PROMOTION OF DRUGS AND DRUG-RELATED SUPPLIES BY PHARMACEUTICAL COMPANY REPRESENTATIVES

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook provides specific direction, guidance, and procedures related to Pharmaceutical Company Representative (PCR) activities in Department of Veterans Affairs (VA) medical facilities.
AUTHORITY: Title 38 Code of Federal Regulations (CFR) Part 1, § 1.220.

2. SUMMARY OF MAJOR CHANGES. This is a new Handbook based on the Department of Veterans Affairs 38 CFR Part 1, § 1.220, Drug and Drug-Related Supply Promotion by Pharmaceutical Company Representatives at VA Facilities.

3. RELATED DIRECTIVES. VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry and VHA Directive 1108 (to be published).

4. RESPONSIBLE OFFICE. The Chief Consultant, Pharmacy Benefits Management Strategic Health Group (10P4P) in the Office of Patient Care Services is responsible for the contents of this Handbook. Questions may be addressed at 202-461-7326.

5. RESCISSIONS. None.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working day of December 2017.

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Under Secretary for Health

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PROMOTION OF DRUGS AND DRUG-RELATED SUPPLIES BY PHARMACEUTICAL COMPANY REPRESENTATIVES

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides specific direction, guidance, and procedures related to Pharmaceutical Company Representative (PCR) activities in Department of Veterans Affairs (VA) medical facilities.

2. AUTHORITY

This Handbook provides operational guidance for VHA employees on title 38 Code of Federal Regulations (CFR) § 1.220, on-site activities by PCRs at VA medical facilities.

3. DEFINITIONS

See Glossary in Appendix A.

4. SCOPE

This Handbook governs on-site, in-person promotional activities, including educational activities, by PCRs at VA medical facilities. It does not apply to the distribution of information and materials through other means.

5. RESPONSIBILITY OF THE UNDER SECRETARY FOR HEALTH

In the event that multiple representatives of a pharmaceutical company have their visiting privileges suspended or permanently revoked by a VA facility Director, and the pharmaceutical company requests a one-time appeal of the decision, the Under Secretary for Health is responsible for providing a ruling on the appeal.

6. RESPONSIBILITIES OF THE FACILITY DIRECTOR

The facility Director, or designee, is responsible for:

a. Approving, in accordance with the criteria set forth in this Handbook and in local policy, 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 for proper storage, documentation, and dispensing;

b. 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;

c. Levying limitations, suspensions, or the permanent revocation of the privileges of a PCR or entire sales force of a given manufacturer, in accordance with the criteria set forth in this Handbook and in local policy;

d. Approving, in accordance with the criteria set forth in this Handbook and local policy, items donated by PCRs to a medical facility library or individual department for use by all employees; and

e. Coordinating the review process as specified in 38 CFR 1.220(i)(5).

7. RESPONSIBILITIES OF THE FACILITY CHIEF OF PHARMACY SERVICES

The Chief of Pharmacy Services, or designee, is responsible for:

a. Receiving, storing, securing, labeling, dispensing, and disposition of all drugs and supplies in their assigned facilities;

b. Providing copies of this Handbook and the local medical facility policy to all PCRs who seek access to VA medical facilities prior to initiating any activities;

c. Communicating permissions to the PCR as outlined in this Handbook;

d. Granting permission for pharmaceutical company promoted or supported educational activities that are deemed acceptable, at their VA facilities;

e. Granting permission for promotional and educational materials that meet all requirements set forth in this Handbook, and locally established criteria;

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

g. Developing a local medical facility policy that is consistent with this Handbook by February 28, 2013.

8. RESPONSIBILITIES OF THE PHARMACEUTICAL COMPANY REPRESENTATIVE

The PCR must ensure:

a. All VA National Formulary (VANF) and non-VA National Formulary (non-VANF) products are discussed, displayed and represented accurately, in accordance with United States Food and Drug Administration (FDA) and VANF guidelines and restrictions as outlined in this Handbook and local medical facility policy.

b. A summary of any educational event or promotion is provided to the VA medical facility's Chief of Pharmacy Services (or designee), Chair of the Facility Education Committee or other designated VA staff in accordance with local medical facility policy. This summary must be provided well in advance of the proposed date, so that a determination of the program's suitability can be made, see subparagraph 9h(1)-(7).

