

**LEE MEMORIAL HEALTH SYSTEM  
POLICY & PROCEDURE MANUAL**

<b>HEALTHCARE INDUSTRY REPRESENTATIVE VISITATION WITHIN RESTRICTED ACCESS / PROCEDURAL AREAS</b>		<b>LOCATOR NUMBER</b>																					
<b>T Y P E</b>	<input checked="" type="checkbox"/> <b>System-wide</b> - A formal statement of values, intents (policy), and expectations (procedure) that applies to every employee throughout the System.	<b>CHAPTER: M03</b>																					
	<input type="checkbox"/> <b>Multidisciplinary</b> - A formal statement of values, intents (policy), and expectations (procedure) that applies to more than one discipline and is usually of a clinical nature. <b>Check below all areas to which this applies.</b>	<b>TAB: 05</b>																					
	<input type="checkbox"/> <b>Departmental</b> - A formal statement of values, intents (policy), and expectations (procedure) exclusive to a particular department or group of people within a department at one or multiple locations that does not impact any other area.	<b>POLICY #: 361</b>																					
<b>Disciplines / locations to which this multidisciplinary policy applies:</b>																							
<table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Health Information Management</td> <td><input type="checkbox"/> Pharmacy</td> <td><input type="checkbox"/> Acute Care Hospital Nursing</td> </tr> <tr> <td><input type="checkbox"/> Housekeeping</td> <td><input type="checkbox"/> Plant Operations</td> <td><input type="checkbox"/> Ambulatory Services</td> </tr> <tr> <td><input type="checkbox"/> Information Systems</td> <td><input checked="" type="checkbox"/> Radiology</td> <td><input type="checkbox"/> Home Health</td> </tr> <tr> <td><input type="checkbox"/> Laboratory</td> <td><input type="checkbox"/> Rehabilitation Services</td> <td><input type="checkbox"/> HPCC</td> </tr> <tr> <td><input type="checkbox"/> Legal Services</td> <td><input checked="" type="checkbox"/> Respiratory</td> <td><input type="checkbox"/> Physician Offices</td> </tr> <tr> <td><input type="checkbox"/> Nutrition</td> <td><input checked="" type="checkbox"/> Security</td> <td><input type="checkbox"/> Rehab Hospital</td> </tr> <tr> <td><input checked="" type="checkbox"/> Other <u>Surgical Services,</u> <u>Cath Lab</u></td> <td><input checked="" type="checkbox"/> <u>Supply Chain Management</u></td> <td><input checked="" type="checkbox"/> <u>CSF/LeeSar</u></td> </tr> </table>			<input type="checkbox"/> Health Information Management	<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Acute Care Hospital Nursing	<input type="checkbox"/> Housekeeping	<input type="checkbox"/> Plant Operations	<input type="checkbox"/> Ambulatory Services	<input type="checkbox"/> Information Systems	<input checked="" type="checkbox"/> Radiology	<input type="checkbox"/> Home Health	<input type="checkbox"/> Laboratory	<input type="checkbox"/> Rehabilitation Services	<input type="checkbox"/> HPCC	<input type="checkbox"/> Legal Services	<input checked="" type="checkbox"/> Respiratory	<input type="checkbox"/> Physician Offices	<input type="checkbox"/> Nutrition	<input checked="" type="checkbox"/> Security	<input type="checkbox"/> Rehab Hospital	<input checked="" type="checkbox"/> Other <u>Surgical Services,</u> <u>Cath Lab</u>	<input checked="" type="checkbox"/> <u>Supply Chain Management</u>	<input checked="" type="checkbox"/> <u>CSF/LeeSar</u>
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<b>Education Plan Required:</b> <input checked="" type="checkbox"/> <input type="checkbox"/> Jaime Tyrna, RN, BSN, MS		<b>Date:</b> 7/15/10																					
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<b>Medical Director:</b>		<b>Date:</b>																					
<b>Board of Directors:</b>		<b>Date:</b>																					

**PURPOSE:**

To define the circumstances in which Healthcare Industry Representatives (HCIR) may be present in restricted access / procedural areas, and to outline the process required when HCIR, staff, and

surgeons and their assistants bring new and / or special request products / equipment into the these department(s) for patient use.

