

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

1. SUMMARY OF MAJOR CHANGES: Major changes include:

a. Including virtual modalities in addition to on-site promotional activities (see paragraph 2.h.).

b. Clarifying policy related to requests and use of donated drug and drug-related supplies (see paragraph 2.g.).

c. Adding minor sanction examples for Pharmaceutical Company Representative violations of this directive (see paragraph 6.h.).

2. RELATED ISSUES: VHA Directive 1108.08, VHA Formulary Management Process, dated July 29, 2022; VHA Handbook 1004.07, Financial Relationships between VHA Health Care Professionals and Industry, dated November 24, 2014.

3. POLICY OWNER: Pharmacy Benefits Management (PBM) Services (12PBM) is responsible for the content of this directive. Questions may be addressed to the Executive Director, PBM Services at VHA12-PCSAAction@va.gov.

4. RESCISSION: VHA Directive 1108.10, Promotion of Drugs and Drug-related Supplies by Pharmaceutical Company Representatives, dated June 13, 2018, is rescinded.

5. RECERTIFICATION: This Veterans Health Administration (VHA) directive is scheduled for recertification on or before the last working day of December 2027. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

6. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

**BY DIRECTION OF THE OFFICE OF
THE UNDER SECRETARY FOR HEALTH:**

/s/ M. Christopher Saslo
DNS ARNP-BC, FAANP
Acting Assistant Under Secretary for Health
for Patient Care Services/CNO

December 23, 2022

VHA DIRECTIVE 1108.10

NOTE: *All references herein to the Department of Veterans Affairs (VA) and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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

1. POLICY

It is Veterans Health Administration (VHA) policy that Department of Veterans Affairs (VA) medical facilities ensure that, as part of an ethical health care delivery environment, relationships between VA employees and Pharmaceutical Company Representatives (PCRs) maintain appropriate limits and adhere to U.S. Food and Drug Administration (FDA) and VA regulations, policies and guidelines. **AUTHORITY:** 38 C.F.R. § 1.220.

2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Providing a ruling on the appeal of a suspension or permanent revocation of PCR privileges at VA medical facilities.

b. **Assistant Under Secretary for Health for Patient Care Services.** The Assistant Under Secretary for Health for Patient Care Services is responsible for supporting Pharmacy Benefits Management (PBM) Services with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations, is responsible for:

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

(2) Assisting VISN Directors in resolving implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **Executive Director, Pharmacy Benefits Management Services.** The Executive Director, PBM Services is responsible for providing implementation guidance for VISN oversight of VA medical facility compliance with this directive. This includes providing guidance to VISNs related to resolving non-compliance at VA medical facilities.

e. **Deputy Chief Consultant for Formulary Management, Pharmacy Benefits Management Services.** The Deputy Chief Consultant for Formulary Management, PBM Services is responsible for:

(1) Providing guidance to PCRs, when requested, on alignment of professionally

developed educational materials intended for the patient or VA health care provider with VA National Formulary (VANF) initiatives and directives. See paragraph 4.

(2) Reviewing educational materials submitted by PCRs, when requested, to help streamline the approval process when PCRs intend to use the materials in multiple VA medical facilities. See paragraph 2.h.(3).

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

f. **Veterans Integrated Services Network Director.** The VISN Director is responsible for:

(1) Communicating the contents of this directive to each VA medical facility within the VISN.

(2) Providing oversight of VA medical facilities to assure compliance with this directive, relevant standards and applicable regulations by communicating with the VISN Pharmacy and Therapeutics Committee and VA medical facility Directors at least annually.

g. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring overall VA medical facility compliance with this directive and that appropriate corrective action is taken if non-compliance is identified.

(2) Ensuring that continuing education materials and textbooks from PCRs that exceed the permissible value for acceptance under Government ethics rules are not given to individual VA employees and approving such items donated to a VA medical facility library or individual department for use by all VA employees. See paragraph 5.c.

(3) Ensuring attendance records are completed for staff attending pharmaceutical company presentations or training sessions.

(4) Ensuring that all pharmaceutical company donations to a VA medical facility to support education or VA research comply with existing VHA Employee Education System and VISN procedures related to accepting donations for education and research. **NOTE:** *Generally, VHA deposits include donations into the General Post Fund, or an approved VA Not-for-Profit Research or Education Corporation. See VHA Directive 4721, VHA General Post Funds - Gifts and Donations, dated August 13, 2018.*

(5) Approving donations of drugs and drug-related supplies. **NOTE:** *Requests must not be approved for products that are donated solely to allow VA clinicians to gain familiarity with that product.* This includes:

(a) 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 for proper storage, documentation and dispensing. **NOTE:**

Drugs or drug-related supplies should not be routinely accepted as they would not be included in any national procurement surveillance such as inventory management and recalls; if donated drugs or drug-related supplies are dispensed to VA patients they should not be labeled with the words sample, professional sample or similar wording. Rare exceptions to accepting donated drugs or drug-related supplies and labeling as samples, such as in the case of product shortages, are permissible if such use is in the best interest of patient care.