c. Adequate disclosure is provided regarding all educational activities. ***NOTE:*** *Sponsorship includes any contribution, whether in the form of staple goods, personnel, or financing, intended to support the program.*

d. Drug samples and drug-related supplies donated to a VA medical facility for the intended purpose of patient use are approved by the VA medical facility Director, or designee, and delivered to the Office of the Chief of Pharmacy Services for proper storage, documentation, and dispensing. These donated items must not be labeled on the agent (e.g., tablet, capsule, syringe, etc) or outside packaging as a "sample" or "professional use."

e. Donations to a VA medical facility, to support education or VA research, must be 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. ***NOTE:*** *Generally, VHA deposits such donations into the general post fund, or an approved VA Not-for-Profit Research or Education Corporation.*

f. Donated drugs and supplies may be received only when approved by the VA medical facility Director, or designee. If these donated products are intended to be used solely to allow VA clinicians to gain familiarity with the product, such use must be pre-approved by the VISN Pharmacist Executive and/or VISN Formulary Committee as stated in local medical center policy. Information pertaining to the trial use of these products must be forwarded to the VISN Pharmacy Benefits Management Office and/or VISN Formulary Committee. Drugs or supplies dispensed to VA patients from donated inventory 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 the patients.

g. Continuing education materials and textbooks that exceed the value permissible for acceptance under government ethics rules are not given to individual employees. ***NOTE:*** *For dollar designation limits refer to subparagraph 9n.*

h. Food items, of any type or any value, are not to be brought into VA facilities for provision to VA staff or non-VA staff (e.g., employees of affiliates, volunteers, without compensation employees, etc).

9. PROCEDURES

a. PCRs may only promote VANF and Non-VANF drugs and drug-related products in accordance with applicable FDA and VA guidelines, including Pharmacy Benefits Management (PBM) Criteria-for-Use or applicable prescribing restrictions, which exist for those products.

b. VANF drugs and drug-related supplies may be promoted in VA medical centers (including community-based outpatient clinics (CBOC) and other VA medical facilities) provided that <u>all</u> of the following conditions are met:

(1) The promotion has been approved by the VA medical facility's Chief of Pharmacy Services, or designee;

(2) The drugs and drug-related supplies are discussed, displayed, and represented accurately (e.g., regarding formulary status, FDA approved indications, etc.);

(3) The promotion has significant educational value and does not inappropriately divert VA staff from other activities they would otherwise perform during duty hours, including patient care and other educational activities; and,

(4) The drug or drug-related supply has not been classified by VA as non-promotable.

c. Non-VANF drugs and drug-related supplies may be promoted in VA medical centers (including CBOCs and other VA medical facilities) provided that all of the following conditions are met:

(1) The promotion has been approved by the VA medical facility's Chief of Pharmacy Services, or designee;

(2) The promotion is consistent with the existing Pharmacy Benefits Management (PBM) Criteria-for-Use guidance;
NOTE: *PCRs may access information regarding VA Criteria-for-Use from the PBM Web site at: www.pbm.va.gov.*

(3) The drugs or drug-related supplies are discussed, displayed, and represented accurately;

(4) The promotion has significant educational value and does not inappropriately divert VA staff from other activities they would otherwise perform during duty hours, including patient care and other educational activities; and

(5) The drug or drug-related supply has not been classified by VA as non-promotable.

d. Non-VANF drugs and drug-related supplies where PBM Criteria-for-Use have not been developed, may be promoted in VA medical centers (including CBOCs and other VA medical facilities) provided that all of the following conditions are met:

(1) The promotion is specifically permitted by the VA medical facility's Chief of Pharmacy Services, or designee;

(2) Drugs or drug-related supplies are discussed, displayed, and represented accurately;

(3) The promotion has significant educational value and does not inappropriately divert VA staff from other activities they would otherwise perform during duty hours, including patient care and other educational activities; and

(4) The drug or drug-related supply has not been classified by VA as non-promotable.
NOTE: *The PBM maintains a National listing of formulary medications that are not to be promoted or detailed by PCRs on the PBM intranet (http://vaww.pbm.va.gov) and internet (www.pbm.va.gov) Web sites. The list also may be requested by contacting the VA medical*

facility's Chief of Pharmacy Services. The PBM intranet Web site is an internal Web site and is not available to the public.

e. New molecular entities (NME) may be promoted in VA medical centers (including CBOCs and other VA medical facilities) provided that all of the following conditions are met:

(1) Promotion is specifically permitted by the VA medical facility's Chief of Pharmacy Services, or designee;

