

POLICY MEMORANDUM

VA Medical Center
1030 Jefferson Avenue
Memphis, TN 38104



Number: 00-82

Dated: May 15, 2008

Expires: June 30, 2009

Title: SALES REPRESENTATIVE AND VENDOR VISITORS ON VA PREMISES

1. PURPOSE: To establish medical center policy and procedures on the relationships between medical center personnel and vendor representatives, solicitors, all other manufacturer's representatives and visitors to OR/invasive procedure areas within the Medical Center. Pharmaceutical Sales Representatives are not included in this policy; please refer to MCM 119-23 for guidance. Henceforth in this policy, vendor representatives, solicitors, and all other manufacturer's representatives shall be referred to as vendor representative(s).

2. POLICY:

a. Vendor representatives may only have controlled access to medical center facilities and staff. Vendor representative are afforded opportunity to furnish interested medical center staff with appropriate information regarding products and services only to the extent that such activity does not interfere with patient care or the mission of the medical center.

b. Vendor representatives will not be permitted access to the medical center or staff unless they have a previously scheduled appointment. Vendor representatives are required to schedule appointments in advance to meet with VA personnel. Unannounced visits and promotional activities within clinics, corridors, cafeteria, or public areas are prohibited. Vendor representatives will not use government telephones to schedule appointments, or overhead public address systems to locate staff. Appointments may be made by telephone through, or as directed by, the respective service secretary or designee. Vendor representatives visiting the facility for a previously scheduled appointment may not request impromptu meetings with other staff whom they encounter, should not contact staff members in elevators, corridors, canteen, or other public areas, and are prohibited from posting announcements or flyers in the medical center or clinics. Vendor representatives may respond to requests to meet if VA staff initiates them.

c. Vendor representatives are required to display proper medical center vendor ID badge when visiting the medical center. If any staff personnel observe vendor representatives in the medical center without a vendor ID badge, they shall direct the vendor representative to Police Service to obtain proper identification.

d. In the interest of privacy, patient care areas are off limits to unescorted or unsupervised vendor representatives at all times. Vendor representatives are not allowed to attend meetings or conferences where patient-specific information is discussed or presented.

e. Penalties for violations of procedures range from, but are not limited to, restricted or temporary suspension of visiting privileges within the medical center. The decision of the Assistant Medical Center Director, or designee, is final.

f. VA employees may only contact vendor representatives to request product information and literature or for product education purposes.

g. Only Purchase Cardholders and Contracting Officers are authorized to agree to purchase, negotiate prices, barter, or divulge the intent of a VA procurement action to vendor representatives. Only Purchase Cardholders and Contracting Officers have authority to obligate or financially commit the government, within their delegated authority. VA employees who enter into an unauthorized commitment to purchase supplies or services may be held personally liable for the amount of the obligation.

h. Government employees are governed by the Standards of Ethical Conduct, Title 5 CFR 2635. This standard prohibits government employees from soliciting or accepting any gifts or gratuities from sale reps or other prohibited sources. A "prohibited source" includes anyone seeking to do business with or official action by his or her agency and anyone "substantially affected" by performance of worker's official duties. For further guidance and exceptions to the standards refer to the Standards of Ethical Conduct, at Subpart B, Section 2635.201 to 205, Gifts from Outside Sources. All employees should avoid the appearance of impropriety and perform the duties in an impartial manner.

i. Exceptions: This policy does not cover construction contractors and service/repair personnel. Construction contractors and service/repair personnel are governed by contract requirements and are required to report to the location designated by the Contracting Officer or Contracting Officer Technical Representative (COTR), to report their arrival and obtain proper identification if required. Canteen Service is exempt from this policy.

j. The Memphis VA Medical Center recognizes the need for a structured system within the peri-operative setting to achieve the goals of education, training and the introduction of new procedures, techniques, and technology. Often to achieve these goals, vendor representatives will be allowed into the surgical/invasive procedure area during episodes of patient care. Professional, ethical and legal standards and requirements dictate that the VA takes seriously its mission of safeguarding patients' safety, privacy, dignity and confidentiality of their individually identifiable information and records. This policy seeks to establish the administrative policies and procedures governing vendor representatives that wish to visit surgical/invasive procedure areas within the Medical Center, while recognizing the overall goal which is to ensure patient safety and privacy, to conform to all existing rules, regulations, laws and standards, and to promote efficiency in the use of Medical Center resources.

