

Hennepin County Medical Center
Title: Supplier Access – Policy # 002071
Policy Champion: Director of Supply Chain Management
Policy Sponsor: Supply Chain Steering Committee, OR Management Committee
Stakeholder: HCMC Employees
Final Approval Body: Clinical Practice Committee
Original Approval Date: 12/07/04
Reviewed/ Revised: 10/08/2012

PURPOSE

The purpose of this policy is to establish a clear and consistent set of rules governing sales representative activities while conducting business with Hennepin County Medical Center (HCMC). It is intended to establish guidelines for sales representative conduct that will meet the needs of both HCMC staff and patients. This policy is not meant to be punitive nor is it a statement about the honesty, fairness or good will of any individual representative.

DEFINITIONS

Detailing: The provision of information relating to a medication or medical device, including clinical information about prescribing, comparative information about other like medications or devices, or information regarding safety

Educational Program: An educational program is any lecture, seminar or meeting featuring content that is chosen by HCMC Staff and considered to be consistent with the educational, research and patient care mission of the institution

Executive Leadership Team (ELT): That group of senior-most executives reporting directly to the Chief Executive Officer

Gifts: Goods, services, food, or money provided either unconditionally or as a reward or incentive for conference attendance, interviews, meetings, receiving or reviewing literature or advertising, access to staff or patients, proposing the purchase or inclusion on the formulary of commodities or medications, or similar quid pro quo activities, even if of trivial monetary value

In-service: An in-service is an informational presentation focused on a specific product, procedure or service

Conference: A prearranged meeting for consultation or the exchange of information which normally includes a formal agenda

POLICY

Representatives are to maintain the highest level of professional and ethical behavior, and be supportive of hospital and medical center operations at all times. Non-compliance with this policy may result in the loss of access and privileges at Hennepin County Medical Center (HCMC)

PROCEDURE

I. Solicitation

- A. Sales representatives shall not solicit at HCMC Campus and Clinics with the exception of the following circumstances:
 - 1. To meet with a hospital staff member who has requested an appointment.
 - 2. To deliver product information (on medications, supplies, etc.) for evaluation by hospital services departments.
 - 3. To deliver products to be considered for evaluation to the respective hospital departments after prior approval. Adequate descriptive literature shall accompany the product evaluation purposes.
 - 4. To expedite the removal of recalled products in coordination with Pharmacy or Purchasing.

II. Ethical Behavior

- A. Sales representatives conducting business at HCMC shall maintain the highest level of professional and ethical behavior, as represented by the HCMC Missions and Values.
- B. Representatives shall respect the rights and privileges of HCMC staff, patients, and other representatives calling on HCMC
- C. Confidentiality of patient medical or demographic information must be maintained and can only be accessed by authorized HCMC personnel. Unauthorized access to patient information is strictly forbidden and cause for disciplinary actions. All Sales Representatives will sign an HCMC confidentiality agreement which shall be filed with the Online Supplier Compliance Network.
- D. Representatives will not be allowed to attend HCMC conferences except as provided by Section V. F.

III. Registration Requirements

A. Registration

- 1. Sales representatives conducting business at HCMC must be registered. They shall register with the Online Supplier Compliance Network.
- 2. At the annual registration, the sales representatives will:
 - a. Sign a statement acknowledging receipt of the policy and agreeing to comply with the policy.
 - b. Sign a confidentiality agreement.
 - c. Provide proof of credentialing requirements as noted in IX.
- 3. Managers or medical/scientific liaisons accompanying the local representatives are required to check in at the Supply Chain Management Department when visiting. This policy shall apply to their conduct at HCMC.

- B. Identification Badge
 - 1. The badge must be worn at all times while at HCMC and its facilities.
 - 2. Representatives who are not in possession of a current badge will not be allowed access to HCMC and its facilities.
 - 3. If desired, sales representatives may wear a company-supplied nametag in addition to, but not in place of, an authorized badge.
- C. Database
 - 1. A common database of representatives will be maintained by the Online Supplier Compliance Network.
 - 2. The database will be used solely by HCMC Supply Chain Management and Pharmacy.
- D. Sign-In Procedure
 - 1. Every supplier representative must sign in and out at designated locations for every visit to HCMC's campus.