NOTE: *In instances where a given VISN has permitted the promotion of a NME prior to any National decision regarding its VANF status, that VISN Formulary Committee need to revisit their decision when: either the drug or drug-related supply has been granted VANF status but is labeled non-promotable; or the drug or drug-related supply is designated as Non-formulary at the National level.*

(2) The NME is discussed, displayed, and represented accurately;

(3) Promotion has significant educational value and does not inappropriately divert VA staff from other activities that VA staff would otherwise perform during duty hours, including patient care and other educational activities; and

(4) The drug or drug-related supply has not been classified by VA as non-promotable.

f. The practice of bringing guest speakers to VA facilities for educational purposes is acceptable. However, all activities must be pre-scheduled and approved by the Chief of Pharmacy Services or designee, as specified in local policy.

g. Educational program submissions and promotional materials must be provided to the VA medical facility's Chief of Pharmacy Services, or designee, at least 60 days before the proposed date of the educational program or distribution of such materials unless the VA medical facility's Chief of Pharmacy Services, or designee, agrees to an earlier date.

h. All educational and promotional materials must be approved by the appropriate continuing education accreditation agency before submission to the facility designee for review. Industry sponsorship of such materials must be adequately disclosed in the following manner.

(1) Disclosure of industry sponsorship (financial or otherwise) of any educational program conducted at a VA medical facility must be included in the introductory remarks and in the announcement brochure.

(2) If industry-sponsored and non-sponsored sources of data or other analytical information exists for FDA approved uses of a particular drug, a direct comparison between the two sources must be disclosed in the introductory remarks and in the announcement brochure.

(3) 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.

(4) Educational materials or literature regarding a new drug or a new therapeutic indication for a drug already on the VANF, that has not been reviewed by the VHA Medical Advisory Panel (MAP) and VISN Formulary Leaders (VFL) Committees, must be identified as such prior to being displayed or discussed.

(5) Educational programs and associated materials focusing primarily on non-VANF drugs or drug related supplies may be promoted as stated in subparagraphs 9c(1)-(5).

(6) Educational and promotional materials which offer patients an opportunity to participate in manufacturer sponsored programs and require the furnishing of Protected Health Information are not permitted.

(7) Educational and promotional materials are not to be placed in any patient care area.

i. VA medical facilities are to encourage PCRs to present any professionally developed educational materials, intended for the patient or provider, to the Office of the Deputy Chief Consultant, Hines, Illinois, for review. Although permission to use the materials at a given facility still rests with the VA medical facility's Chief of Pharmacy Services, or designee, a national approval by the Office of the Deputy Chief Consultant will in most cases streamline this process for PCRs who intend to use this specific educational material in multiple facilities.

j. VA medical facility's Chief of Pharmacy Services, or designee, must determine if the educational program and associated materials are suitable based on the following requirements:

(1) Industry sponsorship must be disclosed in the introductory remarks and in the announcement brochure. Sponsorship includes any contribution, whether in the form of staple goods, personnel, or financing, intended to support the educational program.

(2) When industry-sponsored and non-sponsored sources of data or other analytical information exist for FDA approved uses of a particular drug or drug related supply, a direct comparison between the two sources must be disclosed in the introductory remarks and in the announcement brochure.

(3) The educational program must not solicit protected health information or patient participation in pharmaceutical company-sponsored programs, except as may be required by Federal laws and regulations such as an educational program that is part of a risk evaluation and mitigation strategy required by FDA.

(4) Patient educational materials must not contain the name or logo of the pharmaceutical manufacturer or be used for promotion of a specific medication, unless the VA PBM Service determines that the logo or name is inconspicuous and the legal requirements (e.g., trademark requirements) make their removal impractical. However, this requirement does not apply to labeling required by FDA.

(5) All educational activities and distribution of promotional materials in which a PCR provides on-site, in-person information about a drug or drug-related supply must be pre-scheduled and approved by the VA medical facility's Chief of Pharmacy Services, or designee,

as specified in local policy. This includes educational programs and associated materials regarding drugs already on the VANF, or any new therapeutic indication for a drug that is already on the VANF but has not been reviewed by VA.