3. RESPONSIBILITY:

a. SERVICE CHIEFS are responsible for:

(1) Assuring staff members are familiar with and comply with this policy;

(2) Assuring service secretaries or other designees, schedule vendor representative visits per local procedures, only after Service Chief approval has been obtained;

(3) Providing a copy of this policy and any other applicable VHA, VISN, or Medical Center Policy to the vendor representative;

(4) Surgical/Invasive Procedure areas: The Service Chief of the surgical/invasive procedure area is responsible for communicating this policy to attending physicians, residents, fellows, consultants, and other staff who work in, or assist in the management of the surgical/invasive procedure areas;

(a) The Service Chief, attending physician, or designee, is ultimately responsible for determining what vendor representatives are allowed into the OR/invasive procedures areas;

(b) The OR/Invasive procedure area Nurse Manager or designee is responsible for ensuring that no vendor representatives are allowed in the OR until the forms and approvals as described in the policy have been obtained and reviewed by him or her;

(c) All Service Staff are responsible for ensuring when vendor representatives are present in the surgical/invasive procedure areas, that they conform to the rules set forth in this policy.

b. The ASSISTANT MEDICAL CENTER DIRECTOR, or designee, is responsible for the overall control of vendor representatives visiting the medical center and will:

(1) Assure the integrity of the program through random frequent audits;

(2) Ensure that products demonstrations and trial usage are conducted properly through random frequent audits.

c. POLICE SERVICE will:

(1) Keep a record of vendor representative visits;

(2) Provide vendor representatives with a visitor ID badge;

(3) Provide a copy of this policy to vendor representatives (when requested); and

(4) Obtain vendor representative signatures on the Statement of Compliance form (attachment B).

d. VENDOR REPRESENTATIVES will:

(1) Upon arrival are required to report and sign in with Police Service identifying whom they are meeting with and obtain vendor ID badge;

(2) Shall be required to present credentials, if appropriate;

(3) Shall sign the Statement of Compliance, attached to this policy;

(4) Are restricted from all patient care areas and outpatient clinics unless authorized by the Service Chief / Care Line Manager and accompanied by a VA employee; and

(5) Shall not accept an order from anyone other than a Purchase Cardholder or Contracting Officer.

e. Vendor representatives that approved for access to OR/Invasive Procedure Areas will provide:

(1) Documentation of current negative IPPD (intermediate purified protein derivative) TB Skin test;

(2) Documentation of current competencies for the procedure/equipment the vendor representative will be observing and/or providing technical guidance for; and

(3) Evidence of insurance coverage for liability (bodily injury and property damage) of at least \$1,000,000.00.

4. PROCEDURE:

a. SALES VISITS: All visits must be scheduled in advance, prior to arrival. Upon arrival, all vendor representatives shall report to the Police Services office, VAMC 1030 Jefferson Avenue, Memphis, TN. Each vendor representative must sign in and indicate the individual and/or areas he/she has scheduled to visit. Each vendor representative will sign a statement of compliance (Attachment B) and will be provided with a copy of the medical center policy upon request. A release from liability for the product loss or damage will be signed, if required. The vendor representative will obtain a vendor ID badge, which must be worn above the waist and easily visible at all times while at the medical center. Upon leaving the medical center, the vendor representative shall report back to Police Service, sign out and return the vendor ID badge. Sales representatives visiting any of the VA staffed Community Based Outpatient Clinics (CBOC's) must report to the administrative director at the site to receive their visitor ID badge.

b. PRODUCT SAMPLES:

(1) All samples of medical supplies and Service / Care line requests for samples of medical supplies will be referred to the Commodity Standards Committee. The Commodity Standards Committee will approve/disapprove the use of samples of medical supplies.

(2) Medication samples are strictly prohibited; see MCM 119-23 for further guidance.