(b) Forwarding information pertaining to the use of approved donated products to the National PBM Formulary Office.

(6) Ensuring VA employees who meet with PCRs are aware of a report by VHA's National Ethics Committee (NEC), "Gifts to Health Care Professionals from the Pharmaceutical Industry," that discusses the nature of gift relationships and the reasons gifts to VA health care providers from the pharmaceutical industry may be ethically problematic. **NOTE:** *The report is available at <https://www.ethics.va.gov/pubs/necreports.asp>.*

(7) Ensuring corrective action is taken if a VA employee inappropriately accepts a gift from a PCR. For further details regarding gifts, see paragraph 5.

(8) Limiting, suspending or permanently revoking the privileges of a PCR or entire sales force of a given manufacturer when appropriate, as follows:

(a) Issuing a written notice to the PCR and their supervisor of non-compliance and of the VA medical facility Director's interim action. The PCR will have 30 calendar days to respond to the notice; however, the interim action is enforced effective the date of the notice.

(b) Issuing a final written order to the PCR and their supervisor, after receipt of a response within the 30-day response period or after the response period has ended, either confirming the action taken as indicated in the notice or specifying another action to be taken in accordance with 38 C.F.R § 1.220.

h. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff (CoS) is responsible for:

(1) Ensuring that clinicians refer PCRs to the VA medical facility pharmacy before an initial appointment is scheduled to ensure PCRs receive the necessary policies and procedures.

(2) Notifying the Chief, Pharmacy Service of any PCR-requested educational or promotional material that needs review and approval prior to release to patients or VA health care providers. **NOTE:** *The CoS is responsible for ensuring corrective action if clinical service chiefs permit PCRs to provide educational or promotional material without Chief, Pharmacy Service approval.*

(3) Ensuring clinicians do not receive medications or accept drug or drug-related

supply donations from PCRs. **NOTE:** *Only the Chief, Pharmacy Service is permitted to receive donations of drugs and drug-related supplies on behalf of the VA medical facility.*

i. **VA Medical Facility Associate Director for Patient Care Services.** The VA medical facility Associate Director for Patient Care Services (ADPCS) is responsible for:

(1) Ensuring that nursing staff refer PCRs to the VA medical facility pharmacy before an initial appointment is scheduled to ensure PCRs receive the necessary policies and procedures.

(2) Notifying the Chief, Pharmacy Service of any PCR-requested educational or promotional material that needs review and approval prior to release to patients or VA health care providers. **NOTE:** *The ADPCS is responsible for ensuring corrective action if nursing managers permit PCRs to provide educational or promotional material without Chief, Pharmacy Service approval.*

(3) Ensuring nursing staff do not receive medications or accept drug or drug-related supply donations from PCRs. **NOTE:** *Only the Chief, Pharmacy Service is permitted to receive donations of drugs and drug-related supplies on behalf of the VA medical facility.*

j. **VA Medical Facility Chief, Pharmacy Service.** The VA medical facility Chief, Pharmacy Service is responsible for:

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

(2) Collecting and reviewing all information regarding usage of approved samples of drugs and drug-related supplies within the VA medical facility at least annually to assure that samples were stored and dispensed in accordance with paragraph 2.g.(4)(a) of this directive.

(3) Coordinating the review of on-site and virtual promotional activities by PCRs, including educational activities; recommending PCRs present any professionally developed educational materials intended for patients or VA health care providers to the Office of the Deputy Chief Consultant for Formulary Management, PBM Services, for review. **NOTE:** *Although permission to use the materials at a given VA medical facility still rests with the VA medical facility's Chief, Pharmacy Service, a national review 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 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 medical facilities unless the VA medical facility Chief, Pharmacy Service and PCR agree on an earlier date.

(5) Approving or denying use of PCR educational programs or promotional materials at the VA medical facility within 60 calendar days of receipt.

(6) Determining whether the educational program or promotional materials proposed by a PCR comply with VA requirements. The determination is based on the requirements in paragraph 4.a.-h.

(7) Communicating VA medical facility access and educational permissions to the PCR including requirements in paragraphs 4 and 6.

(8) Approving the promotion of all VANF, non-formulary, New Molecular Entity (NME) and biologic drugs and drug-related supplies in VA medical facilities (see paragraph 3.b.).

(9) Approving guest speakers at VA medical facilities for educational purposes.

(10) Maintaining and providing to PCRs upon request a list of individuals or departments that wish to be contacted by PCRs. **NOTE:** *An acceptable alternative is utilizing an electronic scheduling system where individuals or departments can accept and schedule appointments or deny requests.*

(11) Developing local VA medical facility written guidance that can be given to PCRs in addition to this directive to explain processes for accessing VA medical facility staff or locations. **NOTE:** *Local processes are subject to change at any time due to dynamic conditions and situations at VA medical facilities.*

(12) Receiving and providing appropriate management of all approved donated drug or drug-related supplies on behalf of the VA medical facility.

3. PROMOTION PROCEDURES

a. **Pharmaceutical Company Representatives.** PCRs must only promote VANF and non-formulary drugs and drug-related products in accordance with applicable FDA and VA guidelines, including PBM Services criteria-for-use or other applicable prescribing restrictions which exist for those products.

b. **VA National Formulary, Non-VA National Formulary, New Molecular Entity and Biologic Drugs and Drug-Related Supplies.** Drugs and drug-related supplies may be promoted in VA medical facilities (including Community-Based Outpatient Clinics (CBOCs) and other VA points of care) provided all of the following conditions are met:

(1) The promotion has been specifically approved by the VA medical facility Chief, Pharmacy Service. **NOTE:** *In instances where a given VA medical facility has permitted the promotion of an NME or biologic prior to any national decision regarding its VANF status, the VA medical facility must conform their decision to any subsequent decision by the national VANF Committee. For VANF Committee responsibilities, see VHA Directive 1108.08, VHA Formulary Management Process, dated July 29, 2022.*

(2) The drugs and drug-related supplies are discussed, displayed and represented accurately with content consistent with VA formulary status, VA criteria-for-use and FDA approved indications. **NOTE:** For non-formulary drugs or drugs with criteria-for-use, the promotion must be consistent with existing PBM Services documents that are accessible using the Formulary Search Tool at: <https://www.pbm.va.gov/apps/VANationalFormulary/>.

(3) The promotion has significant educational value and does not divert VA staff from activities they are required to perform during duty hours, including patient care and other educational activities.

(4) The drug or drug-related supply has not been classified by VA as non-promotable. **NOTE:** PBM Services maintains a national listing of formulary drugs that are not to be promoted or detailed by PCRs on the PBM Services website at: <https://www.pbm.va.gov/PBM/NationalFormulary.asp> and PBM Services SharePoint at: <https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/National%20Formulary/Forms/AllItems.aspx/>. The latter is an internal VA website that is not available to the public. The list may also be requested by contacting the VA medical facility Chief, Pharmacy Service.

4. EDUCATIONAL AND PROMOTIONAL MATERIALS

VA medical facilities should recommend that PCRs present any professionally developed educational materials intended for the patient or VA health care provider to the Office of the Deputy Chief Consultant for Formulary Management, PBM Services, for review. Although permission to use the materials at a given VA medical facility still rests with the VA medical facility's Chief, Pharmacy Service, a national review 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 VA medical 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. Sponsorship includes any contribution, whether in the form of staple goods, personnel or financing, intended to support the educational program.

b. If industry-sponsored and non-sponsored sources of data or other analytical information exists 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. 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. All educational activities and distribution of promotional materials in which a PCR

provides on-site or virtual information about a drug or drug-related supply must be approved by the VA medical facility Chief, Pharmacy Services. This includes educational programs and associated materials regarding drugs already on VANF, or any new therapeutic indication for a drug that is already on VANF but has not been reviewed by VA (this status must also be identified prior to information being displayed or discussed).

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

f. Educational and promotional programs and materials that solicit protected health information or patient participation in manufacturer-sponsored programs and require the furnishing of protected health information are not permitted, 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 at <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems>.

g. Patient educational materials must not contain the name or logo of the pharmaceutical manufacturer or be used for promotion of a specific medication unless PBM Services 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.

h. Educational and promotional materials must not be placed in any areas with patient access such as outpatient clinics, inpatient rooms, waiting areas and canteen areas.

5. GIFTS

a. 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:** *VA employees are subject to VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry, dated November 24, 2014, and 5 C.F.R. § 2635.204(a).*

b. A report by VHA's NEC, "Gifts to Health Care Professionals from the Pharmaceutical Industry," available at <https://www.ethics.va.gov/pubs/necreports.asp>, discusses the nature of gift relationships and the reasons gifts to VA health care providers from the pharmaceutical industry may be ethically problematic. This reference offers practical guidance for VA health care providers and VA medical facilities for avoiding inappropriate interactions with representatives. To ensure a consistent

approach to relationships with representatives throughout VHA, clinical staff are encouraged to review this report and incorporate its recommendations into VISN, VA medical facility and service-level 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 C.F.R. § 2635.204(a). However, such items may be donated to a VA medical facility library or individual department for use by all VA employees. Gifts in support of VA official travel may be accepted by the department in accordance with 31 U.S.C. § 1353, 41 C.F.R. § 304 and VHA Handbook 1004.07. **NOTE:** *Government ethics rules (5 C.F.R. § 2635.204(a)) authorize acceptance of items valued at \$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 VA staff member to whom a gift is offered 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 to VA medical facilities for provision to VA staff or non-VA staff (e.g., employees of affiliates, volunteers, without compensation employees).

6. VA MEDICAL FACILITY ACCESS FOR PHARMACEUTICAL COMPANY REPRESENTATIVES

a. PCRs must be granted controlled access by the VA medical facility Chief, Pharmacy Service to all VA medical care facilities and staff who are on the contact list. PCRs must contact the VA medical facility pharmacy before scheduling any appointments with VA medical facility staff and 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 on-site or virtual visit. Appointments may be made by either telephone, email, or local scheduling process, but must be made in advance of visiting the staff member. 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. **NOTE:** *VA medical facilities can restrict PCR access to virtual visits.*

(2) VA medical facility clinicians and nursing staff must ensure the PCR has contacted the pharmacy prior to scheduling any appointments to ensure the PCR has received the necessary policies and procedures.

(3) The VA medical facility must prohibit the PCR from using the overhead public address (paging) system to locate any staff member of the VA medical facility. Contacts using the electronic paging system (beepers) or cell phones are generally discouraged, but are permissible if specifically requested by an individual VA health care provider.

(4) The VA medical facility must prohibit a PCR visiting a VA medical facility for a previously scheduled appointment from initiating 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, VA medical facility or clinic without a previously scheduled appointment is prohibited.

(5) VA medical facilities must develop a list of individuals or departments that wish to be contacted by PCRs. The VA medical facility must prohibit a PCR from attempting to make appointments with or leaving materials for any individuals or departments who are not on the list. **NOTE:** *This list may be obtained from the VA medical facility Chief, Pharmacy Services.*

(6) To maximize learning opportunities and minimize potential confusion on the part of health professions trainees (HPTs) still serving in their primary educational programs, the VA medical facility must prohibit PCRs from marketing or promoting to HPTs, both when on the VA campus and when practicing at affiliated sites outside of the VA campus. Any exceptions must be approved in advance by and conducted in the presence of their clinical staff supervisor or mentor.

(7) The VA medical facility must prohibit PCRs from attending a VA 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 (e.g., log-in and log-out-sheets, photo identification badges).

(9) The VA medical facility must prohibit PCRs from leaving promotional materials or making 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 Departments.
- (g) Urgent Care sites.
- (h) Ambulatory treatment centers.

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

c. The VA medical facility must prohibit PCRs from waiting 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. The VA medical facility must prohibit drug or drug supply samples from being provided by PCRs to VA health care providers outside of Pharmacy Service for any reason, including VA staff member personal use or for use by family or friends of the VA staff member.

e. PCRs and VA account managers are strongly discouraged from contacting individual members of VHA MAP for the purposes of product promotion. Requests to meet with a VHA MAP member must be coordinated through the Office of the Deputy Chief Consultant for Formulary Management, PBM Services.

f. PCRs are not allowed to complete or assist in completing required VA documentation to request that a product be evaluated for addition to the VANF. **NOTE:** See VHA Directive 1108.08.

g. The VA medical facility must prohibit PCRs from discussing specific patients with VA staff members. Patient-specific issues must be handled internally by VA health care providers.

h. The VA medical facility must prohibit PCRs who conduct business with VA from engaging in, permitting or encouraging conduct in violation of this directive. This includes any actions that may be reasonably perceived by VA staff to be in conflict with this directive.

i. PCRs must be made aware that local processes, including previously approved appointments, are subject to change at any time due to conditions and situations at the VA medical facility.

j. 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 VA medical facilities. Multiple occurrences may lead to additional sanctions. **NOTE:** Any sanctions issued may be communicated by the VISN Director, VA medical facility Director or Chief, Pharmacy Service to all VA medical facilities and VISNs.