## **POLICY:**

- A. **No Healthcare Industry Representatives (HCIR) will be allowed into any Lee Memorial Health System (LMHS) department without a vendor badge. The badge must be worn and visible, attached to the surgical scrub top, at all times while in our facilities.**
- B. The HCIR will comply with all System patient confidentiality policies and procedures. All HCIR must follow all procedures outlined in this LMHS Policy as well as Policy S07 02 362 Healthcare Industry Representatives Visitation Acute Care, prior to presenting to any / all restricted access / procedural location.
- C. HCIR will be allowed only in those rooms or areas where the service(s) that they are present to support are being provided, and may observe and / or provide technical support or consultation for their product only, and only from a position outside of the sterile field.
- D. Access may be revoked when an HCIR does not comply with the policies and procedures outlined in this document and LMHS Policy S07 02 938 Healthcare Industry Representatives Visitation Acute Care. In addition, non-compliance will be reported to the Corporate Compliance division of the company being represented.

## **PROCEDURE:**

### **I. VISITATION**

- A. HCIR will park only in the designated Employee Parking Lots and **are not** to park in designated Patient or Physician parking areas.
- B. HCIR will sign in with the Supply Chain Management (SCM) or Central Supply Department, depending on the designated facility location, every time they visit the facility. Vendor badges will be issued by SCM through Status-Blue log-in.
- C. HCIR must check in with the department director / manager / charge nurse or their designee upon arrival within the department. HCIR will enter and leave the areas as directed by the department Director or her / his designee. **In some cases the HCIR may be required to sign in on an additional log at the control desk of the department being visited. This requirement should be verified with the department leadership.**
- D. After hours and weekends; the HCIR will sign in and out with Security in the Emergency Department at each location and sign in on Vendor Guest Register document ([FM # 0791](#)). Security will issue a plastic VENDOR badge and may retain the HCIR Drivers License or car keys during visit. The HCIR needs to return to Security at the conclusion of their visit and sign out and return vendor badge.
- E. HCIR who wish to meet with clinical staff must schedule appointments in advance of the meeting. No representative will be allowed into restricted access / procedural areas without an appointment.

- F. HCIR may be present in restricted access, procedural or patient care areas when the following conditions are met:
1. The physician or a LMHS Representative requests their presence for a specific procedure.
  2. **When their presence is requested directly by the surgeon**, the HCIR must inform the department Director of the request and provide the date, the name of the physician / surgeon making the request, and the procedure to be supported.

**LMHS strongly discourages access to training or traveling representatives into our facilities. Any such visits will need to be approved by the respective facility's department leader and then admittance will only be approved when the visiting/trainee HCIR has been cleared in Status-Blue. Visiting HCIR Managers or Supervisors will also need pre-approved clearance or access will be denied.**

G. Healthcare Industry Representatives **WILL NOT**:

1. Provide patient care.
2. Operate any equipment, (except in those areas where this support is essential to the product being consumed and appropriate clearance has been approved for this service).
3. Open any sterile packages or components.
4. Touch or handle any bio-hazardous materials.
5. Discuss any financial, reimbursement, or issues related to patient admission status with staff and / or physicians.
6. Be present in the operating room while patient is being prepped and draped.

H. All HCIR must be registered through our credentialing company Status-Blue by visiting [www.status-blue.com](http://www.status-blue.com) and completing required LMHS documentation. HCIR registration process will include but not be limited to:

1. Health Insurance Portability and Accountability Act Confidentiality Agreement ([FM # 0762](#)).
2. Review of LMHS HCIR Visitation Policies S07 02 938 and M03 05 361.
3. LMHS Compliance Standards of Conduct.
4. Verification of company's contracting or agreements relationship with Cooperative Services of Florida (CSF).
5. Verification of TB screening.
6. Verification of liability coverage insurance.