(3) Unsolicited samples of expendable supplies (i.e. pens, note pads, etc) may be accepted. See the Standards of Ethical Conduct, 5 CFR 2635 for further guidance.

c. PRODUCT DEMONSTRATION: Vendor product fairs, product demonstrations, trial or testing of samples, must be authorized by the Logistics Manager to ensure adherence to Federal and VA Acquisition Regulations. Requests for non-drug product demonstrations, trials or testing must be submitted by the requesting service to the Logistics Manager in writing. The request should indicate the proposed time and date, nature of the item to be tested/trialed and specific reasons for the product fair, demonstration, trial or testing of samples. Also, if known, specify whether the vendor has a GSA or VA Federal Supply Schedule. After approval/disapproval of the request, A&MMS will specify if there are any

special procedures to follow. In some cases the Service may be permitted to contact and coordinate with the vendor and in other cases A&MMS will coordinate the event. The Logistics Manager will make that determination.

d. CONTRIBUTIONS AND SUPPORT FOR EDUCATION AND RESEARCH: Sales representatives are encouraged to support valid educational and/or training programs and endeavors within the medical center.

(1) An educational program is considered valid if it is been reviewed and approved in advance by the respective Service Chief, Chief of Staff, or Clinical Care Line Manager. Such programs must have defined educational goals or objectives and, if possible, approval for professional continuing education credits (e.g., CME, ACPE, etc).

(2) In some cases, a vendor representative may provide approved training on the use of a specific tool, hardware, equipment or machine already purchased or leased by the medical center. A vendor representative may not be the speaker, educator or trainer for any medication, since that activity is considered promotional (marketing). For any program involving medications, someone other than a vendor representative must be the speaker.

(3) All sources of support and/or sponsorship for the program must be disclosed to attendees and participants.

(4) Gifts or donations of continuing education materials, textbooks, or funds to purchase texts should be donated to the respective Service or Medical Center Library. Standards of Ethical Conduct, Title 5 CFR 2635 restrict gifts to individual VA employees to a value of no more than \$20 per occurrence and \$50 per year per source. Most textbooks exceed those limits; therefore, an individual should not accept one, but refer the gift to the Medical Center Library to be accepted on behalf of the medical center (refer to VHA Handbook 1932.1 for Library Service or Library Section Procedures for guidance).

(5) The designated agency ethics official has determined that VA employees may not accept free meals provided by vendor representatives without creating the appearance of using their official office for private gain. Therefore, no food or refreshments of any kind may be brought in or provided by the vendor representatives.

e. VENDOR REPRESENTATIVES THAT ARE APPROVED ACCESS TO OR/INVASIVE PROCEDURE AREAS: The following rules will be followed by vendor representatives that are granted access to OR/Invasive procedure areas:

(1) Must wear an ID badge that is clearly visible at all times while on VA property;

(2) Are not allowed to have any physical contact with the patient;

(3) Are not allowed to scrub, enter the sterile field or open sterile products without approval from the Service Chief or designee;

(4) Will conduct themselves appropriately in surgical/invasive procedure areas. This means they will follow all instructions given them by the Service representatives or

designees. Visitors who fail to follow instructions will be removed from the area, and may have future visitations suspended;

(5) Are not allowed to touch or take any material removed from the patient during the course of the surgical episode;

(6) Must be in good health, with no obvious potential for spreading communicable disease and evidence of current negative IPPD (intermediate purified protein derivative) TB Skin test;

(7) All will be required to sign the VA Confidentiality Agreement (Attachment C);

(8) When a vendor representative arrives at the surgical/invasive procedure area, this person will be referred to the area Nurse Manager, or designee;

(9) The Nurse Manager or designee will:

(a) Ensure that a Valid Standard Form 522 *“Request for Administration of Anesthesia and for The Performance of Operations and Other Procedures”* (Informed Consent) and/or iMed Consent form is present in the chart prior to the start of the procedure;

(b) Ensure that the appropriate release of information/consent forms have been signed by the patient (VA Form 10-5345, *Request for and Authorization to Release Medical Records or Health Information*) in cases where their presence in the OR/invasive procedure area would allow them access to individually identifiable and protected health information as set forth in Title 45 Code of Federal Regulation (CFR) Parts 160- and 164. Examples include a vendor observing his/her product in use or providing administrative training and/or education opportunities outside of medical education.

