

This policy applies to: <input checked="" type="checkbox"/> <i>Stanford Hospital and Clinics</i>	Date Written or Last Revision: March 2013
Name of Policy: Vendor Management Policy	Page 1 of 10
Departments Affected: All Departments	

I. PURPOSE

It is the policy of Stanford Hospital and Clinics (SHC) to provide innovative care while maintaining patient privacy and safety. SHC is committed to providing reasonable opportunities for external representatives/vendors to present and demonstrate their products and/or services to the appropriate SHC personnel. However, the primary objective of SHC is patient care and it is therefore necessary for all sales representatives/vendors to follow guidelines that protect patient rights and the vendor relationship. The purpose of this policy is to protect the patient’s right to privacy and confidentiality and to establish safety guidelines for the presence and participation of industry representatives in patient care activities at SHC.

II. POLICY

It is the policy of SHC to ensure that all sales representatives, vendors and visitors with whom SHC or its faculty conducts business are correctly identified and have completed the appropriate training, including HIPAA training. In order to comply with SHC policy and HIPAA requirements, all sales representatives, vendors and visitors must follow both the SHC Industry Interactions Policy and the procedures below.

III. DEFINITIONS

- A. Health Care Product Sales Representatives
 - 1. Any health care product, medical device, or medical equipment company employee whose job falls under the rubric of the marketing and sales department and whose job duties include increasing sales of their company’s product through interaction with physicians and staff.

- B. MedSamples
 - 1. Medication samples that are distributed by pharmaceutical companies and packaged with the manufacturer’s label “Sample medication” or “Professional sample”.

- C. Patient Care Areas
 - 1. Any area in which patients are seen for the purpose of registration, consultation, diagnosis, or treatment.

- D. Pharmacy representative
 - 1. An employee or agent of a pharmaceutical company whose professional role is to provide support and/or guidance regarding the selection and use of pharmaceutical products.

- E. Vendor

This policy applies to: <input checked="" type="checkbox"/> <i>Stanford Hospital and Clinics</i>	Date Written or Last Revision: March 2013
Name of Policy: Vendor Management Policy	Page 2 of 10
Departments Affected: All Departments	

1. A person or representative of a company (including independent contractors for a company) that has a contract or Business Associates Agreement with SHC or is seeking to provide support, services and/or maintenance for a company's product(s) or services at Stanford Hospital and Clinics or Lucile Salter Packard Children's Hospital.

F. Visitor

1. An individual who may observe patient care but is not actively involved in direct patient care. Visitor requirements are covered under the SHC Visitors Policy.

IV. PROCEDURES

A. For Health Care Product Sales Representatives

1. Health care product/medical device/equipment sales representatives are not allowed to interact with patients and may not interact with medical students, residents, physicians, or members of the medical staff in the physician lounges or employee break rooms. Health care product/medical device/equipment sales representatives are not allowed in any patient care areas except to provide in-service training and then only by prior agreement of the clinical leadership.
2. Health Care Product sales representatives must have registered with the SHC Materials Management department's on-line vendor system Vendormate at <https://stanfordpackard.vendormate.com>. Company and individual representative information, as required, must be accurately entered in the system to obtain a vendor badge. The Health Care Product sales representative must obtain a badge in the Materials Management department or from a designated badging station. The Health Care Product representative must display the vendor badge at all times while in SHC. The vendor badge is good only during normal business hours, Monday through Friday, from the date issued and for the department and/or individual shown on the badge. The Health Care Product sales representative must sign out and return the badge to the Materials Management department or a badging station.
3. Health Care Product sales representatives may only be seen if they have obtained prior approval and may only visit the physician/department with whom they have arranged a meeting

This policy applies to: <input checked="" type="checkbox"/> <i>Stanford Hospital and Clinics</i>	Date Written or Last Revision: March 2013
Name of Policy: Vendor Management Policy	Page 3 of 10
Departments Affected: All Departments	

4. Health Care Product sales representatives may not leave literature, promotional items such as pens, paper, or any item with the company logo or product on it.
5. Product Demonstrations:
 - a. Health Care Product sales representatives may not demonstrate their products in public areas such as lobbies or corridors.
 - b. For training related to new products in the OR, Cath Angio Lab, Radiology Department, or Laboratory the physician or department interested in the product must provide notice (at least 24 hours) to the OR Director, Cath Angio Lab Manager, Director of Radiology, Lab Director or designee.
 - c. Health Care Product sales representatives will be restricted to demonstrating the device or equipment under consideration and must receive approval for additional equipment, instruments and/or supplies from the appropriate Director prior to utilizing the item in a demonstration .

B. For Pharmaceutical Company Representatives

1. Sign in Procedure
 - a. To ensure that pharmaceutical representatives are appropriately identified, pharmaceutical representatives must sign in at the Pharmacy Office.
 - b. Pharmacy Representatives must obtain a badge from SHC Security or the Pharmacy Secretary.

2. Promotion of Products

To ensure that the Pharmacy and Therapeutics Committee is aware of all products being presented, pharmaceutical representatives desiring to promote a new product, or new indication of an existing product must:

- a. First leave a written request for the Director of Pharmacy including their business card.