7. Verification of training in:
  - a. OR protocols
  - b. Sterile fields
  - c. Aseptic techniques
  - d. Universal precautions
8. Verification of Training in LMHS Environment of Care (EOC):
  - a. emergency codes
  - b. fire procedures
  - c. EOC
- I. HCIR will be in compliance with the LMHS Surgical Services Dress Code. When in the procedural area during a surgical procedure, the HCIR will stay on the periphery of the room, well outside of the area where s/he may come in contact with any bio-hazardous materials. If an HCIR scrub uniform should become grossly soiled with bio-hazardous materials, the uniform must be bagged, labeled with the HCIR name, and presented to the nurse in charge of the department for laundering. LMHS will launder the uniform.
- J. HCIR is allowed only in the areas / operating rooms where the physician / surgeon and / or procedure that they are supporting are being performed.
- K. The HCIR will follow all LMHS procedures / precautions related to isolation patients and comply with our isolation protocols.

## II. New Product, Equipment and Instrument Items

The following must occur prior to new products and equipment being brought into LMHS: *(Product for urgent critical need cases/procedures may be acquired concurrent to these requirements in order to prevent impact on urgent patient care however they will be requested and authorized by the Department Director they must complete New Items Request form ([FM# 1246](#)))*

- A. Communication with department buyer at LeeSar Centralized Purchasing, LMHS's purchasing arm.
- B. Contractual or Agreement compliant pricing and product information has been received by LeeSar Centralized Purchasing or Cooperative Services of Florida, LMHS's Group Purchasing Organization.
- C. The Department Director has requested the item on a New Items Request form ([FM# 1246](#)) for use in their designated location.

- D. The product / equipment has been determined acceptable by the Supply Management Action Team (SMAT) and approved by the Surgical Supply Management Action Team.
- E. Products / Equipment being shipped into any LMHS facility **must have a purchase order** prior to shipment. This can be arranged through Supply Chain Management or Centralized Purchasing and must be clearly identified on the packing list accompanying the shipment so that product / equipment can be properly tracked and delivered to the appropriate department.
  - 1. To leave any equipment for demo or trial use on-site at any LMHS Facility, the vendor must have the equipment inspected and approved/tagged by Bio-Medical Engineering. (Electrical equipment and products may not be used until they have been inspected and approved.)
  - 2. Department Staff, and all other appropriate facility staff, have been informed / educated / instructed about product operating instructions and safety procedures / issues prior to the delivery of the equipment.
- F. Manufacturer / Vendor loaner trays of instruments and implants brought into the System must arrive on site at the appropriate facility, no less than 24 hours prior to the day and time of procedure so that the proper decontamination and sterilization processes can be completed. This is a critical process and unless prior arrangements have been made, on a case-by-case basis, this is the LMHS expectation. If Monday is the day of procedure, the expectation is that the trays be in the facility by 7PM on the Friday before the Monday procedure. When a holiday occurs on a weekday, the trays must be in the facility by 7PM the business day before the holiday.
- G. Manufacturers / vendors will provide complete and detailed packing list/count sheets for each instrument and implant tray brought into the department. The count sheet will list every item in the tray with catalog number and quantity. LMHS will not pay for product (to include implants) or equipment that is brought into our System when the above procedures are not followed. This includes sets of instruments or implants with missing or incomplete count sheets
- H. Until the system SMAT approves any new items; when approved for use on a case by case basis, LMHS will not pay more for an item than it is currently paying for like items already existing in the System.
- I. LMHS will not pay loaner fees for trays or equipment to the vendor or their representatives unless the fees have been previously negotiated in writing with CSF.

### III. Bill Only Requisition / Purchase Orders

Bill only requisition / purchase orders are issued for **authorized products** which are consumed within a specific department, i.e. Surgery Services, Cath Lab, and Radiology, from a non-LMHS owned, non-inventory consignment or Industry Representative "Bank" inventory. These PO's are authorization to pay for the consumption of the identified products use; however, the PO will not generate a reorder of the product.

