health System, Inc. assures reasonable control and identification of medical industry vendor representation at all (UH) acute care facilities.
- University Hospital Health System, Inc. manages vendor representative visits to UH departments to minimize disruption to patient care and staff productivity.
- University Hospital Health System, Inc. ensures all electrical equipment brought in by vendor representative is evaluated and approved by the biomedical engineering department prior to initial use.

Policy & Procedure

1. Vendor representatives are personnel employed by various companies that UH purchases supplies, equipment and/or services. Vendor representatives may perform sales presentations or other service as reasonably requested by authorized UH personnel. It is the vendor representatives' duty to understand and comply with this policy.
2. All vendors:
 - 2.1. Abide by the UH Code of Conduct and UH Policies
 - 2.2. Abide by their relevant industry's code of ethics
 - 2.3. Are not permitted to have any active participation in operative or other patient procedures
 - 2.4. Register in advance of visit with the hospitals' designated credentialing company and obtain the appropriate Identification Badge
 - 2.5. Have a scheduled appointment with an authorized UH employee or physician prior to visiting the institution
 - 2.6. Without a VCS/Symplr badge, are not permitted within any UH Facility
 - 2.7. Have current credentials on file with Symplr. (Previously Vendor Credentialing Services)
 - 2.8. Upon arrival to the facility, vendor reports to the Symplr scanner/kiosk located at each facility to receive a time stamped badge.
 - 2.9. All vendor representatives visiting the hospital for the first time are signed in and added to the hospital's credentialing company. An email is sent to the representative with instructions on how to complete the proper registration. The Vendor Representative has 30 days from the date of their first visit to complete their registration.
 - 2.10. Vendor representatives are not permitted to distribute or post any type of hand printed or handwritten invitations, advertisements, signs or promotional materials unless pre-approved by the department director.
 - 2.11. Vendor representatives are not permitted by bring any product or material into a UH Facility to or demonstrate or sell testing kits or devices without the knowledge and prior approval from Supply Chain.

- 2.12. Vendor representatives are to adhere to the dress code if one is present in the department they are scheduled to meet with.
- 2.13. Vendor representative will abide by all changes to vendor visitation Policy SC-4 due to escalation of pandemic surges.

3. Safety/Security:

- 3.1. An officer of the UH Police Department, the UH Ahuja Police Department, Protective Services and/or local police, depending on the UH location, may, at any time, request to inspect the vendor representative identification badge.
- 3.2. Vendor representatives without proper identification badge are to be escorted off of the premises.
- 3.3. VCS/Symplr badges are to be visible at all times and clipped above the waist.

4. Introduction of New Supplies/Equipment:

- 4.1. No new product, medical supply, procedure, service or piece of equipment is accepted or paid for without the authorization of the user department.

5. Trials, Evaluations, Loaners and Demonstrations:

- 5.1. Trials, evaluations, and demonstrations are conducted only when a completed Trial Agreement has been signed by both the vendor and UH.
- 5.2. Products or equipment brought in for evaluation/loaner are frequently provided free of charge by the manufacturer/vendor. No payment is made for products brought in without prior authorization in the form of an official Purchase Order.
- 5.3. Equipment loaners are to be brought in only after a Placement Agreement has been signed by the vendor representative and UH. For tracking purposes, all loaners need to have an associated no-charge Purchase Order.
- 5.4. Conforming to contractual obligations is actively pursued. Purchase of items not on contract are not accepted without approval by Supply Chain.
- 5.5. Electrical equipment provided by a vendor representative for product evaluation or loan is tested and approved by the Bio-Medical Department prior to use.
- 5.6. Appropriate staff orientation to new equipment, instrumentation or products is coordinated through the Educator or Department Manager. Vendor representative is fully trained and knowledgeable of all products which they demonstrate/train staff members. All educational/training materials provided are accurate and complete.
- 5.7. If pre or post-use sterilization of an evaluated product, instrument or equipment is required, vendor representative provides detailed instructions for use prior to start of evaluation or loan.

