

# UI Health Care Vendor Policy Guidance

At University of Iowa Hospitals and Clinics (UI Health Care), we are proactive in protecting the privacy of our patients to facilitate compliance with all government and University health and safety regulations and policies. Although we recognize the value of vendors interact with our staff, we also have high expectations that all vendors will comply with UI Health Care Vendor Policy and Handbook with rules and additional guidelines established by individual departments and units. The detailing of products and services at the UI Health Care by vendors is a granted privilege, not a right.

For purposes of this handout, vendor is defined as any person or company seeking to do or doing business with University of Iowa Health Care, including any pharmaceutical, medical device, medical publishing, or medical equipment companies.

The following information is UI Health Care's process and expectations of our vendor's. If you have questions regarding the content please contact Procurement and Value Implementation (PVI) Services at 319-384-9800.

## Professionalism

All vendors must maintain a professional and respectful attitude while detailing at UI Health Care or interacting with UI Health Care staff, students, and faculty.

## Registration

All vendors selling products or services or providing information to UI Health Care staff that are involved in patient care are required to register and obtain a one-time use UI Health Care badge. This badge is only valid for the day it is issued. If the representative will be on-site multiple days, they will need to get a badge every day.

Annual UI Health Care registration and badges may be required for vendors who provide service, repairs or rental deliveries or installations. Internal University, freight forwarders (e.g. UPS), floral and food delivery services and consultants of professional services are excluded. Construction vendors have a separate policy based within Safety & Security policies.

All vendors must be registered with the Purchasing Department to obtain a University of Iowa Vendor ID prior to engaging in any activities, or "detailing," involving their company's products and services at UI Health Care. Detailing privileges are not transferable from one company representative to another.

All vendors are required to register and comply with UI Health Care requirements via SEC3URE web-based community prior to engaging in any detailing at UI Health Care. If you will be visiting staff within UI Health Care, you will need to provide evidence within SEC3URE of Measles, Mumps and Rubella (MMR) vaccination or immunity and tuberculosis (TB) status once upon registration. You will also need to provide certification and training for Evidence of Employer Product/Service Competency. All vendors should follow current Covid-19 guidance posted on PVI website at <https://uihc.org/procurement-services-vendor-information>. All vendors will need to review all policies and documents provided online via SEC3URE and must pass the review test with a score of 90% or higher when policies are updated. Sponsored Research Coordinators and Clinical Educators are required to join SEC3URE at the base level. You may also be asked to provide verification of TB and MMR at the time of visit.

Members of the Procurement & Value Implementation (PVI) Services Department staff are available to meet with Medical/Surgical Representatives between the hours of 8 AM and 4:30 PM, Monday through Friday, with the exception of University holidays. Appointments are recommended. Appointments before 8 AM and after 4:40 PM may be arranged when necessary.

Vendors must follow all hospital policies and procedures when detailing as a representative of their company while visiting here at UI Health Care or any offsite UI Health Care Clinic. Appointments with Pharmacy staff are scheduled through the Pharmacy Administrative Office (319-356-2577).

## Identification Badge Check-In

### For check –in at the UI Health Care campus, please follow the steps below:

- All Vendors must check in and receive a vendor badge from the PVI Services Department, Room 3057-1 SRF, upon each visit.
  - The office is open 6:30 AM to 4 PM, Monday through Friday.
  - SEC3URE credentials will be assessed at each visit; it will be up to the PVI’s discretion to approve a visit if credentials are incomplete.
- Between the hours of 4 PM and 6:30 AM Monday through Friday, weekends and holidays all vendors are required to sign in at the After Hours Vendor Check-In Kiosk located to the left of the Information Desk at the Main Entrance.
- Badges are one-time use and do not need to be returned. For questions, call PVI Services at 319-384-9800.
- Badges must be worn at the breast pocket or lapel level and visible at all times while conducting business at UI Health Care.
- Only during sterile procedures is it acceptable for the badge to be covered.
- One-time guests accompanying a registered vendor will be required to check in and receive a vendor badge as well. Vendor guests must also provide proof of MMR vaccination and negative TB status, if visiting a patient care area.
- All visits, for whatever purpose, must be prearranged with the department, physician, or staff member prior to arrival at UI Health Care.
- Company scrubs are not permitted. If scrubs are necessary for procedures, UI Health Care will issue white scrubs and shoe covers.

