BUSINESS RELATIONSHIPS BETWEEN STAFF AND PHARMACEUTICAL INDUSTRY REPRESENTATIVES

1. PURPOSE. To establish guidance governing the business relationships between Department of Veterans Affairs (VA) medical facility personnel and representatives from the pharmaceutical industry.

2. POLICY. Pharmaceutical Sales Representatives may only have controlled access to all medical care facilities and staff.

3. DEFINITIONS.
   a. Pharmaceutical Sales Representative. The term “Pharmaceutical Sales Representative(s),” hereafter referred to as “sales representatives,” refers to anyone acting on behalf of a pharmaceutical manufacturer or its business partners for the purpose of promoting the use of items managed under the VA formulary process. These items primarily include drugs, but to a lesser extent also include any medical supplies, nutritional supplements, and similar commodities managed under the VA formulary process. In consideration of VA staff time, patient privacy, formulary management goals, physical plant security and government ethics rules as set out in the Standards of Ethical Conduct for Employees of the Executive Branch; it is VHA policy to control access to all its medical care facilities and staff by sales representatives. Standards of Ethical Conduct for Employees of the Executive Branch are hereafter referred to as “government ethics rules.”
   
   b. Visit. The term “visit,” as it applies to sales representatives, refers to any contact with VHA staff, to include drug fairs, drug displays, and other multi-vendor events.

4. PROCEDURE.
   a. Sales Representatives’ Contacts with VA staff

      (1) In order to minimize the potential for disruption of patient care activities, sales representatives must schedule an appointment prior to each specific visit. Appointments may be made by either telephone or e-mail, but must be made in advance of visiting the medical center. Sales representatives may not use the overhead public address paging system to locate any member of the medical staff, housestaff, pharmacy staff, or nursing staff. Contact using the VA electronic paging system (beepers) is generally discouraged, but is permissible if specifically requested by an individual VA staff member.

      (a) Access to VA health care facilities by sales representatives who have not made a previously scheduled appointment is not permitted under any circumstances.

      (b) Sales representatives visiting VA facilities for previously scheduled appointments may not initiate requests for impromptu meetings with other VA staff whom they may happen to encounter during their scheduled visit, but may respond to requests for meetings initiated by VA staff during the visit.
(c) VA health care facilities are permitted to develop a list of individuals or departments that do not wish to be called upon by sales representatives. Facility personnel may provide such lists to each sales representative. Sales representatives must not attempt to make appointments with individuals or departments on the list.

(2) To maximize learning opportunities and minimize potential confusion on the part of students (including residents) still serving in their primary educational programs, sales representatives are prohibited from marketing to medical, pharmacy, nursing and other health profession students without the presence of a faculty professional.

(3) Sales representatives are not allowed to attend medical care treatment facility conferences where patient-specific material is discussed or presented.

(4) In the interests of physical plant security, the following procedures will be followed:

(a) **Appointments.** Appointments with all providers (physicians, nurses, pharmacy personnel, etc.) must be scheduled through Pharmacy Service. The sales representative and/or the provider’s service or section secretary or clerk will contact the Pharmacy Service secretary or clerk to confirm the appointment time.

(b) **Sign In.** The pharmaceutical manufacturers’ sales representative visiting the medical centers, outpatient clinics, and community based outpatient clinics must sign in at the Pharmacy Administration Office or administration office of the CBOCs not more than 15 minutes prior to the scheduled appointment and sign out within 15 minutes of completing the appointment. A visitor’s badge must be worn while in the medical center, outpatient clinic, or community based outpatient clinic. In addition, the pharmaceutical manufacturers’ sales representative must wear a photo ID badge with their company’s name on the badge.

(5) Sales representatives are encouraged to schedule appointments in VA medical care facilities between the business hours of 8:00 a.m. and 3:30 p.m., Monday through Friday; however, if necessary for the convenience of VA staff, appointments at other times are permissible.