(c) Ask the vendor representative to complete the *“Request for Visitor Access to a Surgical/Invasive Procedure Area”* (Attachment “A”) and the *VA Confidentiality Agreement (Attachment C)*. It is expected that these documents will be filled out well in advance of the planned surgical episode in order to avoid disruptions the day of surgery.

(d) Ensure the Service Chief, or authorized designee(s), signs the *Request for Visitor Access* form (Attachment A) indicating approval or disapproval of the visit, and sets forth any special conditions for approved visits.

(e) Verifies proof of insurance coverage for liability (bodily injury and property damage) of at least \$1,000,000.00 for vendor representatives approved access to OR/invasive procedure areas and attaches a copy to the completed *Request for Visitor Access* form (Attachment A).

(f) The consent and confidentiality agreements will be returned to the area Nurse Manager. These documents will be filed and maintained by the Service for three years.

h. RELEASE OF INFORMATION TO IMPLANTABLE DEVICE VENDORS: When implantable devices such as stents or heart pacemaker devices are being placed into patients during a surgery, the Memphis VA Medical Center will follow the minimum necessary

standard as outlined in VHA Handbook 1605.2 when making disclosures to vendors assisting with the implantation or calibration of these devices. Though the minimum necessary standard in the HIPAA Privacy Rule does not apply to disclosures to or requests by a health care provider for treatment (Ref. 45 CFR §164.502(b)(2)(i)), VHA will still apply the minimum necessary standard when disclosing information to vendors. The disclosure to the vendor is made not only for treatment purposes but also for public health tracking required by the Federal Drug Administration (FDA) for implantable devices. Therefore, only the requested amount of information will be disclosed to the vendor when providing or releasing information for the purpose of tracking the device in the event of a recall.

Patient consent is required when Vendors request to observe implantation of devices that their company sells in order to learn about these surgeries or learn how to assist in the future. A signed, written authorization from the patient must be obtained before allowing disclosures to the vendor or allowing them to view the surgery and/or procedure. This must be accomplished in the following manner:

- (1) The patient must be informed that the vendor wants to observe the surgery for the purpose of learning how the device is implanted;
- (2) The patient must be willing to have the vendor in attendance; and
- (3) The patient must complete VA Form 10-5345 prior to their surgery authorizing the disclosure of information to the vendor.

If the vendor requests to take a photograph of the implantation, the request must be coordinated with the medical center's Office of Public Affairs. The patient must sign VA Form 10-3203 for authorization to take the photograph in addition to the VA Form 10-5345 for authorization to disclose information.

All disclosures made to implantable device vendors must be reported to the Release of Information Department for inclusion in the ROI Records Management Software so that an accounting of the disclosures is maintained.

f. **PARKING REGULATIONS:** Sales representatives will park in authorized areas only. No parking is allowed on curbs, roadways, lawn areas, posted reserved spaces, and/or fire lanes.

g. **SECURITY ENFORCEMENT:** The VA Police have the responsibility for the overall security and law enforcement at the medical center, with power to enforce VA policy, rules, regulations and laws. The VA Police may question and search any persons or vehicle entering or leaving medical center grounds to include packages, equipment, or other materials. Violators of medical center policy or Federal and State laws may be charged as appropriate by issuance of a United States District Court Violation Notice and/or arrest by VA Police.

5. **REPORTING REQUIREMENTS:** None.

6. **RESPONSIBLE OFFICE:** Assistant Medical Center Director (00A).