### For check-in at UI Health Care off-campus clinics or offices, please follow the steps below:

- All vendors must check in via the SEC3URE mobile app., upon each visit.
- All visits, for whatever purpose, must be prearranged with the clinic, physician, or staff member prior to arrival at the clinic.
- Company scrubs are not permitted.

Please note, vendors are prohibited from visiting UI Quick Care Clinics.

## New Non-Pharmaceutical Products

Be advised that hospital administration has a product review process mandated by our governing board. This process involves product evaluation, financial evaluation, education, training, inventory matters, etc. New product requests (non-pharmaceutical) will be managed through MedApproved, a web-based product request management tool. This will:

- Allow all communication to be funneled through one system.
- Ensure that your product is being reviewed by all key decision makers.
- Allow for transparency into our decision-making process, including the ability to see what stage the product is in and an estimated decision date.
- Reduce the number of visits and phone calls to the hospital for status updates.
- Automatically email alerts regarding requests for additional information and updates, including final decisions or requests for needed documents.

New product submissions will be initiated internally by a staff member, as a vendor responsible for a specific systems or services you will need to visit [www.medapproved.com](http://www.medapproved.com), and register, if you are not already a member. A UI Health Care staff member is required to sponsor/champion a new request and will initiate the new product request process. A UI Health Care staff member is required to sponsor/champion a new request and will initiate the new product request process.

Once the request is submitted by the sponsor/champion the vendor representative will receive an email from MedApproved Notifications. Vendors are required to fill out their portion of the new product request including the spreadsheet. Once the request is submitted, the sponsor/champion will approve or decline their support of the request; if the request is declined by the sponsor, you will be required to identify another sponsor and resubmit the request.

All requests for trial or purchase of a product not currently being utilized within UI Health Care, even if the product(s) were submitted and awarded through the bid process, are required to have prior approval by one or more Product Committees. Each Product Committee meets monthly on specified dates. Requests submitted and sponsored on or before the 1st business day of the month will be reviewed at the next meeting. Approvals/Denials will be sent out through MedApproved after the committee's decision has been made.

Products supplied for use to a UI Health Care staff member prior to approval by a committee are prohibited. These products will be considered no-charge items and will not be paid. UI Health Care physicians are unauthorized to act as agents to amend or re-negotiate these provisions nor can they legally bind the institution in purchase/lease/rental agreements. Vendors leaving products without permission from PVI Services will be subject to discipline under Section F, "Enforcement of Hospital Policy."

## Meeting and Communication

Meetings with UI Health Care staff will occur at the request of a staff member (e.g., Physician, Nurse Manager, Assistant Nurse Manager, Educator, Faculty, Pharmacy Manager, etc.). These meetings are to be by appointment only. Verification of the scheduled meeting may be completed to ensure compliance with hospital policy. A "Do Not Call" list of staff will be available and vendors are not to call or e-mail these staff members. Meeting places must occur in staff offices, conference rooms in non-patient care areas or areas open to the general public.

Vendors must leave the visited area immediately upon completion of a meeting. Loitering at UI Health Care in an attempt to facilitate a non-scheduled meeting, showing of a new product, education, etc. with a UI Health Care staff member is prohibited. This includes but is not limited to corridors, cafeterias, patient care areas, MOR/ASC/Procedural rooms/corridors, staff office hallways, or any other area. Vendors are not permitted in inpatient care areas, outpatient clinics, or pharmacy dispensing areas in order to protect patient privacy (except as allowed within the guidelines outlined in the policies linked below).