IV. Authorized and Unauthorized Areas

- A. To protect patient confidentiality and avoid disruptions in patient care, sales representatives are prohibited from patient care areas. They may travel through these areas en route to a scheduled meeting, but are prohibited from conducting business in or lingering in these areas. Equipment demonstrations that require a special location are exempt from this restriction.
- B. Sales representatives are prohibited from detailing house staff or medical students except in the presence of a faculty physician.
- C. All staff members have the right to refuse to meet with any sales representative.
- D. OR suppliers are required to make an appointment before access to any area of surgical services or the Central Processing Department.
 - 1. Appointment times are 7:00am – 12 pm for Central Processing. Appointments to access implant trays require an appointment except in the case of an emergency procedure
 - 2. Meetings must be scheduled in advance through HCMC's online supplier credentialing system.
 - 1. By exception, the Director of Surgical Services may request a waiver to this requirement for select sales representatives in writing to the Director of Supply Chain Management.
 - 2. A list of these sales representatives will be retained by the Supply Chain Management Department located here:
<https://infoshare/sites/FinancialServices/SCM/Shared%20Documents/SalesRepExceptionList2012.xlsx>
 - 3. Suppliers will not be allowed access to any surgical services patient care area without prior approval of the surgeon and the patient per the informed consent form.
 - 4. Sales representatives will report to the control desk before entering any surgical services area.
 - 5. Suppliers must wear surgical scrubs provided by Hennepin County Medical Center.
 - 6. Suppliers must have identification issued on the day of the visit prior to access.
- 7. Supplier representatives are restricted from requesting or reviewing patient schedules or any patient information.

- F. A sign off of this change is mandatory and must be strictly adhered to. Any supplier who does not comply with this change will be denied access HCMC.

V. Sales (Detailing) Activities/Promotional Material

- A. All sales activities must be conducted in such a fashion as to not compromise HCMC's mission of providing quality patient care.
- B. All information presented by sales representatives must be accurate. Provision of inaccurate or misleading statements will result in disciplinary action pursuant to this policy.
- C. Sales representatives are prohibited from engaging in sales activities for products or medications that have been denied formulary status or are not on contract, with the exception of new products, medications or technologies.
- D. In the event a product is added to the HCMC formulary with restrictions or guidelines for use, sales representatives are similarly prohibited from detailing the product for indications and uses excluded by the restriction or practice guideline. When detailing any products, sales representatives must include all HCMC restrictions and guidelines. Information on those guidelines is available from the Pharmacy or Supply Chain Management (non-pharmaceutical products).
- E. Product displays are not allowed.
- F. In-services or product demonstrations and educational programs are allowed only at the request of HCMC.
 - 1. The content of the in-service or educational program shall be limited to the information requested by HCMC, and shall not involve other unrelated supplier products or programs.
 - 2. The HCMC staff requesting the event, or his/her designated representative, shall attend the in-service or program.
 - 3. The purpose of an in-service is to provide information that is not available or readily accessible elsewhere.
 - 4. The purpose of an educational program is to provide educational materials or resources to assist in HCMC staff-initiated and supervised educational programs.
 - 5. Invitations for supplier sponsored in-services or educational programs must be approved by a member of Executive Leadership Team (ELT) (or designee) and the Director of Pharmacy (for medications) or Director of Supply Chain Management (for other products or services). Requests for in-services must indicate if a product or service is not on contract or a medication is not on formulary.
 - 6. In-service or educational instruction involving a sales representative may be held in patient care areas provided there is compliance with the above items.
- G. Sales representatives are prohibited from providing meals or food within any HCMC facility. This includes meals, coffee, snacks, donuts, bagels, candy etc. for all physicians and staff.
- H. The offer of gifts by suppliers to HCMC employees is prohibited. (See related policy on Rules of Conduct)
- I. **Circumventing HCMC policy.** Sales representatives who attempt to circumvent HCMC policy by complying with the letter but not the intent of these policies may be barred from access to HCMC.