(6) In respect of patient privacy, sales representatives are not permitted to make presentations in patient care areas. Restricted patient care areas include, but are not limited to:

(a) Patient rooms and ward areas when patients may be encountered,

(b) Clinic examination rooms,

(c) Nursing stations,

(d) Intensive care units,

(e) Operating room suites, and

(f) Emergency rooms, urgent care centers, ambulatory treatment centers.
4. **PROCEDURE.** (Continued)

(7) Provided there are no breaches of patient privacy, exceptions to prohibiting access to patient care areas is permissible if a VA staff member’s office is located in a patient care area and it is necessary to meet with the sales representative in the office. Sales representatives may not wait for appointments in patient care areas, but may briefly travel through them, when necessary, to meet in a staff member’s office.

b. **Promotional Materials, Promotional Activities, and Medical Literature.**

(1) Sales representatives may only promote products that are included on the VA National Formulary and/or VISN Formulary, and only in accordance with applicable Food and Drug Administration (FDA) and VA guidelines, and/or VA restrictions and criteria which may exist for those products, except as outlined in following subparagraph 4b(2). It is the sales representative’s responsibility to ensure that the formulary status of all drug products discussed and/or displayed is represented accurately. Educational materials or literature for new drug products that have not yet been reviewed by the VA Medical Advisory Panel VISN Formulary Leaders Committee, or the VISN Formulary Committee, or new therapeutic indications for products already on the formulary, may only be displayed and discussed according to the processes outlined below.

(2) All educational materials or literature (including journal articles, etc.) and/or discussions regarding any drug that has a status of “Formulary with Restrictions,” “Non-formulary,” or other similar status designations, or has not yet been reviewed, must be clearly articulated and conspicuously identified as such by the sales representative. Promotional materials are not to be placed in any patient care area.

(3) The practice of bringing guest speakers to VA facilities for educational purposes is acceptable, but must be at the invitation of VA staff and must be approved by the Chief, Pharmacy Service; Chief of Staff; or Service Chief. Sales representatives must provide the Chief, Pharmacy Service; Chair of the Facility Education Committee; or other similarly responsible VA staff member a summary of such plans well in advance of the proposed visit, so that a determination of the program’s suitability can be made. An education activity may be subject to further requirements by continuing education providers that have certified the activity for credit for pharmacists, physicians, or other health professionals.

(4) Disclosure of industry sponsorship of any educational program conducted at VA medical care facilities must be included in the introductory remarks and in the announcement brochures for educational programs. It is the responsibility of the sales representative to ensure adequate disclosure is provided. Sponsorship includes any contribution, whether in the form of staple goods, personnel, or legal tender, intended to support the program. Sales representatives are prohibited from conducting marketing activities during a sponsored educational program. An educational activity may be subject to further requirements by continuing education providers.

c. **Drug Samples and “Free Goods.”** Drugs and medical supply items donated to VHA which are intended for patient use, such as starter packs or free goods, must be delivered to the Chief, Pharmacy Service, or person with similar responsibilities, for proper storage, dispensing and documentation, using the normal VHA prescription delivery processes. The Director or designee, is the individual authorized to approve receipt of donations of drugs or supply items to VA. If donated drugs are intended to be used solely to allow VA clinicians to gain familiarity with the product, such use must be pre-approved by the Chief, Pharmacy Service and the local Pharmacy and Therapeutics (P&T) Committee. Information
4. **PROCEDURE. (Continued)**

pertaining to the trial use must be forwarded to the VISN Pharmacy Benefits Management Office or VISN Formulary Committee. Drugs dispensed to VA patients from donated drug stock are ordinarily not labeled with the words “sample,” “professional sample,” or similar wording. Rare exceptions to labeling as samples, such as in the case of product shortages, are permissible if such use is in the best interests of VA patients.

d. **Gifts to VA Staff including Refreshments.**

(1) No food, beverages or refreshments of any kind will be permitted.

(2) In order to avoid violating or giving the appearance of violating government ethics rules, VA employees must exercise careful judgment when considering the acceptance of any gift, gratuity, favor, entertainment, loan, or anything of monetary value from a sales representative or any other person seeking to become involved, or who is currently involved, in business interactions with VA.