UI Health Care telephones may not be routinely used; public telephones are available throughout the facilities. The use of cell phones is restricted to areas greater than three feet from electronic patient care equipment. Do not place communication devices on top of, or in direct contact with, any medical device. Overhead hospital paging systems are off limits to vendors. Other paging is limited to request by UI Health Care staff members only. Departmental mailboxes and University campus mail systems are off limits to all vendors. Commercial mail services may be used to disseminate information to UI Health Care staff.

Vendors are required to pick up after meetings, in-services or displays. Leaving materials, empty boxes or information after meetings will be considered an infraction of the vendor policy. Vendors are not to leave unsolicited promotional material or information in any UI Health Care location.

Vendors who need parking may park in Ramp 3. Valet parking is restricted to use by our patients and their visitors. For offsite locations, vendors must park in approved locations.

## Sales & Service

Vendors are not to communicate or pressure UI Health Care staff during a bid or during the negotiation process. Any concerns regarding reimbursement, competitors' ability to meet needs and/or competitors' performance issues should be addressed with PVI Staff.

Regarding OR/ASC loaner instrumentation, All reusable items need to be cleaned and sterilized by the Central Sterilizing Services Department (CSS) prior to use. Cleaning and sterilizing instructions must be presented to CSS with all products. All items requiring processing must be in the CSS department by a minimum of 24 hours prior to the start of surgery for the MOR and ASC. See Supplements below for additional information..

The Pharmacy and Therapeutics Working Group (P&T) and the Department of Pharmaceutical Care have the additional requirements listed below:

- Vendor-supplied drug samples, drug-containing devices, may not be distributed to faculty, staff, trainees, and patients at UI Health Care. Vendor-supplied drug coupons and vouchers are only allowed in the UI Health Care Medication Assistance Center.
- All industry-provided patient educational materials must be reviewed by P&T. These P&T-approved industry-provided drug related educational devices will not contain active drugs and may be kept in specified clinics for patient education concerning drug information, administration, and monitoring.
- Only UI Health Care and company-approved materials may be distributed to health care professionals or trainees within UI Health Care.
- Distribution of written promotional information regarding restricted and non-formulary drugs at journal clubs or in displays is not permitted. Restricted drugs are defined as those drugs on the formulary whose use are limited to a specific clinical service(s) or prescribers or location, and/or have specific criteria for use.

The Tissue Bank has the additional requirements listed below:

- All implantable material containing human cells must have prior approval through the Surgical Services Product Evaluation, Standardization and Review work group (except for sperm, oocytes, and vascular organs). If these implantable materials containing human cells are FDA-approved as a drug or biologic, they must also be approved by P&T [e.g., CAR T-cell therapies, Autologous cultured chondrocytes on porcine collagen membrane (MACI)].
- Vendors must stop at the Tissue Bank before they accompany tissue to the OR. This will allow the tissue to be accessioned into the inventory.
- Vendors of tissue not accessioned in the Tissue Bank before implantation will not be paid for tissue.

Items requiring electricity will need to be evaluated by UI Health Care Bioengineering prior to use.

## In-Services

All in-servicing and/or education must be preapproved by:

- Medical/Surgical Products - The Associate Director Nursing Chair of the General Products Review and Standardization Committee and arranged by Nursing Education in conjunction with PVI Services, as needed.
- Pharmaceuticals - A manager, Assistant Director, or Director of Pharmacy or Chief Pharmacy Officer.
- Approval is to be obtained by UI Health Care staff and not by a vendor representative.

In-service approval notification will come from PVI Services, Nursing Education, or Pharmacy. This is to ensure:

- All appropriate departments have been contacted for education;
- UI Health Care Policies and Procedures are followed in relation to product use;
- Product is available for use;
- In-service dates have been determined;
- Drop-in/unscheduled in-services are prohibited.

In-services must be held in areas inaccessible to patients and visitors. Appropriate venues include staff report rooms, conference rooms and staff lounges. In-services are prohibited at the nurses' desk and patient care areas/hallways. In-services are prohibited at the patient bedside, unless it has been determined necessary to the successful use of the product by UI Health Care staff.

After checking in at PVI Services, Representatives entering a unit for the purpose of In-servicing must:

- Report to the front desk or nurses' station or, if arranged for Pharmacy, at the Pharmacy Administration Office.
- Introduce themselves and explain their purpose for being present.
- Ask to speak with the Nurse Manager/Assistant Nurse Manager/Charge Nurse or pre-arranged contact, if applicable.
- Be escorted directly to the designated area by staff. If for any reason staff is unavailable to receive the in-service at a scheduled time, the rep is to leave the unit.
- Leave only material related to the product being in-serviced for staff to review.

- Clean up the area after in-servicing, if educational samples were used.
- Be escorted off the unit by UI Health Care staff immediately following the in-service.

## Vendor Supported Training

Written approval is required by one of the Product Committees. Only products/supplies/equipment that are currently purchased by UI Health Care may be demonstrated. No new products are allowed to be shown or demonstrated during training.

Contracts with the UI Health Care should contain the following Education Clause:

Training (Company) will provide technical training and education at your institution, as reasonably necessary, on the safe and effective use of its products, procedures and surgical techniques to health care professionals (HCPs) affiliated with your institution. In addition, (Company) may provide technical training and education at a location outside of your institution on the safe and effective use of its products, procedures and surgical techniques to HCPs affiliated with your institution. Any meals, travel and/or lodging provided in connection with such training and education will comply with the UI Health Care Conflict of Interest and the UI Travel policies.

Use of UI Health Care or UI -CCOM space must be pre-arranged and approved by staff overseeing said area.

Manufacturer logoed vehicles will not be allowed to be parked in plain view of the public. Parking on UI Health Care property for the purpose of training requires clearance from Safety and Security and UI Parking.

The Department of Anatomy Deeded Body Program must approve of the use of cadavers or other remains. Proper documents for the transport of cadavers or other remains will need to be available for review by receiving department.

## Single-Use Device (SUD) Reprocessing Program - OEM

The University of Iowa Hospitals and Clinics (UI Health Care) have utilizes a single-use device (SUD) reprocessing program. Do not distribute any materials about SUD reprocessing to any UI Health Care employee. This includes verbal, written, email or any other communications. Do not offer seminars or CEU programs to UI Health Care employees designed to discourage or negatively impact participation with reprocessing.

## Attendance at Hospital Meetings

Attendance at meetings that are not open to the general public where protected health information is disclosed is not permitted. Attendance at Grand Rounds, Departmental meetings, Product Committee meetings, etc., will only be allowed by invitation of a committee leader or organizer.

## Enforcement of Hospital Policy

Failure to comply with this policy may affect the entire company's representation at UI Health Care. All UI Health Care staff will assist in monitoring the level of compliance and will report violations to the PVI Services Department or the UI Health Care Compliance Helpline at (319) 384-8190. Upon notification of a potential policy violation, PVI Services or the Joint Office for Compliance will investigate the matter to determine if a violation has occurred, and upon confirming a violation, will determine the seriousness of the infraction.

In order to complete its investigation, UI Health Care may contact the vendor and may require the company representative(s) involved in the matter to be interviewed at the UI Health Care regarding the details surrounding the incident. Based on the seriousness of the infraction and the information obtained during the investigation, the resultant action may include a verbal reinforcement of the UI Health Care Statement of Vendor Policy or the disciplinary actions outlined below.

Failure to comply with these policies may result in the following actions:

- First infraction: A face-to-face meeting, a note in the file and possibly a letter of reprimand, loss of detailing and display privileges for one week or more.

- Second infraction: A face-to-face meeting which includes a letter of reprimand with a copy being sent to the representative's immediate supervisor, and the company's possible loss of detailing and display privileges for one month or up to six months depending on severity of the infraction.
- Third infraction: A face-to-face meeting which includes a letter of reprimand with a copy being sent to the representative's immediate supervisor, and the company's loss of detailing and display privileges to be defined and determined at the meeting or no further access depending on the severity of the infraction.
- HIPAA violations will be subject to UI Health Care discipline grid which includes progressive discipline up to and including permanent loss of detailing and display privileges.
- Alternative or more serious discipline may result depending on the context of the infraction.