7. REFERENCES:

- a. Federal Acquisition Regulations (FAR) Parts 1, 4, and 6.
- b. Veterans Administration Acquisition Regulations (VAAR) 801.601, 801.602 and 801.603.
- c. VA Handbook 1730.1 Purchase Card Procedures.
- d. Standards of Ethical Conduct for Employees of the Executive Branch issued by the U.S. Office of Government Ethics.
- e. VHA Handbook 1932.1 for Library Service or Library Section Procedures for Guidance.
- f. Schultz, M. Sales Representatives in the OR. Are they Prepared? AORN J 1994; 59:651- 662

8. RESCISSION: None.

/s/

PATRICIA O. PITTMAN
Medical Center Director

Attachments

VA MEDICAL CENTER
MEMPHIS, TN

STATEMENT OF COMPLIANCE FROM VENDOR REPRESENTATIVES ON VA PREMISES

It is the medical center's policy to afford vendor representatives opportunity to furnish interested medical centers staff with information regarding products and services, so long as such activity does not interfere with patient care or the mission of the medical center and appointments are made in advance of the visit.

Vendor representatives will report to the Police Service office on the day of the visit, for the purpose of signing the "Visitor" registration log and obtaining a vendor ID badge. Vendor representatives, who visit the Medical Center without an appointment will be informed of the Medical Center policy and will be required to make an appointment in advance. The insistent or unmindful vendor representative may be escorted off medical center grounds by the VA Police.

(initial) I understand that vendor representatives are prohibited from offering or providing gifts or gratuities to any employee of this medical center.

(initial) I understand that product samples for medical supplies must be submitted to the Logistics Manager, A&MMS.

(initial) I understand that product samples for subsistence items must be submitted to the Chief, Nutrition & Food Service.

(initial) I understand that product samples for pharmaceutical items must be submitted to the Chief, Pharmacy Service.

(initial) I understand that VA employees (except authorized Purchase Cardholders and Contracting Officers) are prohibited from agreeing to purchase, negotiate prices, barter, or divulge the intent of the VA in a procurement situation. Only authorized Purchase Cardholders and Contracting Officers may obligate or financially commit the Government.

I have received a copy and consent to the policies and procedures of this Medical Center Policy and agree that failure to adhere to this Policy may result in the forfeiture of my visitation privileges.

Signature

Date

Vendor/Sales Representative Name

Company – name, address, and telephone number

Veterans Health Administration Confidentiality Agreement

1. I, _____ understand that, in the course of my involvement with the Veterans Health Administration (VHA) I may be given access to Protected Health Information (PHI) of the U.S. Department of Veterans Affairs and other Government contractors. For purposes of this agreement, "Protected Health Information (PHI)" is health information created or received by VHA that relates to any of the following:

- the past, present, or future physical or mental health or condition of an individual;
- the provision of health care to an individual;
- the past, present, or future payment for the provision of health care to an individual

AND that does either of the following:

- identifies the individual
- could be used to identify the individual.

2. I agree that I will successfully complete the VHA Privacy Policy training prior to my visit to the VA Medical Center Memphis. The training is web-based and can be accessed at:

<http://www.vhaprivacytraining.med.va.gov/>

I agree that I will comply with VHA Privacy and Release of Information policy and procedures, as documented in VHA Handbook 1605.1. This Handbook may be accessed at:

<http://www.va.gov/publ/direc/health/handbook/1605-1hk.pdf>

3. I agree to use PHI only in the performance of work requirements necessary to carry out my duties under the above referenced contract. I will report to the VAMC Memphis Privacy Officer any actual or attempted violations of this agreement. I will access PHI only to the minimum extent necessary to fulfill my job duties. I will use PHI only for the purposes required and permitted by my job duties.

4. I will use reasonable and appropriate safeguards to prevent unauthorized use or disclosure of PHI in my possession.

5. I will promptly report to the facility Privacy Officer any unauthorized use or disclosure of PHI of which I become aware.

6. I will use the physical storage facilities for PHI that has been provided by the VHA, depending on my work site. PHI will not be left in the "open" for viewing by unauthorized persons, nor discussed where such discussions may be overheard by unauthorized persons. PHI will always be protected, especially when moved/removed from controlled areas.

7. I agree to return or certify that I have destroyed any and all PHI made available to me pursuant to my involvement with VHA and upon request by VHA, whenever the information is

no longer required, upon completion of my involvement with VHA, or termination of my relationship with VHA.