(6) Educational programs and associated materials focusing primarily on non-VANF drugs or drug-related supplies without criteria-for-use must receive prior approval from the VA medical facility's Chief of Pharmacy Services or designee.

k. The VA medical facility's Chief of Pharmacy Services, or designee, will determine if the educational program complies with VA initiatives and all locally established criteria. ***NOTE:*** *The VA medical facility's Chief of Pharmacy Services, or designee, determines whether to grant permission for the use of promotional material*.

l. Maintaining appropriate relationships between VA employees and PCRs is essential to ensuring an ethical health care delivery environment. To avoid violating or giving the appearance of violating government ethics rules or professional ethics standards, VA 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 representative who is currently involved or seeking to become involved in business relations with VA). Appearance of a conflict of interest is as impermissible as an actual conflict of interest. ***NOTE:*** *VHA employees are subject to Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry.*

m. A report by VHA's National Ethics Committee (NEC), "Gifts to Health Care Professionals from the Pharmaceutical Industry" discusses the nature of gift relationships and why gifts to health care professionals from the pharmaceutical industry may be ethically problematic. This reference offers practical guidance for health care professionals and facilities for avoiding inappropriate interactions with representatives. To ensure a consistent approach to relationships with representatives throughout the VHA system, clinical staff members are encouraged to review this report and incorporate its recommendations into VISN, medical facility and service-level policies and procedures where appropriate, see Appendix C-1.

n. No PCR is to give, and no VA employee is to receive any item (including but not limited to promotional items, continuing education materials, textbooks, entertainment, and gratuities) that exceeds the value permissible for acceptance under government ethics rules, 5 CFR 2635.204(a). However, such items may be donated to a medical facility library or individual department for use by all employees, in accordance with medical facility policy. Gifts in support of VA official travel may be accepted by the department in accordance with title 31 United States Code (U.S.C.) 1353, 41 CFR 304, and VA policy regarding such gifts. ***NOTE:*** *The value permissible for acceptance under government ethics rules (5 CFR 2635.204(a)) is $20 or less per occasion, not to exceed $50 in a calendar year from one source. Different PCRs from the same company are considered one source for the purposes of calculating this total. Government ethics laws apply to VA staff regardless of whether the staff member is located on VA property or off VA property, on duty or off duty.*

o. PCRs are to be granted controlled access to all VA medical care facilities and staff who are not on the do-not call list. However, PCRs must comply with the following procedures:

(1) In order to minimize the potential for disruption of patient care activities, a PCR must schedule an appointment prior to each specific visit. Appointments are to be made by either telephone or e-mail, but must be made in advance of visiting the medical center.

(2) The PCR may not use the overhead public address (paging) system to locate any member of the medical, house, pharmacy, or nursing staffs. Contacts using the electronic paging system (beepers) are generally discouraged, but are permissible if specifically requested by an individual VA provider.

(3) Access to VA medical facilities by a PCR who has not made a previously scheduled appointment is not permitted under any circumstances.

(4) A PCR visiting a VA medical facility for a previously scheduled appointment may not initiate requests for impromptu meetings with other VA staff. However, they may respond to requests for meetings initiated by VA staff during the visit. Entering any area of a VA campus, medical facility, or clinic without a previously scheduled appointment is prohibited.

(5) VA medical facilities are permitted to develop a list of individuals or departments that do not wish to be called-on by PCRs. A PCR must not attempt to make appointments with or leave materials for the individuals or departments on the list. ***NOTE:*** *This list may be obtained from the VA medical facility's Chief of Pharmacy Services, or designee.*

(6) To maximize learning opportunities and minimize potential confusion on the part of students still serving in their primary educational programs, PCRs are prohibited from marketing or promoting to medical, pharmacy, nursing and other health profession students including residents. ***NOTE:*** *Exceptions may be permitted when approved in advance by and conducted in the presence of their clinical staff supervisor or mentor.*

(7) A PCR is not permitted to attend a medical facility conference where individual patient information is discussed or presented.

(8) PCRs must comply with VA security requirements and VISN procedures for accurately monitoring their whereabouts when visiting VA medical facilities (i.e., log-in and log-out-sheets, photo identification badges, etc).

(9) All PCRs are encouraged to schedule appointments in VA medical 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 may be permitted.

(10) PCRs are not permitted to make presentations in patient care areas. These restricted areas include, but are not limited to:

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

(b) Clinic examination rooms,

(c) Nurses stations,

(d) Intensive care units,

(e) Operating room suites,

(f) Emergency rooms,

(g) Urgent care centers, and

(h) Ambulatory treatment centers.

(11) When it is necessary to meet with a PCR in the staff member's office, which is located in a patient care area, PCR access to the patient care area is permissible provided there are no breaches of patient privacy.