6. Gifts, gratuities, food and favors:

- 6.1. Refer to Policy CE-9 for vendor gifts, meals, other business courtesies and consulting payments.

7. Presentations:

- 7.1. Staff educational or in-service programs presented or supported by vendor representatives have prior approval from the department responsible for the commodity being discussed. Education programs are reviewed and approved in advance by the Education Department and/or department leadership. This approval is obtained at least two weeks in advance of the scheduled presentation. All trials are coordinated with the Contract Administrator in charge of that commodity and all Product Trial Agreements are completed before the trial begins.

8. User Departments are responsible for assuring that vendor representatives interacting with the department comply with this Policy. Non-compliant vendor representatives are immediately reported to Symplrcredentialingcomments@uhhospitals.org
9. Consignment Inventory:
 - 9.1. Consignment inventory includes items (implants/instruments and equipment) that “reside” at a UH Facility, but are NOT owned by said UH Facility. Management of consignment inventory PAR levels is the responsibility of UH in conjunction with the vendor representative. The vendor representative is responsible for any “outdated” items. Due to storage limitations, PAR levels are established based upon usage and the order/ship time for the product. Placement of consignment inventory follows the following protocol:
 - 9.1.1. A complete inventory list accompanies the inventory. This includes the description, catalog number, quantity, and pricing for single use items.
 - 9.1.2. For reusable items (i.e. -instruments) that is sterilized, a complete inventory list with description, catalog number and quantity, along with written directions for cleaning, packaging and sterilizing is provided to Central Sterile Supply.
 - 9.2. Consignment inventory cannot be added to or removed from the facility without approval of the Department Manager and Supply Chain. Appropriate paperwork is required when consignment is removed or added.
 - 9.3. Contract agreement for pricing is required in conjunction to consignment placement agreement.
 - 9.4. When a consigned product is used, the department submits a replacement request to Purchasing, who then issues a PO for replacement in accordance with established purchasing procedures.
10. Pharmaceutical Representatives:
 - 10.1 Only physicians, nurse managers, supply chain and pharmacy staff may be informed about pharmaceutical products. A professional speaker or Licensed Medical Professional may make an educational presentation to nursing for approved formulary products when deemed appropriate and approved by the Director of Pharmacy.
 - 10.2 Promotional material on pharmaceuticals is NOT posted or displayed
 - 10.3 Promotion of pharmaceuticals that are currently on the drug formulary and those that have been reviewed the Pharmacy Committee are permitted. Promotion of any pharmaceuticals that are not listed on the formulary and that have not been previously presented to the pharmacy Committee include notification of this fact prior to the time the product is being promoted. Products that have been presented and denied or deleted from the formulary are not promoted.
 - 10.4 Department managers or physicians that invite a pharmaceutical representative into the hospitals for in-servicing on a pharmaceutical contact the Director of Pharmacy

prior to making the appointment to determine if the particular pharmaceutical is on the hospital formulary.