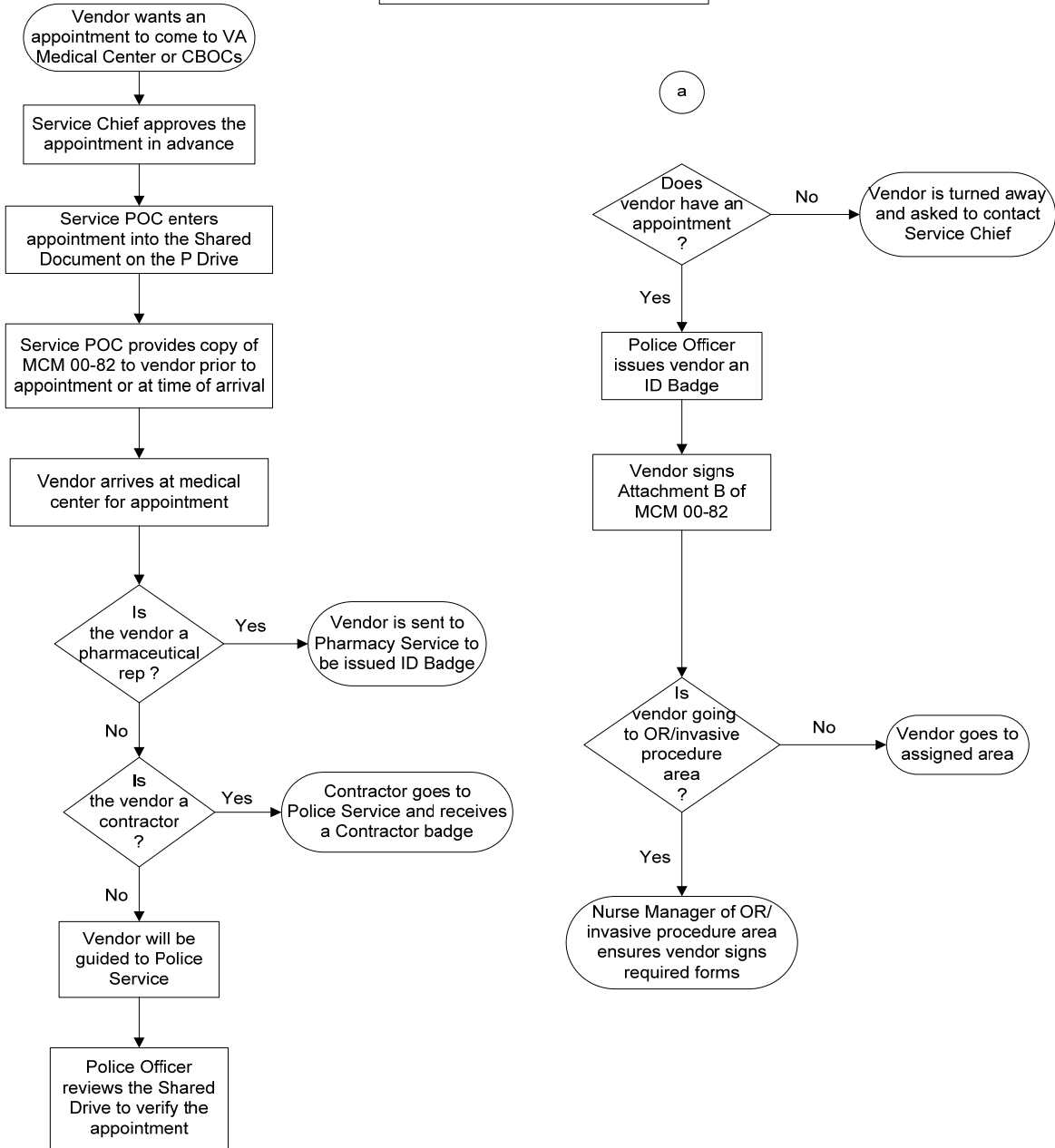
8. I verify that I have read and fully understand this Agreement, and agree to abide by all requirements and restrictions contained herein. I understand that my strict compliance with the terms of this agreement is essential for the fulfillment of my obligations.

Printed Name of Individual Signing this Agreement

Signature

Date

Sales Representatives and Vendors on VA Premises



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