

EMMC

Interdepartmental Directives

To: All Department Heads

Title: Policy for Sales Representatives

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Related References:

IDD 10.035 EMMC Code of Ethical Behavior
IDD 10.041 Financial Relationships with Physicians
IDD 10.042 Professional Appearance
IDD 10.046 Conflict of Interest
IDD 14.010 Radio Transmitter Restrictions
IDD 14.004 Hazard Communication Standard
IDD 15.002 Confidentiality of Healthcare Information
IDD 15.044 Limited Data Set- HIPAA
IDD 17.018 Name Badges
IDD 18.001 Centralized Purchasing and Supply Policies
IDD 18.015 Solicitation/Canvassing
IDD 18.016 New Product Trials/Evaluations
IDD 19.001 EMMC Parking Policy
Contractors, Consultants, and Vendors Manual
<http://www.emhs.org/resources/for-vendors.aspx#>

Attachments:

EMMC Life Safety Checklist
Requirement for Vendors of Medical Equipment Maintenance Services
Required Documentation Checklist for Vendor Reps

Definitions:

Sales Representatives are employed by manufacturers and suppliers to represent a business and to sell its merchandise or services on their behalf. EMMC classifies sales representatives on three levels, depending on the degree to which they are exposed to patients:

Level I: Sales Representatives who do not visit any patient care area and whose business is restricted to administrative offices or repairing/servicing equipment in clinical settings. Absolutely no patient interaction. Although by definition a service technician is not classified as a sales representative, EMMC has elected to include these representatives in the category of a Level 1.

Level II: Sales Representatives who may visit any patient care area ***except*** operating rooms, heart catheterization labs, angiography rooms, or any other procedural rooms.

Level III: Sales Representatives who may visit any patient care area ***including*** operating rooms, heart catheterization labs, angiography rooms, and any other procedural rooms.

Policy Statement: The following policy governs the promotion and evaluation of products and services as well as EMMC personnel who evaluate such products and services, and it is applicable on EMMC premises as well as off campus at EMMC sponsored events.

Policies:

A. EMHS Compliance Policies and Procedures

Sales Representatives are expected to read EMHS Compliance Policies and Procedures located on the EMHS Website: <http://www.emhs.org/resources/for-vendors.aspx#>.

B. *Immunization and Screening Requirements*

Sales Representatives who visit EMMC, especially those who visit patient care areas, are at risk for exposure to and transmission of tuberculosis and vaccine-preventable diseases. The health and safety of sales representatives and the patients to whom they are exposed are central to EMMC's sales representative immunization and screening policy.

See attached Required Documentation Checklist for Sales Representatives-applicable for all Level II and Level III vendors (Hepatitis B and Influenza not required but recommended). While the Screening Requirements do not apply to Level I vendors, EMMC recommends that they meet these requirements. (See definition section at the beginning of this document for vendor levels).

Sales Representatives are responsible for complying with these requirements at their own expense and must upload all immunization, screening documentation, and any other requirement as specified on the Vendormate portal in order to visit the facility. If the required documentation is not uploaded and approved by Vendormate, the Sales Representative will be denied a badge and access to the facility.

C. *Exceptions and Declinations*

A Vendor may be exempted from EMMC's Immunization and Screening Requirements with the following documentation:

1. A physician's written statement that immunization against one or more of these diseases is medically inadvisable.
2. The vendor's written statement in opposition to immunization for sincere religious or philosophical reasons.

- D. *Contracted service representatives, such as grounds maintenance, housekeeping, pest control, etc. are considered contractors and are exempt from registering with Vendormate and must comply with the Contractors, Consultants, and Vendors Manual.*

I. **Vendor Appointments**

Vendors who conduct business on EMMC premises must:

- A. Register with Vendormate, Inc.
- B. Read, acknowledge and upload all required documentation to Vendormate before meeting with any EMMC personnel for the first time. If the required documentation is not uploaded and approved by Vendormate, the Sales Representative will be denied a badge and access to the facility.
- C. **Make an appointment in advance** with the appropriate EMMC Manager or designee to conduct business with EMMC personnel. Most clinical **equipment service representatives** do not require appointments; however, they must check in/out with Security and must comply with the Requirements for Vendors of Medical Equipment Maintenance Services document. **Clinical Equipment service representatives/technicians are considered a Level I vendor.**
- D. **Sign in and out with Security** at the front entrance at 489 State Street when visiting the main campus or Security located at the EMHS Healthcare Mall on Union St. when visiting an EMMC department on Union St. **Pharmaceutical representatives must also sign in and out with the Pharmacy Department and share material that will be presented prior to the appointment.** Appointments with Pharmaceutical Representatives may be scheduled for the following purposes:
- to provide information useful for product evaluation
 - to facilitate procurement of a pharmaceutical product
 - to obtain and provide information necessary to support the Hospitals formulary system
 - to discuss education program support
- E. **Park in approved area:** When visiting the EMMC campus, Sales and Service Representatives may park in the West Parking Garage which is adjacent to Hancock St.. Service representatives who require dock access may use the service entrance located at the receiving dock. Use of valet parking is not permitted. All Sales Representatives must have their picture ID, professional card, vehicle information including make, model and license plate number to complete the sign-in process before being allowed to proceed to their appointment.
- F. **Go directly to and from their appointment** and may not loiter in any area outside of their appointment area, including public places such as the cafeteria, Medical Library, or Gift Shop. **Wear a temporary identification badge** provided by Security so that it is plainly visible while they are conducting business on EMMC premises.
- G. **Be denied access to any patient-identifiable health information** unless the company that the vendor represents has signed an agreement with EMMC on

Vendormate, Inc. that complies with the business associate provisions of the Health Insurance Portability and Accountability Act. ("HIPPA").

II. Promotional Practices

- A. Sales Representatives may not use EMMC personnel's pagers to solicit them.
- B. No promotional displays of any kind are allowed unless approved by a Vice President, Patient Care Administrator, or Department Head.

Displays must adhere to all of the following conditions:

1. It is part of a one or two-day educational conference sponsored by the Hospital.
2. The purpose of the display is educational.
3. It provides reprints from evidence based literature on the product.
4. The display is continuously staffed by a vendor representative who can provide product information.

Displays are not allowed at educational luncheon conferences, Grand Rounds, or in-service sessions.

- C. Sales Representatives are not permitted to provide promotional presentations at any grand rounds or medical education program regardless of sponsorship. This does not preclude the activities of speakers who are sponsored by manufacturers provided that the presentation has an unbiased approach to medical literature evaluation, product use, and/or research study design.
- D. Vendor Site Visits and Training and Education Programs- Refer to EMMC IDD 10-046/EMHS IDD 10-003.
- E. Acceptance of Meals- Refer to EMMC IDD 10-046/EMHS IDD 10-003. .
- F. Gifts- Refer to EMMC IDD 10-046/EMHS IDD 10-003
- G. Invitations by Vendors to Social Events- Refer to EMMC IDD 10-046/EMHS IDD 10-003
- H. Invitations by Vendors to Sponsored Fundraising Activities- Refer to EMMC IDD 10-046/EMHS 10-003
- I. All medical devices and pharmaceuticals must be approved by the FDA or Institutional Review Board and EMMC formulary. No promotion for non-formulary drug is allowed.
- J. All vendors, distributors, and manufacturers are expected by EMMC to comply with all federal law and regulations with regard to the manufacture, sale and distribution or medical devices. All vendors will be checked against all applicable governmental sanctioned lists.
- K. It is the policy of EMMC to procure and use only furnishings, bedding and decorations manufactured and successfully tested in accordance with the National Fire Protection Agency 1997 101 Life Safety Code, Chapters 12 and 13.

- L. Prior to bringing equipment or product in for evaluation or demo, the Sales Representatives must contact the buyer. If permissible, a no charge PO will be issued. All patient related equipment must be checked by Clinical Engineering prior to use.
- M. EMMC complies with and requires vendors to comply with the equal opportunity provisions of the following laws as amended and the rules and regulations issued pursuant thereto: Executive Order 11246, including 41 CFR 60-1.4(a), Section 504 of the Rehabilitation Act of 1973, including 41 CFR 60-741.5(a), and the Vietnam Era Veterans' Readjustment Assistance Act, including 41 CFR 60-250.5(a).

IV. Approved Area of Business for Sales Representatives

- A. No sales representatives are allowed in any patient care area including outpatient treatment areas unless they have an approved scheduled appointment and received approval.
- B. Sales Representatives calling on the Cardiac Cath Lab, Interventional Radiology, Surgical Services Departments, Eye Center and/or Endoscopy must contact the buyer in the Purchasing Department. Sales Representative access will be granted to those areas by the buyer if deemed appropriate.
- C. All provisions of this policy are applicable to educational conferences and events held off campus where the Hospital is the provider of the CME or CEU contact hours.
- D. Sales Representatives, who are present during patient care, diagnostic, surgical, and interventional procedures, must comply with the following process:
 - 1. The sales representatives must be registered and approved with Vendormate, Inc. as a Level II or Level III vendor. Approved status will only be granted if all required documentation has been submitted to Vendormate, Inc..
 - 2. The requesting physician must supervise the activities of the sales representative in this setting. This is not a responsibility of the patient's nurse or other hospital staff. The Department Head must receive prior notification by physician or physician office staff.
 - 3. Unless the sales representative is providing guidance with respect to the use of a medical device or prosthesis, the requesting physician must obtain prior informed written patient authorization to release healthcare information (MR 2N-15, Barcode 445) before permitting any access to the patient or to any patient Information.
 - 4. The representative must be 18 years of age or older.