This policy applies to: <input checked="" type="checkbox"/> <i>Stanford Hospital and Clinics</i>	Date Written or Last Revision: March 2013
Name of Policy: Vendor Management Policy	Page 4 of 10
Departments Affected: All Departments	

- b. The Director of Pharmacy will assign a clinical pharmacist to meet with the representative. The clinical pharmacist will schedule the meeting with the representative. Prior to the meeting, the representative should leave, with the Pharmacy Secretary, copies of the best possible studies from reputable peer reviewed journals discussing the drug and the other drugs in its class. If possible, double blind controlled studies are preferred by the physicians and the Pharmacy and Therapeutics Committee. Articles that both support the use of the product, any studies pertaining to a cost-benefit analysis, as well as, contraindications are encouraged to be left with the Pharmacy Secretary and any appropriate physicians.
- c. If additional meetings or information is needed, the representative will be contacted by pharmacy personnel. Pricing, contracts, etc., information is to be left for the Director of Pharmacy. If pricing meetings are needed, pharmacy will take the responsibility to set them up with the representative.
- d. Pharmacy representatives may not leave literature, promotional items such as pens, paper, or any item with the company logo or product on it.

C. Drug Samples

- 1. Manufacturer's representatives providing MedSamples will have physician access in accordance with Pharmacy Protocol #4 for Medication Samples.
- 2. Dispensing of medication samples are not allowed in the inpatient setting. Dispensing of medication samples are allowed in specific ambulatory clinics that must adhere to the requirements outlined in the Pharmacy Protocol #4 for Medication Samples policy.

D. Educational Programs

- 1. Educational programs provided by Pharmaceutical Representatives must be conducted in accordance with the SHC/SoM Industry Interactions Policy.
- 2. The Pharmaceutical Representative must notify the Pharmacy Director in writing at least five (5) business days prior to the scheduled meeting or group discussion.

This policy applies to: <input checked="" type="checkbox"/> <i>Stanford Hospital and Clinics</i>	Date Written or Last Revision: March 2013
Name of Policy: Vendor Management Policy	Page 5 of 10
Departments Affected: All Departments	

3. The written request must contain the name of the speaker, date, time, place, product(s) and provide any relevant articles that will be discussed.
4. The Director of Pharmacy will try to have a clinical pharmacist to attend, in order to provide information regarding the current perspective of the organization for that class of drugs. The pharmacist and the representatives will work together to provide cost and therapeutic comparison data relative to the hospital.

E. Hospital Data

1. The Pharmacy Department will not provide usage or sales data to pharmaceutical representatives, pharmaceutical or medical science liaisons, clinical specialists, sales representatives or agents of pharmaceutical companies. This information is restricted, and is intended for review only by SHC clinical pharmacists for the purpose of evaluating drug usage, costs, and prescribing trends.
2. Patient specific usage information shall not be disclosed unless in accordance with HIPAA regulations and SHC policy.
3. The Pharmacy Department will not provide any written material or communications intended only for circulation to SHC practitioners. SHC specific drug treatment guidelines, protocols, and restrictions will be not distributed to pharmaceutical representatives, pharmaceutical or medical science liaisons, clinical specialists, sales representatives or agents of pharmaceutical companies.
4. The Department of Pharmacy will provide usage and sales information for the following exceptions:
 - a. As a specific stipulation in a drug purchase contract; or
 - b. As a specific stipulation in a drug discount or rebate program; or
 - c. To resolve drug contract-or discount related issues.
5. The Department of Pharmacy will provide written material or guidelines for the following exceptions:
 - a. The requested information is a necessary component of a drug purchase contract; or

This policy applies to: <input checked="" type="checkbox"/> <i>Stanford Hospital and Clinics</i>	Date Written or Last Revision: March 2013
Name of Policy: Vendor Management Policy	Page 6 of 10
Departments Affected: All Departments	

- b. The requested information is a necessary component of a drug discount or rebate program.

F. For Vendors

1. All health care product vendors must have registered in the SHC Materials Management department on-line vendor system (<https://stanfordpackard.vendormate.com>). All vendors must sign in at the Materials Management Department or a designated badging station and obtain a vendor badge prior to visiting any department. Vendor representatives are not to present equipment or supplies or participate in any procedure, demonstration, or training unless they have registered with the Materials Management Department
2. SHC or School of Medicine faculty or staff shall not do business with vendor representatives unless they have registered with the SHC Materials Management Office. All departments are responsible for advising vendors of the necessity to comply with this policy, as failure to comply may result in the vendor's inability to return to SHC.
3. SHC will not pay for any product or device brought in by a vendor representative that has not been approved by Materials Management and/or the appropriate SHC committee.
4. Vendors are required to wear their vendor badge at all times while on SHC property and to return the vendor badge to SHC Materials Management department or a designated badging station by the end of each business day.
5. Vendors are required to wear scrubs prior to entry to any procedure or control room.
6. All FDA approved equipment, devices, or supplies for the intended use must have received prior approval by Materials Management and be entered into the Hospital's Chargemaster, if applicable.
7. All non-FDA approved or off-label equipment, device or supplies must have received prior approval from the Committee on Management of New Technologies, SPCTRM, the OR Medical Committee, the Clinical Engineering Department and Human Investigation Committee, as appropriate.

This policy applies to: <input checked="" type="checkbox"/> <i>Stanford Hospital and Clinics</i>	Date Written or Last Revision: March 2013
Name of Policy: Vendor Management Policy	Page 7 of 10
Departments Affected: All Departments	

8. If a vendor is presenting during a medical procedure, the physician is responsible for obtaining the appropriate patient consent and documenting it in the patient's medical record.
9. Vendors who will be participating in procedures in the OR must obtain prior approval from the OR Director or designee before the scheduled procedure.
10. Vendors who will be participating in procedures in the Cath Angio lab must call (650) 723-7676 and obtain prior approval from the Cath Angio Lab Manager. Only vendors who are scheduled through the Cath Angio Lab Manager will be allowed to enter the Cath Angio Lab.
11. On the day of the procedure or service, all vendors check in at the respective OR/ASC Control Desk or the Cath Angio administrative office (Room H2318) after obtaining their badge from Materials Management or a badging station.

G. Vendors – Emergency Services

1. The Chairman of the OR Medical Committee, the Chief of Staff or the Vice President of Clinical Services are the only individuals who may approve exceptions to this policy which must be limited to emergency situations.
2. Vendors are still required to notify the Director of the OR Region or the Cath Angio Lab Manager and sign in if his/her participation is due to an emergency situation.

H. Compliance

1. All vendors, Health Care Product sales representatives and pharmaceutical company representatives are required to comply with this policy.
2. Every vendor, Health Care Product sales representative and pharmaceutical company representative must provide an annual certification to confirm that the vendor or representative has read and is in compliance with SHC policies including the Industry Interactions Policy and that the vendor will not provide any gifts or compensation described in the SHC Industry Interactions Policy to any Medical Staff, faculty, staff, students and trainees of SHC, LPCH or SoM.

This policy applies to: <input checked="" type="checkbox"/> <i>Stanford Hospital and Clinics</i>	Date Written or Last Revision: March 2013
Name of Policy: Vendor Management Policy	Page 8 of 10
Departments Affected: All Departments	

3. Vendor and/or representative access is a privilege and approved by the appropriate individuals identified in this policy. Under no circumstances will any Vendor be allowed to participate in patient care without complying with this policy.
4. Vendor and/or representatives may not leave any unapproved products, equipment or other items on SHC property.
5. Violations of this policy will be reported to SHC Materials Management, Compliance Department, Risk Management and the Department Manager. Violations will be investigated to determine the nature, extent and potential risk involved as well as to determine if the vendor or representative acted independent of or in consort with the applicable company. Violations of this policy may include termination of the company's contract or prohibition of the vendor and/or representative from further interactions at SHC.
6. All workforce members including credentialed medical staff, employees, agents, students and volunteers representing or engaging in the practice at SHC are responsible for ensuring that vendors and/or representatives comply with this Policy.

V. COMPLIANCE

- A. All workforce members including employees, contracted staff, students, volunteers, credentialed medical staff, and individuals representing or engaging in the practice at SHC are responsible for ensuring that individuals comply with this policy;
- B. Violations of this policy will be reported to the Department Manager and any other appropriate Department as determined by the Department Manager or in accordance with hospital policy. Violations will be investigated to determine the nature, extent, and potential risk to the hospital. Workforce members who violate this policy will be subject to the appropriate disciplinary action up to and including termination.

VI. RELATED DOCUMENTS

- A. Conflict of Interest and Commitment Policy
- B. SHC Industry Interactions Policy
- C. SHC Visiting Observer Policy

VII. DOCUMENT INFORMATION

- A. Legal Authority/References

This policy applies to: <input checked="" type="checkbox"/> <i>Stanford Hospital and Clinics</i>	Date Written or Last Revision: March 2013
Name of Policy: Vendor Management Policy	Page 9 of 10
Departments Affected: All Departments	

PhRMA Code: <http://www.phrma.org/publications/>

- B. Author/Original Date
Kathryn S. Pyke, June 2006
- C. Gatekeeper of Original Document
SHC Administrative Manual Coordinator
- D. Distribution and Training Requirements
 1. This policy resides in the Administrative Manuals of both hospitals.
 2. New documents or any revised documents will be distributed to Administrative Manual holders. The department/unit/clinic manager will be responsible for communicating this information to the applicable staff.
- E. Review and Renewal Requirements
This policy will be reviewed and/or revised every three years or as required by change of law or practice.
- F. Review and Revision History
Revision by Materials Management, October 2009
Reviewed by Rex Fieck Administrative Director Materials Management January 2013
- G. Approvals
August 2006, SHC Medical Board
August 2006, SHC Hospital Board
November 2009, Quality, Patient Safety & Effectiveness Committee
December 2009, SHC Medical Executive Committee
December 2009, SHC Board Credentials, Policies & Procedures Committee
February 2013, SHC Quality, Patient Safety & Effectiveness Committee
March 2013, SHC MEC
March 2013, SHC Board Credentials, Policies & Procedures Committee