BUSINESS RELATIONSHIPS BETWEEN STAFF AND PHARMACEUTICAL COMPANY REPRESENTATIVES

1. **PURPOSE.** To establish policy and procedure for business relationships between staff and pharmaceutical company representatives.

2. **POLICY.** Relationships between staff and pharmaceutical representatives will be controlled in accordance with VHA policy.

3. **DEFINITIONS.**
   a. **Pharmaceutical Company Representative.** The term “Pharmaceutical Company Representative(s),” hereafter referred to as “sales representatives or PCRs”, 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 also include any medical supplies, nutritional supplements, and similar commodities managed under the VA formulary process. 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. **PCRs’ Contacts with VA staff**

      (1) In order to minimize the potential for disruption of patient care activities, PCRs 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. PCRs 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 or Cisco phones is generally discouraged, but is permissible if specifically requested by an individual staff member.

      (a) Access by PCRs who have not made a previously scheduled appointment is not permitted under any circumstances.

      (b) PCRs visiting facilities for previously scheduled appointments may not initiate requests for impromptu meetings with other staff whom they may happen to encounter during their scheduled visit, but may respond to requests for meetings initiated by staff during the visit.

      (c) A list of individuals or departments that do not wish to be called upon by PCRs may be developed and provided to each PCR. PCRs 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, PCRs are prohibited from marketing to medical, pharmacy, nursing and other health profession students without the presence of a professional staff.

(3) PCRs are not allowed to attend medical care treatment 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, etc.) must be scheduled through Pharmacy Service. The sales representative and/or the provider’s service will contact Pharmacy Service to confirm the appointment time.

(b) Sign In.

1. On their initial visit the PCR visiting the medical centers will go to Police Service where they will be issued a visitor’s badge.

2. The PCR 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 and a photo ID badge must be worn.

(5) PCRs are encouraged to schedule appointments in 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 staff, appointments at other times are permissible.

(6) In respect of patient privacy, PCRs are not permitted to make presentations in patient care areas including but 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.

(7) Provided there are no breaches of patient privacy, exceptions to prohibiting access to patient care areas is permissible if a staff member’s office is located in a patient care area and it is necessary to meet with the PCR in the office. PCRs may not wait for appointments in patient care areas but may briefly travel through them to meet in a staff member’s office.
b. Promotional Materials, Promotional Activities, and Medical Literature.

(1) PCRs may only promote products that are included on the VA National 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 below. It is the PCR’s responsibility to ensure 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, 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 PCR. Promotional materials are not to be placed in any patient care area.

(3) The practice of bringing guest speakers for educational purposes is acceptable, but must be at the invitation of VA staff and must be approved by the Chief, Pharmacy Service or Chief of Staff. Sales representatives must provide education program submissions and promotional materials at least 60 days prior to the proposed date of the education program or distribution to either the Chief, Pharmacy Service or Chair of the Facility Education Committee 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 system facilities must be included in the introductory remarks and in the announcement brochures for educational programs. It is the responsibility of the PCR 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. PCRs 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 for patient use, such as starter packs or free goods, must be delivered to the Chief, Pharmacy Service designee, for proper storage, dispensing and documentation, using the normal VHA prescription delivery processes. The Chief, Pharmacy Service or designee, is the individual authorized to approve receipt of donations of drugs or supply items to VA. All donated drugs must be pre-approved by the facility Director and the Pharmacy and Therapeutics (P&T) Committee. Information pertaining to the trial use must be forwarded to the VISN Pharmacy Benefits Management Office, VISN Formulary Committee, and/or the facility Director. 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) Food items, of any type or any value, are not to be brought into the VA facilities for provision to VA staff or non-VA staff (e.g., employees of affiliates, volunteers, without compensation employees, etc).

(2) In order to avoid violating or giving the appearance of violating government ethics rules, employees must exercise careful judgment when considering the acceptance of any gift, gratuity, favor, entertainment, loan, or anything of monetary value from a PCR or any other person seeking to become involved, or who is currently involved, in business interactions with VA. 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 PCRs from the same company are considered one source for the purposes of determining the appropriateness of gifts. PCRs must be aware that government ethics rules apply to staff regardless of whether the staff is located on VA or off VA property, or are on duty or off duty.

(3) PCRs may not provide samples of medications to providers for their personal use or the use of their families on VA property.

(4) PCRs may offer donations to support education or 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 facility library or individual departments for use by all employees in those departments.


(1) Failure of PCRs to comply with the provisions outlined 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 PCRs 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 facility Director. When the VA medical facility Director suspends or permanently revokes the privileges of multiple PCRs of a given manufacturer, a one-time appeal may be requested of the Under Secretary of Health. Until such time that the Under Secretary of Health provides a ruling, the visiting privileges of the PCR remain suspended or permanently revoked.

5. RESPONSIBILITIES.

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

(1) Monitoring business relationships between personnel and representatives from the pharmaceutical industry.
(2) Ensuring personnel and representatives from the pharmaceutical industry adhere to the procedures outlined in this policy and levying limitations, suspensions, or the permanent revocation of the privileges of a PCR or entire sales force of a given manufacturer when not in accordance with procedures outlined in this policy.

(3) Approving all drug samples and drug-related supplies donated to the VA medical facility by pharmaceutical companies and their PCRs and ensuring they are delivered to the Office of the Chief of Pharmacy Services.

(4) Forwarding all usage information related to approved samples of drugs and drug-related supplies to the Veterans Integrated Service Network (VISN) Pharmacist Executive or VISN Formulary Committee.

b. The Chief, Pharmacy Service and the Pharmacy Manager designee are responsible for:

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

(2) Educating PCRs about the VHA policy regarding business relationships between personnel and representatives from the pharmaceutical industry which will include providing copies of VHA Handbook 1108.10 and local policy to all PCRs who seek access to the VA medical facility prior to initiating any activity. A signed receipt of said material for documentation purposes will be required and filed for future reference within the pharmacy.

(3) Receiving, storing, securing, labeling, dispensing, and disposition of all drug samples and drug-related supplies donated to the facility by pharmaceutical industry and their PCRs through the facility Director’s office.

(4) Granting permission for pharmaceutical company educational activities and materials that are deemed acceptable and meet requirements set forth in this policy.

(5) Maintaining and making available a list of individuals or departments that do not wish to be called on by PCRs.

6. REFERENCES.


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

7. RESCISSIONS. Memorandum No. 119-11, Change 4, dated June 20, 2012.


9. FOLLOW-UP RESPONSIBILITY. Chief, Pharmacy Service.
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