(3) In the interest of patient safety and/or facility accreditation processes, sales representatives may not provide samples of medications to VA providers for their personal use or the use of their families on VA property. Samples may be provided to VA staff via their home addresses or other non-VA property; such samples are regulated by applicable ethics rules. Current government ethics rules restrict gifts to a value of no more than $20 per occurrence, and no more than $50 in aggregate value over a given consecutive 12-month period from any one source. Different sales representatives from the same company are considered one source for the purposes of determining the appropriateness of gifts. Sales representatives must be aware that government ethics rules apply to VA staff regardless of whether the staff is located on VA or off VA property, or are on duty or off duty.

(4) Sales representatives may offer donations to a VA medical facility to support education or VA research in accordance with existing VHA, Employee Education System (EES), and VISN policies on accepting donations for education and research. Special rules may apply if the donation is for VA staff travel expenses.

(5) Continuing education materials and textbooks that exceed the value permissible for acceptance under government ethics rules may not be given to individual employees, but may be donated to the medical care facility library or individual departments for use by all employees in those departments.

e. **Non-adherence with Policy Requirements.**

(1) Failure of sales representatives to comply with the provisions outlined in this Directive may result in the suspension, limitation, and temporary or permanent revocation of visiting privileges for one or more VA medical care facilities.

(2) Suspension of sales representatives consisting of a 3-month, 6-month, or 12-month suspension; limitation of visiting privileges; or the permanent removal of a sales representative may be evoked if deemed appropriate by the Chief, Pharmacy Service; VISN Formulary Leader; or designee(s). If a sales representative’s visiting privileges are suspended, a determination must be made by the facility Chief of Staff or the VISN Chief Medical Officer (as appropriate), as to whether the sales representative’s employer will be permitted to replace its suspended sales representative with a different sales representative.
4. **PROCEDURE.** (Continued)

(3) When evidence exists that a pharmaceutical manufacturer, or other similar vendor, conducting business with VA permits, endorses or encourages its' sales representatives to engage in widespread and serious misconduct in violation of VHA Directive 2003-060, or in any actions which are perceived to be in conflict with VA’s drug therapy and formulary management goals, VA may impose a VHA-wide or VISN-wide suspension or limitation of visiting privileges for that manufacturer’s sales representatives. Such a VHA-wide or VISN-wide revocation of privileges must consist of a minimum 12-month suspension, or limitation of visiting privileges as deemed appropriate and recommended by the:

(a) Chief Consultant, Pharmacy Benefits Management Strategic Healthcare Group, for a VHA-wide suspension or limitation of privileges; or

(b) VISN Formulary Leader for a VISN-wide suspension or limitation of privileges.

5. **RESPONSIBILITIES.**

a. The Director, or designee, is responsible for:

   (1) Monitoring business relationships between VA medical facility personnel and representatives from the pharmaceutical industry, and

   (2) Ensuring the facility personnel and representatives from the pharmaceutical industry adhere to the procedures outlined in this policy.

b. The Chief, Pharmacy Service; the Pharmacy Manager; or designee in each facility is responsible for:

   (1) Monitoring business relationships between personnel and representatives from the pharmaceutical industry.

   (2) Educating sales representatives about the VHA policy regarding business relationships between VA medical facility personnel and representatives from the pharmaceutical industry.

   (3) Providing a copy of this Policy to each sales representative, and documenting with a signed receipt that the sales representative has received a copy.

6. **REFERENCES.**


c. Title 38 CFR, Part 0, (Conflict of Interest)

7. **RESCISSIONS.** Memorandum No. 119-11, Change 1, dated March 5, 2004.

8. **EXPIRATION DATE.** June 1, 2008.
9. **FOLLOW-UP RESPONSIBILITY.** Chief, Pharmacy Service.

F. L. MALPHURS, FACHE
Director

DISTRIBUTION
“A”
“D” – All physicians including housestaff