- A. For each patient that has received any billable implant, equipment or other product or service HCIR must complete a Special Order Invoice Form ([FM # 1217](#)) provided by an LMHS representative. The form must be completed immediately after the procedure and given to the Supply Specialist during business hours and left in the Supply Specialists communication box when the procedure occurs after hours. *(An **exception** to this process is the Total Joint Bill Only which requires that all documentation related to the consumption and products is faxed to the Centralized Purchasing department @ 239-303-0735 post case.)*
- B. The Special Order Invoice Form is complete only when the following information is provided:
1. Patient identification sticker,
  2. Company name,
  3. Date,
  4. Physician/Surgeon,
  5. Location,
  6. Part number of each item used,
  7. Description of each item used,
  8. Lot or serial number of each item used,
  9. Indicate waste in appropriate column,
  10. Quantity of each item used,
  11. Each cost,
  12. Total cost.

As this document is critical to the patient charge documentation process, when the Special Order Invoice form is not completed and submitted post procedure by the vendor representative, payment may be delayed. When the patient has been billed for their surgical procedure, prior to the submission of this document, LMHS may not approve payment for the product.

#### **IV. Consigned Instrumentation, Implants, Supplies and Equipment**

Consigned instrument trays, implants, supplies and equipment, that is housed in LMHS facilities will be documented with a consignment agreement per policy S07 01 138 Consignment Product Acquisition Process, through Supply Chain Management (SCM). These consignments will be updated annually or more often as needed for changes.

**LMHS strongly discourages any loan/borrow to entities outside of LMHS facilities from consignments placed in our inventories.** LMHS also understands that on rare occasions an urgent situation may arise that would require the need to access a consignment for a

critical patient care need. Consigned items will not be taken from the facility without written permission of the Surgical Services department director or her / his designee, and then only after the following:

- A. Prior to removal of any assets from an LMHS facility, the HCIR will work directly with an authorized LMHS staff member to complete a Loan/Borrow document (form 5672 or 2094). If an implant set is removed, the surgical services representative will complete a signed count sheet validating the tray or its contents. A copy of the signed count sheet will travel with the tray / item, and the department will retain the original.
- B. When the consigned items are returned, the HCIR with an LMHS staff member will recount the items and indicate on the count sheet the contents and their condition prior to returning them to service. LMHS will not be responsible for damaged or missing items identified at this count.

#### **V. Solicitation or Distribution of Print or Electronic Media**

Non-employees are prohibited from distributing any communication in print or electronic media or soliciting on LMHS premises at any time. This includes, but is not limited to complimentary newspapers, magazines, catalogues, and product information and non-LMHS brochures unless approved by Press & Public Affairs (Reference Policy S09 06 835).

- A. Publishers and Distributors are not permitted to drop off copies of their publications in the lobbies, waiting rooms or offices of LMHS without prior approval by Public Relations

#### **VI. The LMHS written policies on the behaviors of HCIR include the following actions, up to and including suspensions, that will be taken against those who violate the policies:**

- A. **First Infraction:**  
Director of Supply Chain Management or designees will meet with the representative to document and review incident and possible future actions if infractions continue
- B. **Second Infraction:**  
Suspension of Representatives privileges at all LMHS facilities for a period of up to three months with a formal notification to the representative's supervisor. Current business will be conducted by an alternate representative from the company
- C. **Third infraction:**  
Suspension of the representatives access and privileges at all LMHS facilities indefinitely, with formal notification to representatives supervisor. Suspension will be enforced for a minimum of one year.
- D. **Final Option:**  
LMHS may terminate an agreement and convert to an appropriate, competitive and acceptable alternate product.

These steps are defined as a guideline for the HCIR and may be moved to any point of action steps for behaviors which are considered gross misconduct.

## **RELATED POLICIES:**

M07 02 362 Healthcare Industry Representative Visitation Acute Care Locations

S09 06 835 Solicitation and Distribution in the Workplace

S07 01 138 Consignment Product Acquisition Process

## **REFERENCES:**

"AORN Guidance Statement: The role of the health care industry representative in the perioperative setting," in *Standards, Recommended Practices, and Guidelines* (Denver: AORN, Inc, 2006) 261-263.

AORN Standards, Recommended Practice and Guidelines (2006). Denver, Colorado.

LMHS Standards of Conduct Brochure #6639