5. The Department Head or designee will provide life safety training orientation specific to their department.
6. For reasons of patient safety and comfort, the sales representative must refrain from wearing fragrances or bringing in strongly scented products.
7. Sales representatives must meet all applicable Standard Credentials as specified for each level on Vendormate, Inc.
8. Any other requirements as deemed applicable by the Hospital or Department Head must be met.

V. Contractor Assurances

The Vendor must assure the competency and eligibility of their employees as follows:

- A. Conducting a criminal background check by Maine Bureau of Investigation and motor vehicle check by Maine Bureau of Motor Vehicles prior to or upon hiring an applicant. Vendors who have lived, worked or studied out of state should have a criminal background check by National Check Protection Services and specific state-by-state motor vehicle checks. Check all current and prior names. Level II and III.
- B. Obtaining U.S. Dept. of Justice Form I-9 with backup and satisfactory references from previous employers and/or schools prior to offering a position to a job applicant. Level II and III.
- C. Checking the OIG Cumulative Sanction Report prior to hiring new employees and annually thereafter; and not assigning any sanctioned employee to work under the Contract. Level II and III.
- D. Ensuring that each employee maintains appropriate and current licensure or certification if applicable, and provides evidence thereof. Level II and III.
- E. Providing orientation and continuing training and education relevant to each position, including age-specific training as appropriate. Level II and III.
- F. Providing initial competency assessment/orientation and continuing training and education relevant to each position including life safety training and age-specific training as appropriate. Level II and III.
- G. Requiring contract vendors to have a negative result on a pre-employment drug screen administered by the contractor pursuant to a testing policy approved by the Maine Department of Labor. Level II and III.
- H. Maintaining documentation of all of the above and of skills, training and competence of each employee, returning by the stated due date to the Client the annual audit checklist certifying the former stated documentation is complete on each employee, and making such files available to the Client as necessary for quality improvement purposes and to provide satisfactory evidence to accrediting and licensing agencies of the competency of each such employee.

VI. Ethical Awareness

- A. All EMMC and employees and Medical Staff members and Allied Health Professionals must adhere to the EMMC Code of Ethical Behavior concerning ethical behavior with regard to vendors.
- B. Sales Representatives are prohibited from recruiting or soliciting employees of EMMC during their visit.

VII. Samples

- A. Pharmaceutical samples: EMMC prohibits the acceptance of samples from pharmaceutical companies or other sales representatives for items to be used in the delivery of patient care. Exceptions to this rule must be reviewed and approved by the VP/CMO. If the VP/CMO approves the sample, sales representatives are prohibited from dropping off or mailing samples to the departments.

Acceptance of pharmaceutical samples must follow the requirements of PCD 35.008 which reads: A sample formulary shall be established and reviewed annually by the physician in charge of the site. New samples shall be reviewed by the physician in charge prior to addition to stock. Special consideration shall be made for look-alike, sound-alike, and high-alert medications.

Non-Pharmaceutical samples (clinical samples used for patient care) must be left with the Director of Materials Management.

- B. Samples of products not directly related to patient care such as common household products, may be accepted by the Director of Materials Management. These samples/products may not be used for direct patient care.

Food samples must be left with Nutrition Services.

- C. The Patient Care Product Review process shall govern all clinical product and equipment review processes and will organize a process of decision making that is applied consistently across the organization. Refer to IDD 18.017.

VIII. Policy Enforcement

- A. Any sales representative violating the provisions of this policy, policies on professional samples, or the Solicitation Policy of EMMC will receive written warning from either the Director of Materials Management or Pharmacy Services. The immediate supervisor of the representative will also receive a copy.
- B. A second violation by the representative will result in a one year revocation of the representative's privileges at EMMC. The Security Department will also be notified of the revocation of privileges.
- C. EMMC employees and contracted employees who violate the provisions of this policy will be subject to disciplinary action as set forth in the Human Resource policy.