VI. Communications

- A. Sales representatives may not use the public address paging system to locate any member of the medical staff or general HCMC staff.

VII. Trial Products and Product Evaluations

- A. The selection and use of sample drugs in the outpatient areas of the Medical Center will be at the discretion of the attending physicians within the clinic or area and must conform to the sample medication policy.
- B. All medications intended for inpatient use on a regular basis need to be approved by the Pharmacy and Therapeutics Committee. There are occasions when non-formulary drugs may be needed and the Pharmacy has a special order procedure established to obtain such drugs.
- C. Any commodity or pharmaceutical samples provided to HCMC shall be for formulary or contract items only. Any samples or trial products requested by HCMC for non-contract or non-formulary items shall be arranged through Purchasing or Pharmacy prior to its use. HCMC will not make payment to a supplier for sample or trial products brought in by a sales representative without the consent of Pharmacy or Purchasing.
- D. Departments requesting product samples or product/equipment evaluations shall submit a no-charge requisition to Purchasing. A purchase order number shall be assigned to the requisition as with any other order. Any products or equipment received on the dock without a purchase order number shall be returned to the supplier. (Please refer to HCMC policy #003122.)

VIII. Non-Compliance with Sales Representative Regulations

- A. Non-compliance with this Sales Representative Policy shall not be tolerated. Enforcement of the policy is a responsibility jointly vested in the Director of Pharmacy and the Director of Supply Chain Management. All violations of the policy shall be reported to one or both of them for evaluation. HCMC reserves the right to enforce this policy by restricting and/or revoking sales representative access for those who fail to comply.

IX. Documentation

- A. Documentation of competency must be on file for Sales Representatives. This documentation must be submitted and approved to the Online Supplier Compliance Network. **Error! Hyperlink reference not valid.** Competencies & requirements include the following based upon being deemed clinical or non-clinical:
 - 1. Principles of aseptic technique in the operating room environment
 - 2. Infection control practices
 - 3. Blood Borne Pathogens
 - 4. Patient rights and confidentiality
 - 5. Documentation of overall product competency
 - 6. Proof of negative TB skin test/annually
 - 7. HIPAA compliance strategies
 - 8. Certification of training for their instrumentation
 - 9. Background check

10. Proof of Insurance

RELATED POLICIES

No Gifts & Gratuities

“No employee of HCMC shall directly or indirectly receive or agree to receive any compensation, gift, reward, or gratuity from any source except Hennepin Healthcare System, Inc. (d.b.a. HCMC) for any matter or proceeding connected with or related to the duties of such employee unless otherwise provided for by this Section. However, honoraria or expenses paid for papers, talks, demonstrations or appearances made by employees on their own time shall not be deemed a violation of this Section provided such activity is approved by the appropriate ELT member.”

Product Evaluation Policy

[This discusses supplier responsibilities: “after receipt of the Evaluation Purchase Order, (the supplier) shall follow one or more of the following product specific delivery pathways;

1. Electrical Equipment: Deliver to Bioelectronics for Electrical Safety Testing. Equipment passing this test will be labeled “tested” and released for use. Untested equipment and items failing the Electrical Safety Test cannot be used!
2. Instrumentation: Deliver to Instrument Room Supervisor (or designee) with written decontamination and sterilization procedures. Once approved, Instrument(s) will be recorded, labeled, cleaned, wrapped, sterilized and released for use.
3. Medical Products: The specific delivery instructions for single use patient care products or related items will be provided on a “case by case” basis.”]

Regulatory Statute/ Standard Reference:
Related Policies: Policy #001977, 004018
References: TJC EC.02.01.01, EP 7
Communication/ Staff Education:
Patient Education: