

**PROMOTION OF DRUGS AND DRUG-RELATED SUPPLIES BY
PHARMACEUTICAL COMPANY REPRESENTATIVES (PCR)**

1. REASON FOR ISSUE: The Veterans Health Administration (VHA) directive provides policy related to Pharmaceutical Company Representative (PCR) activities in Department of Veterans Affairs (VA) medical facilities.

2. SUMMARY OF MAJOR CHANGES: Major changes include:

a. In paragraph 4, Responsibilities:

(1) Adding responsibilities for the Deputy Under Secretary for Health for Operations and Management, Deputy Under Secretary for Health for Policy and Services, Veterans Integrated Service Network (VISN) Directors, and Deputy Chief Consultant for Formulary Management, Pharmacy Benefits Management Services.

(2) Clarifying Chief Consultants and Pharmacy Benefits Manager (PBM) responsibilities.

(3) Removing responsibilities of the PCR.

(4) Added clarifying language addressing VA's responsibility to issue a written notice of interim action or a final written order when the facility determines that a PCR is noncompliant.

b. In paragraph 6, Promotion Procedures, biologic products was included in New Molecular Entities (NME).

c. Adding examples to Education and Promotional Materials.

3. RELATED ISSUES: VHA Directive 1108.08, VHA Formulary Management Process, dated November 2, 2016, and VHA Handbook 1004.07, Financial Relationships between VHA Health Care Professionals and Industry, October 21, 2009.

4. RESPONSIBLE OFFICE: The Chief Consultant, Pharmacy Benefits Management (10P4P) in the Office of Patient Care Services is responsible for the contents of this directive. Questions may be addressed at 202-461-7360.

5. RESCISSION: VHA Handbook 1108.10, dated December 28, 2012, is rescinded.

June 13, 2018

VHA DIRECTIVE 1108.10

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of June 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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CONTENTS

**PROMOTION OF DRUGS AND DRUG-RELATED SUPPLIES BY
PHARMACEUTICAL COMPANY REPRESENTATIVES (PCR)**

1. PURPOSE 1

2. DEFINITIONS 1

3. POLICY..... 2

4. RESPONSIBILITIES 2

5. PROMOTION PROCEDURES 6

6. EDUCATIONAL AND PROMOTIONAL MATERIALS 8

7. GIFTS 9

8. FACILITY ACCESS FOR PCRs 9

9. TRAINING REQUIREMENTS 12

10. RECORDS MANAGEMENT 12

11. REFERENCES 12

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

1. PURPOSE

This Veterans Health Administration (VHA) directive provides policy regarding on-site, in-person promotional activities of drugs and drug-related supplies, including educational activities, detailing, patient and provider contact, and overall conduct in Department of Veterans Affairs (VA) facilities by Pharmaceutical Company Representative (PCR) in VA medical facilities. It does not apply to the distribution of information and materials through other means. **AUTHORITY:** Title 38 Code of Federal Regulations (CFR) 1.220.

2. DEFINITIONS

a. **Criteria-for-Use.** Criteria-for-use is clinical criteria developed by VA at a national level that describes how certain drugs may be used. VA criteria-for-use documents are available to the public at the PBM website: <https://www.pbm.va.gov>. **NOTE:** *Exceptions may be applied at the local level for operational reasons.*

b. **Drug or Drugs.** The term “drug” or “drugs” refers to:

(1) 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;

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

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

(4) Articles intended for use as a component of any article specified in subparagraphs b.(1), b.(2), or b.(3) of this definition.

c. **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.

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

e. **Non-Promotable Drugs.** Non-promotable drugs are drugs designated by VA as non-promotable on the Pharmacy Benefits Management Web site that can be accessed at <https://www.pbm.va.gov/>. **NOTE:** 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.

f. **Non-VA National Formulary (Non-VANF) Drugs or Drug-related Supplies.**

Non-VANF drugs or drug-related supplies are drugs or drug-related supplies that do not appear on the VA National Formulary.

g. **Pharmaceutical Company Representative.** A PCR is any individual employed by or contracted to represent a pharmaceutical manufacturer or retailer.

h. **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.

i. **VA National Formulary (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 via the VA formulary search tool located at: <https://www.pbm.va.gov/apps/VANationalFormulary/>. This may also be requested by contacting the VA medical facility's Chief of Pharmacy Services.

3. POLICY

It is VHA policy that VA medical facilities ensure that, as part of an ethical health care delivery environment, relationships between VA employees and PCRs maintain appropriate limits and adhere to Food and Drug Administration (FDA) and VA regulation, policy, and guidelines.

4. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health, or an individual appointed by the person in position of responsibility, is responsible for:

(1) Ensuring compliance with this directive.

(2) Providing a ruling on the appeal of a suspension or permanent revocation of privileges when:

(a) Multiple representatives of a pharmaceutical company have their visiting privileges suspended or permanently revoked by a VA medical facility Director; and,

(b) The pharmaceutical company requests a one-time appeal of the decision.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management, or an individual appointed by the person in position of responsibility, is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISN);

(2) Ensuring that each VISN Director has the resources required to support the fulfillment of the terms of this directive in all VA medical facilities within that VISN;

(3) Confirming that each VISN has and utilizes on an ongoing basis a means for ensuring the terms of this directive are fulfilled in all the VA medical facilities of the VISN.

c. **Deputy Under Secretary for Health for Policy and Services.** The Deputy Under Secretary for Health for Policy and Services, or an individual appointed by the person in position of responsibility, is responsible for assuring that all local manuals related to PCR activities are aligned with the content of this directive.

d. **Deputy Chief Consultant for Formulary Management Pharmacy Benefits Management Services, Hines, Illinois.** The Deputy Chief Consultant, or an individual appointed by the person in position of responsibility, is responsible for:

(1) Providing national approval to PCRs to present professionally developed educational materials intended for the patient or provider. **NOTE:** *Although permission to use the materials at a given facility still rests with the VA medical facility's Chief of Pharmacy Services, or an individual appointed by the person in position of responsibility, 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.*

(2) Coordinating requests to meet with a VHA Medical Advisory Panel (MAP) member when deemed appropriate.

e. **Veterans Integrated Service Network (VISN) Director.** The VISN Director, or an individual appointed by the person in position of responsibility is responsible for:

(1) Communicating the contents of this directive to each of the VA facilities within the VISN; and

(2) Providing oversight of facilities to assure compliance with this directive, relevant standards, and applicable regulations by communicating with the VISN formulary committee and the facilities directors at least annually.

f. **VA Medical Facility Director.** The VA medical facility Director, or an individual appointed by the person in position of responsibility, is responsible for:

(1) Approving and ensuring that all drug samples and drug-related supplies donated to the VA medical facility by pharmaceutical companies and their PCRs are delivered to the Office of the Chief of Pharmacy Services for proper storage, documentation, and dispensing.

(2) Ensuring that all pharmaceutical company donations to a VA medical facility, to support education or VA research, are in compliance with existing VHA, Employee Education System (EES), and VISN policies on accepting donations for education and research. **NOTE:** *Generally, VHA deposits such as donations into the General Post Fund, or an approved VA Not-for-Profit Research or Education Corporation.*

(3) Approving donations of drugs and supplies. **NOTE:** *If the 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. 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.*

(4) Ensuring continuing education materials and textbooks that exceed the permissible value for acceptance under government ethics rules are not given to individual employees and approving items donated by PCRs to a medical facility library or individual department for use by all employees.

(5) Levying limitations, suspensions, or the permanent revocation of the privileges of a PCR or entire sales force of a given manufacturer when appropriate, as follows:

(a) The facility Director or an individual appointed by the person in position of responsibility will issue a written notice to the PCR of non-compliance and of Director's interim action. The PCR will have 30 calendar days to respond to the notice; however, the interim action will be enforced effective the date of the notice.

(b) After the end of 30-day response period, or after Director or an individual appointed by the person in position of responsibility receives a timely response, the Director or an individual appointed by the person in position of responsibility will issue the PCR and their supervisor a final written order either confirming the action taken as indicated in the notice or specifying another action to be taken in accordance with 38 CFR 1.220(i) (3).

g. **Facility Chief of Pharmacy Services.** The Chief of Pharmacy Services, or an individual appointed by the person in position of responsibility, is responsible for:

(1) Providing copies of the directive and the local VA medical facility policy to all PCRs who seek access to VA medical facilities prior to initiating any activities.

(2) Collecting all information regarding usage of approved samples of drugs and drug-related supplies within the VA medical facility and at least annually and reviewing to assure that samples were stored and dispensed in accordance with this directive.

(3) Coordinating the review of on-site, in-person promotional activities, including educational activities, by pharmaceutical company representatives at VA medical facilities.

(4) Ensuring educational programs or promotional materials presented by a PCR are reviewed within 60 calendar days of receipt prior to presentation and distribution within VA facilities unless the Chief of Pharmacy and PCR agree on an earlier date.

(5) Determining whether the educational program or promotional materials proposed by a PCR complies with VA initiatives and all locally established criteria. The determination is based on the following requirements:

(a) 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.

(b) 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.

(c) 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 (REMS) required by FDA
<https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>.

(d) 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. This requirement, however, does not apply to labeling required by FDA.

(e) 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 an individual appointed by the person in position of responsibility, as specified in a local guidance manual. 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.

(f) 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 an individual appointed by the person in position of responsibility.

(6) Communicating permissions to the PCR.

(7) Pre-scheduling and approving guest speakers to VA facilities for educational purposes.

(8) Maintaining and making available a list of individuals or departments that wish to be called on by PCRs.

(9) Developing local medical facility standard operating procedures (SOPs) by February 28, 2019, that states the rules of engagement for registering what can be promoted at that medical facility.

5. PROMOTION PROCEDURES

PCRs may only promote VANF and non-VANF drugs and drug-related products in accordance with applicable FDA and VA guidelines, including PBM Criteria-for-Use or other applicable prescribing restrictions which exist for those products.

a. **VANF Drugs and Drug-Related Supplies.** VANF drugs and drug-related supplies may be promoted in VA medical centers (including community-based outpatient clinics (CBOCs and other VA points of care 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 an individual appointed by the person in position of responsibility;

(2) The drugs and drug-related supplies are discussed, displayed, and represented accurately regarding formulary status, FDA approved indications, and the like;

(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.

b. **Non-VANF Drugs and Drug-Related Supplies.** Non-VANF drugs and drug-related supplies may be promoted in VA medical facilities (including CBOCs and other VA points of care) 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 an individual appointed by the person in position of responsibility;

(2) The promotion is consistent with the existing PBM Criteria-for-Use guidance. **NOTE:** PCRs may access information regarding VA Criteria-for-Use from the PBM Formulary Search Tool at: <https://www.pbm.va.gov/apps/VANationalFormulary/>;

(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 members 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.

c. **Non-VANF Drugs and Drug-Related Supplies where PBM Criteria-for-Use have not been developed.** Non-VANF drugs and drug-related supplies for which PBM Criteria-for-Use have not been developed, may be promoted in VA medical facilities (including CBOCs and other VA points of care) 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 an individual appointed by the person in position of responsibility;

(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 <https://vaww.cmopnational.va.gov/cmop/PBM/National%20Formulary/Forms/AllItems.aspx?RootFolder=%2Fcmop%2FPBM%2FNational%20Formulary%2FNon%2DPromotable%20List&FolderCTID=0x012000F34DA063B9FFAF4C87A2BBBC779C4B9C&View={C71E48E9-1D7F-41E6-994F-02A5281C723C}> and VA intranet <https://www.pbm.va.gov/PBM/NationalFormulary.asp>.* **NOTE:** *The PBM intranet Web site is an internal Web site and is not available to the public. The list also may be requested by contacting the VA medical facility's Chief of Pharmacy Services.*

d. **New Molecular Entities (NME) and Biologic Products.** New molecular entities and biologic products may be promoted in VA medical facilities (including CBOCs and other VA points of care) 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 an individual appointed by the person in position of responsibility: **NOTE:** *In instances where a given facility has permitted the promotion of a NME prior to any National decision regarding its VANF status, that facility needs 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.

6. EDUCATIONAL AND PROMOTIONAL MATERIALS

All educational programs must be approved by the appropriate continuing education accreditation agency, such as the Accreditation Council for Pharmacy Education (ACPE) or the Accreditation Council for Continuing Medical Education (ACCME), when appropriate, before submission to the facility designee for review. 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 for Formulary Management, Pharmacy Benefits Management Services in 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 an individual appointed by the person in position of responsibility, 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. Industry sponsorship of such materials must be adequately disclosed in the following manner:

a. 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.

b. 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.

c. 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.

d. Educational materials or literature regarding a new drug or a new therapeutic indication for a drug already on the VANF, but which has not been reviewed by the VHA Medical Advisory Panel (MAP) and VISN Pharmacist Executives (VPE) Committees, must be identified as such prior to being displayed or discussed.

e. Educational programs and associated materials focusing primarily on non-VANF drugs or drug related supplies may be promoted with approval of the facility Chief of Pharmacy.

f. 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.

g. Educational and promotional materials are not to be placed in any patient care area.

7. GIFTS

a. Maintaining appropriate relationships between VHA 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, VHA 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 VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry, and 5 CFR 2635.204(a).*

b. A report by VHA's National Ethics Committee (NEC), "Gifts to Health Care Professionals from the Pharmaceutical Industry," downloadable at https://www.ethics.va.gov/docs/necrpts/NEC_Report_20031201_Gifts_From_Pharmaceutical_Industry.pdf, 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.

c. 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 *VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry*. **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 VHA staff regardless of whether the staff member is located on VA property or off VA property, on duty or off duty.*

d. No PCR is to provide food items of any type or any value, into VA facilities for provision to VA staff or non-VA staff (e.g., employees of affiliates, volunteers, without compensation employees, etc.).

8. FACILITY ACCESS FOR PCRS

a. PCRs are to be granted controlled access to all VA medical care facilities and staff who are on the call list. They 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 VHA provider.

(3) 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.

(4) VA medical facilities must develop a list of individuals or departments that wish to be contacted by PCRs. A PCR may not attempt to make appointments with or leave materials for any individuals or departments who are not on the list. **NOTE:** *This list may be obtained from the VA medical facility's Chief of Pharmacy Services, or an individual appointed by the person in position of responsibility.*

(5) 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. Any exceptions must be approved in advance by and conducted in the presence of their clinical staff supervisor or mentor. PCRs are not permitted to discuss VA related matters with medical, pharmacy, nursing and other health profession students, including residents when these trainees are practicing at affiliated sites outside of the VA campus.

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

(7) 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.).

(8) 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 VHA staff, appointments at other times may be permitted.

(9) 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

b. PCR may meet with a staff member whose office is located in a patient care area, provided there are no breaches of patient privacy.

c. 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.

d. Drug or supply samples may not be provided by PCRs to VHA providers outside of Pharmacy Service for any reason, including VHA staff member personal use or for use by family and/or friends of the VHA staff member.

e. 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 for Formulary Management, Pharmacy Benefits Management Services, Hines, Illinois.

f. PCRs are not permitted to discuss specific patient with VHA staff members. Patient specific issues will be handled internally by VA providers.

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

h. Failure of a PCR to comply with the provisions outlined in this directive may result in the suspension, limitation, and temporary or permanent revocation of commercial visiting privileges for one or more VHA medical facilities. Multiple occurrences may lead to additional sanctions. (See paragraph 4.g. (7).) **NOTE:** *Any sanctions issued under the regulation may be communicated to all VA medical facility Directors.*

i. 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.

j. Violations which are sustained after any appeals may be communicated to other facilities or VISNs.

9. TRAINING REQUIREMENTS

There are no training requirements.

10. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive must be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If you have any question to the regarding any aspect of records management you must contact your facility Records Manager or your Records Liaison.

11. REFERENCES

- a. 31 U.S.C. 1353.
- b. 38 U.S.C. 501(a).
- c. 5 CFR 2635.204(a).
- d. 38 CFR 1.220.
- e. 41 CFR 304.
- f. VHA Directive 1108.08, VHA Formulary Management Process, dated November 2, 2016.
- g. VHA Handbook 1004.07, Financial Relationships between VHA Health Care Professionals and Industry, November 24, 2014.
- h. Veterans Health Administration. National Ethics Committee (NEC), Gifts to Health Care Professionals from the Pharmaceutical Industry.
- i. Veterans Health Administration. National Ethics Committee. Compensation to Health Care Professionals from the Pharmaceutical Industry.