(1) Sanctions may be imposed by VA medical facilities and may vary in significance from minor to major based on the type of violation by the PCR. **NOTE:** Suspension or limitation of visiting privileges are considered significant restrictions and need to be used judiciously and only with good cause.

(2) 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.

(3) Violations which are sustained after any appeals may be communicated by the VISN Director, VA medical facility Director or Chief, Pharmacy Service to other VA medical facilities and VISNs.

7. TRAINING

There are no formal training requirements associated with this directive.

8. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management must be addressed to the appropriate Records Officer.

9. DEFINITIONS

a. **Biologics.** For the purposes of this directive, biologics are drugs and drug-related supplies approved by the United States FDA Center for Biologics Evaluation and Research (CBER).

b. **Criteria-for-Use.** Criteria-for-use is a document developed by VA at a national level that describes the patient populations that would most likely benefit from use of the drug through inclusion and exclusion criteria based on available clinical evidence related to safety and efficacy. VA criteria-for-use documents may exist for both formulary and non-formulary drugs and 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.*

c. **Drug or Drugs.** For the purpose of this directive, drugs are:

(1) Articles recognized in the official United States Pharmacopoeia (USP), the Homeopathic Pharmacopoeia of the United States, VANF 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 c.(1), c.(2) or c.(3) of this definition.

d. **Drug-Related Supplies.** For the purpose of this directive, drug-related supplies are those related to the use of a drug, such as test strips or testing devices, inhaler mouthpieces, delivery systems or spacers, insulin syringes and tablet splitters. This

definition may also refer to medical supplies which may be dispensed through VA medical facility pharmacies to allow for on-going prescription refill delivery (e.g., catheters, bandages, ostomy supplies). VANF does not commonly list preferred medical supply products. **NOTE:** Refer to VHA Directive 1169, National Pharmacy Prosthetics and Logistics Committee, dated April 14, 2017, for additional information regarding determination of the responsible service for management and provision of non-drug supplies.

e. **New Molecular Entity.** NME is a drug product containing an active ingredient that has never before received FDA approval.

f. **Non-Promotable Drugs.** Non-promotable drugs are drugs designated by VA as non-promotable on the PBM Services website 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, Pharmacy Service.

g. **Non-Formulary.** Non-formulary, also referred to as non-VANF, refers to drugs or drug-related supplies (e.g., drug therapy supplies, medical foods or nutraceuticals) that are commercially available but are not included on VANF.

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

i. **VA National Formulary.** VANF is a list of therapeutic agents (e.g., drugs and drug-related supplies) that must be available for prescription at all VA medical facilities and cannot be made non-formulary by a VISN or individual VA medical facility. **NOTE:** VANF is maintained at: <https://www.pbm.va.gov/PBM/NationalFormulary.asp>.

10. REFERENCES

- a. 31 U.S.C. § 1353.
- b. 5 C.F.R. § 2635.204(a).
- c. 38 C.F.R. § 1.220.
- d. 41 C.F.R. Part 304.
- e. VHA Directive 1108.08, VHA Formulary Management Process, dated July 29, 2022.
- f. VHA Directive 1169, National Pharmacy Prosthetics and Logistics Committee, dated April 14, 2017.
- g. VHA Directive 4721, VHA General Post Funds - Gifts and Donations, dated August 13, 2018.

h. VHA Handbook 1004.07, Financial Relationships between VHA Health Care Professionals and Industry, November 24, 2014.

i. Veterans Health Administration. National Ethics Committee (NEC). Compensation to Health Care Professionals from the Pharmaceutical Industry.
<https://www.ethics.va.gov/pubs/necreports.asp>.

j. Veterans Health Administration. National Ethics Committee (NEC), Gifts to Health Care Professionals from the Pharmaceutical Industry.
<https://www.ethics.va.gov/pubs/necreports.asp>.

k. Department of Veterans Affairs Formulary Advisor:
<https://www.pbm.va.gov/apps/VANationalFormulary/>.

l. National Listing of Formulary Drugs:
<https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/National%20Formulary/Forms/AllItems.aspx/>. **NOTE:** This is an internal website and that is not available to the public.

m. Pharmacy Benefits Management Services: <https://www.pbm.va.gov/>.

n. Pharmacy Benefits Management Services. VA National Formulary:
<https://www.pbm.va.gov/PBM/NationalFormulary.asp>.

o. Risk Evaluation and Mitigation Strategy:
<https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems>.