(12) PCRs may not wait for appointments in patient care areas, but may briefly travel through them, when they have a scheduled appointment in a staff member's office.

(13) Drug or supply samples may not be provided by PCRs to VA staff for their personal use.

(14) PCRs and VA account managers are strongly discouraged from contacting individual members of the MAP for the purposes of product promotion. Requests to meet with a MAP member must be coordinated through the Office of the Deputy Chief Consultant, Hines, Illinois.

p. PCRs or other vendors, who conduct business with VA, must not engage in, permit or encourage conduct in violation of this Handbook. This includes any actions that may be reasonably perceived by VA staff to be in conflict with this Handbook.

q. Failure of a PCR to comply with the provisions outlined in this Handbook may result in the suspension, limitation, and temporary or permanent revocation of commercial visiting privileges for one or more VA medical facilities. Multiple occurrences may lead to additional sanctions. ***NOTE:*** *Any sanctions issued under the regulation may be communicated to all VA medical facility Directors.*

r. Suspension or limitation of visiting privileges are considered significant restrictions and need to be used judiciously and only with good cause. When a 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 for Health. Until such time that the Under Secretary for Health provides a ruling, the visiting privileges of the PCR remain suspended or permanently revoked.

s. Violations, which are sustained, may be communicated to other facilities or VISNs which would likely be visited by the offending PCR or pharmaceutical company.

10. REFERENCES

a. Department of Veterans Affairs 38 CFR § 1.220, "On-site Activities by Pharmaceutical Company Representatives at VA Medical Facilities," see Appendix B.

b. A report by VHA's National Ethics Committee (NEC), "Gifts to Health Care Professionals from the Pharmaceutical Industry," see Appendix C.

GLOSSARY

1. **Criteria-for-Use.** Criteria-for-use is clinical criteria developed by the Department of Veterans Affairs (VA) at a national level that describe how certain drugs may be used. VA criteria-for-use documents are available to the public at: www.pbm.va.gov. ***NOTE:*** *Exceptions may be applied at the local level for operational reasons.*

2. **Drug or Drugs.** The term "drug" or "drugs" refers to:

(a) Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(c) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(d) Articles intended for use as a component of any article specified in subparagraphs 2(a), 2(b), or 2(c) of this definition.

3. **Drug-Related Supplies.** Drug-related supplies are supplies related to the use of a drug, such as test strips or testing devices, inhalers, spacers, insulin syringes, and tablet splitters.

4. **New Molecular Entity.** New molecular entity refers to a drug product containing an active ingredient that has never before received United States Food and Drug Administration (FDA) approval.

5. **Non-Promotable Drugs.** Non-promotable drugs are drugs designated by VA as non-promotable on the Pharmacy Benefits Management Web site at: http://www.pbm.va.gov. A list of the drugs or drug-related supplies classified by VA as non-promotable may be requested by contacting the VA medical facility's Chief of Pharmacy Services.

6. **Non-VA National Formulary (Non-VANF) Drugs or Drug-related Supplies.** Non-VANF drugs or drug-related supplies mean drugs or drug-related supplies that do not appear on the VA National Formulary.

7. **Pharmaceutical Company Representative (PCR).** PCR is any individual employed by or contracted to represent a pharmaceutical manufacturer or retailer.

8. **VA Medical Facility.** VA medical facility refers to any property under the charge and control of VA used to provide medical benefits, including community-based outpatient clinics and similar facilities.

9. **VANF Drugs or Drug-related Supplies.** VANF drugs or drug-related supplies refer to any drug or drug-related supply that appears on the VANF. The VANF is available at: *www.pbm.va.gov* , or may be requested by contacting the VA medical facility's Chief of Pharmacy Services.

10. **Veterans Integrated Service Network (VISN).** VISN means one of the regions where a VA medical facility is located, as designated by VA.

TITLE 38 UNITED STATES CODE 501(a), § 1.220, ON-SITE ACTIVITIES BY PHARMACEUTICAL COMPANY REPRESENTATIVES AT VA MEDICAL FACILITIES


Rule AN42.pdf

GIFTS TO HEALTH CARE PROFESSIONALS FROM THE PHARMACUETICAL INDUSTRY

A REPORT BY THE NATIONAL ETHICS COMMITTEE OF THE VETERANS HEALTH ADMINISTRATION OCTOBER 2003


National Ethics
Comittee Report 200