## Declaration of Patient Information Confidentiality

University of Iowa Hospitals and Clinics (UI Health Care) is legally required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of the health care information of all patients treated at our institution. Your visit to UI HC may include contact with patients, viewing of computer-stored patient information, viewing information from patient medical records, and/or incidentally overhearing confidential conversations. Under no circumstances may this information be discussed with anyone, unless otherwise required by law or with express written authorization from the patient or their legal guardian.

Your signature on the Declaration of Patient Information Confidentiality is required. Understand that a violation of this Declaration can result in serious administrative action. Direct interactions with clinical staff in order to provide recommendation on tests/procedures/product choices can only be made on products currently purchased by UI Health Care. Patient-specific recommendations are highly discouraged and should only occur when there is a specific consultation request from clinical staff and, whenever necessary, appropriate ancillary services (e.g., Pathology, Pharmacy, Infection Prevention, Quality and Safety, etc.). If necessary, Hospital Legal and/or the Joint Office of Compliance will be engaged to determine the necessity to provide PHI.

## Conflict of Interest/Conflict of Commitment

Vendors will adhere to the standards outlined in the UI Health Care Conflict of Interest/Conflict of Commitment policy. The policy is available at <https://uihc.org/conflict-interest-policy>.

## Central Sterilizing Services Vendor Loaner Guidelines

Central Sterilization Services (CSS) receives, returns, and prepares surgical instruments, trays, and implants acquired from UIHC approved vendor representatives as managed by Procurement. Loaner items are defined as instruments, trays, or implants the vendor representative provides to UIHC on a temporary basis for use on a patient; UIHC does not own loaners. Loaner items are either shipped via a 3rd party carrier (UPS, FedEx, etc.) or brought in by a vendor representative.

Vendors may drop off loaner items at the following locations:

### Integrated Services Center (ISC) – Offsite

- Hours of Operation: Monday thru Friday, 7am-5pm
- ISC In-charge Contact: 319-678-0768 (contact in-charge role each time)
- Vendor Check-in: ISC Soiled Dock
- Vendor Pick-up: ISC Soiled Dock

### Turn Center (TC) – Main Campus

- Hours of Operation: Monday thru Sunday, 24 hours a day.
- TC In-charge Contact: 319-678-1273 (contact in-charge role each time)
- Vendor Check-in: TC Soiled Dock Drop Off/PPE Room Door #42307
- All loaner items will be returned to ISC Vendor Tray Pick-up

Requests for loaner items will be initiated by surgeons or clinical leaders. Loaner items must be received by ISC at least 48 hours (2 business days) prior to the scheduled surgical start time. Loaner items arriving less than 48 hours (2 business days) prior to the scheduled surgical start time will be checked-in at the main campus TC (Example: Friday loaner tray arrival for a Monday case should be dropped off at the TC).

First-time loaner items should be checked-in 72 hours (3 business days) prior to the scheduled surgical start time; to allow extra time for product IFU review and coordinating in-servicing as needed.

All flexible endoscopy, clinic, and procedural area loaner items will be processed at their respective CSS locations: Turn Center (TC), Flexible Endoscopy Reprocessing Center (FERC), or Iowa River Landing (IRL) CSS Departments.

All loaner items entering UIHC should be reprocessed and should not be brought in sterile from a non-UIHC location unless coordinated by CSS.

#### **Methods of Cleaning and Disinfection Available**

- Automated washer-disinfectors.
- Hand-wash only technique used on items that cannot be placed in automated washers, final rinse with critical water.

#### **Methods of Terminal Sterilization Available**

- Steam Sterilization.
- Low Temperature Sterilization (hydrogen peroxide).

The vendor representative will coordinate with Procurement & CSS to coordinate check-in, drop-off, and return as well as any necessary education. Vendor led education may be necessary for reprocessing use. Supply Chain in-charge role will coordinate loaner items during weekend hours: Friday after 5pm thru 7am Monday. Vendor representative will coordinate with CSS weekend in-charge role when loaner items are scheduled to be received by TC on weekends.