- 11. Vendor Representatives in Operating Room and Procedure Areas:**
 - 11.1. All vendor and service representatives have a scheduled appointment with an authorized UH employee or physician prior to visiting the institution.**
 - 11.1.1. Vendor representatives without prior authorization are not permitted in the Operating Room/Procedure Area(s).**
 - 11.1.1.1. In the case of an urgent need, the vendor representative visit is approved by the Perioperative/Procedure area administration.**
 - 11.2. All vendor representatives entering the Operating Room/Procedure (e.g. GI Lab, Labor & Delivery, Radiology, Cath Lab) area have current credentials on file.**
 - 11.2.1. All vendors coming in to these areas, that require scrubs, must use the RepScrub machines located within the facility. It is up to each representative to sign up with RepScrubs and use RepScrubs at any UH Facility where they are located.**
 - 11.2.2 All vendors coming in to these areas must sign in to both RepScrubs and Symplr to meet UH Compliance.**
 - 11.2.3. Vendor representative appointments are scheduled using the on-line appointment scheduling process prior to the appointment. Only vendor representatives that are prescheduled and credentialed may be present in a specific Operating Room/Procedure area. Credentialing requirements at a minimum include record of:**
 - 11.2.3.1. HIPAA training,**
 - 11.2.3.2. Certification of compliance with the UH code of conduct and compliance program,**
 - 11.2.3.3. Criminal background check**
 - 11.2.3.4. Health screening done in compliance with Corporate Infection Control Program, and**
 - 11.2.3.5. Any other certification or documentation that is required by UH.**
 - 11.2.2. All non-credentialed vendor representatives are restricted to public access areas.**
 - 11.3. Upon arrival to the facility, the vendor representative reports to a facility specific designated area to sign in. The sign in process includes the following:**
 - 11.3.1. Verification of appointment.**
 - 11.3.2. Verification that the vendor representative is approved.**
 - 11.3.3. Issuing of locker**
 - 11.3.4. Issuing of vendor representatives name tag expiration label.**
 - 11.4. During their visit the vendor:**
 - 11.4.1. Maintains strict confidentiality of any protected health information as required by UH HIPAA policies and Vendor representatives legal and ethical obligations.**
 - 11.4.2. Identification Badge is visible at all times.**
 - 11.4.3. Refrains from bringing purses, bags, briefcases, or other personal items into the operative/procedural area.**
 - 11.4.4. Received approval from the clinical staff working in the area before entering a patient care area.**

- 11.4.5. Does not provide anything other than authorized products. No outside shipping containers are allowed in clinical areas. Small items may be placed in plastic bags for transport.
 - 11.4.6. Validates that all shipping and storage conditions meet or exceed conditions to maintain product in a useful condition as defined by the manufacturer.
 - 11.4.7. Confines activity to the area of appointment, and not into other clinical areas.
 - 11.4.8. Make all personal phone calls in public access areas.
 - 11.4.9. Follow all rules and regulations of University Hospitals.
 - 11.4.10. Always remember that they are a guest at University Hospitals and act professionally during their visit.
 - 11.5. Vendor representatives are not permitted to have any active participation in operative, or other patient procedures.
 - 11.6. Vendor representatives are not permitted to be in employee designated areas unless accompanied by a UH employee. Upon completion of appointment, the vendor representative leaves the Operating Room/Procedure area.
- 12. Equipment and Supplies:**
- 12.1. Any electrical equipment is evaluated and approved by the biomedical engineering department prior to the initial use.
 - 12.2. All equipment is properly cleaned before entering and upon leaving the department. All product/equipment cleaning and storage requirements is supplied by the vendor representative.
 - 12.3. All deliveries of equipment or supplies are made during normal business hours, a minimum of one business day prior to the procedure unless otherwise approved.
 - 12.4. The vendor representative arranges for pickup of the product/equipment within one business day after completion of use.
 - 12.5. Human and nonhuman cellular-based transplantable and implantable products, whether classified by the U.S. Food and Drug Administration (FDA) as a tissue or a medical device, may not be hand delivered by a supplier/vendor representative. Products that fall under this category can only be transported to the facility directly from a FDA registered tissue establishment.
 - 12.6. Discussion of pricing is in writing and limited to supply chain personnel.
- 13. Vendor representatives provide evidence of FDA status as requested. Clinical trial items are clearly identified and associated with an approved IRB.**
- 14. Investigational devices need IRB approval.**
- 15. All laboratory instruments/devices intended for use in proximity of patients or Point of Care Testing (POCT) are approved by the area responsible for maintaining the CAP & CLIA licensure before clinical trial begins.**
- 16. Emergency service calls or emergency surgical device deliveries after normal working hours or weekends follow the designated departmental after-hours procedure.**
- 17. Violations of any of these standards may result in permanent revocation of vendor representatives privileges**

See Also:

CE-10 Vendor Relations

SC-7 Value Analysis

Electronically approved by Tom Zenty, President and CEO of UH- January 13, 2021
Electronically approved by Eric Beck, DO, MPH, Chief Operating Officer – January 12,
2021