Vendor representative will be expected to review and sign-off on loaner procedures. Additional training on the loaner item check-in and pick-up procedures will be provided by Procurement Services during New Vendor Orientation. Vendor representative will follow the standard loaner check-in process for each scheduled procedure as explained in this Vendor Handbook. Vendor representative must follow all loaner check-in and retagging workflows listed in the vendor binder at each tray check-in location.

The vendor representative will unpack, log inventory, inspect to verify loaner item cleanliness and integrity are intact, and enter instructions for use (IFU) reprocessing instructions. Up-to-date pictures should be logged when a loaner item enters the system and as changes take place to the loaned contents. This should include pictures of each tray level. Each loaner item should be weighed, and scales will be available at designated loaner check-in stations. Loaner trays may consist of multiple trays per procedure and each tray should be numbered and labelled and can weigh no more than 25 pounds each after packaging for sterile processing.

After loaner items are checked-in, the vendor representative will deliver loaned items to the loaner drop-off area. Vendor representatives will provide current contact information and be available for questions. Vendor representative will ensure that no items belonging to UIHC are removed along with their products (i.e., washer baskets, corner protectors). Vendor representative will follow UIHC Clinical Care Policy: CC.P.8 Use of Cadaver or Cadaver Parts in Patient Treatment Areas. Guidance from this policy prevents the transmission of infectious diseases to humans. Soiled instruments used on cadavers should not enter CSS or be mixed with Operating Room (OR) instruments in CSS.

After completion of the surgical procedure the vendor representative will:

- Assist with placement of all used/contaminated loaner items into the correct loaner tray.
- Missing loaner items will be located by the vendor representative. The vendor representative will contact CSS before going into CSS areas to locate any missing vendor instruments.
- Any claim for broken or missing loaner items must be communicated to UIHC within 48 hours after the scheduled case end time.
- Loaner items should be collected by the vendor representative within 48 hours (2 business days) after placement on the loaner pick-up rack.

Supply Chain and CSS can hold loaner items as needed that were not used for the scheduled procedure for up to 30 days. All loaner items must be returned to vendor pick-up location for vendor representative pick-up (unwrapped and not in sterile packaging). CSS will contact vendor representative if loaner items are not picked-up on-time. All loaner items dropped-off at CSS for reprocessing will be considered contaminated and CSS will follow full procedures for processing and sterilization. Loaner items will be processed and sterilized following required IFUs. CSS staff will communicate any concerns immediately to the CSS in-charge role (i.e., questions about IFUs). CSS will reach out to the vendor representative if there are any loaner item quality or reprocessing concerns.

After CSS has reprocessed loaner items:

- Sterile loaner items will be scanned and handed off to Supply Chain or
- Fully decontaminated loaner items will be placed in the vendor pick-up location to be picked-up by the vendor representative within 48 hours (2 business days).

## Central Sterilizing Services Placed Trays Procedure

Placed trays are defined as a multi-use vendor-owned tray built into SPM instrument tracking system and stored within an approved storage location.

Vendor owned trays may be placed within our surgical support areas. Please follow the guidelines below:

- Clinicians should support clinical need for this placement.
- Supply Chain should review this placement to ensure adequate storage is available.
- Entry of placed trays into the system should be coordinated with Central Sterilization Services (CSS).
  - a. CSS Product Realization procedures should be referenced during coordination.
  - b. This process can take a great deal of time. Interim plans should be considered.
- Placed trays should be monitored on a regular basis and low use to no use placed trays should be removed as needed.
- Replacement of lost or broken instruments will be discussed with the vendor.
- Replacement of single-use plates, screws, drill bits are performed by the vendor.

## Resources

For additional applicable policies and resources, please visit the Procurement Services, Vendor Information page at <https://uihc.org/procurement-services-vendor-information>.

## Contact

For questions, please contact Procurement and Value Implementation (PVI) Services.

Phone: 319-384-98000

Fax: 319-356-1102

200 Hawkins Dr., Iowa City, IA 52242