

## VHA FORMULARY MANAGEMENT PROCESS

**1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive states responsibilities and standards for the management of the Department of Veterans Affairs (VA) National Formulary.

**2. SUMMARY OF MAJOR CHANGES:** Major changes include:

a. Updates content to reflect VA's ongoing transition to a new electronic health record (EHR) and to enable implementation of this directive at VA medical facilities using Cerner Millennium.

b. Adds definitions for EHR and prior authorization (see paragraph 3).

c. Removes responsibilities for the Consolidated Mail Outpatient Pharmacy Director and revises responsibilities for the Chair, VA medical facility Pharmacy and Therapeutics (P&T) Committee (see paragraph 5).

d. Removes responsibilities for non-formulary appeal review from the VA medical facility Chief of Staff and assigns them to the Chair, VA medical facility P&T Committee (see paragraph 5).

e. Removes paragraphs regarding compounding of non-sterile pharmaceutical preparations and inventory management as these topics are now addressed in VHA Directive 1108.12, Management and Monitoring of Pharmaceutical Compounded Sterile Preparations, dated November 5, 2018; and VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020, respectively.

f. Expands the discussion in paragraph 6.n. of the prior authorization drug request process to better distinguish between non-formulary and prior authorization drug request processes.

g. Removes paragraph regarding tablet splitting; tablet splitting guidance can now be found at (under Other Documents and Resources): <https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/SitePages/Home.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

**3. RELATED ISSUES:** VHA Directive 1108.10, Promotion of Drugs and Drug-related Supplies by Pharmaceutical Company Representatives, dated June 13, 2018; VHA Directive 1108.15, Continuation of Mental Health Medications Initiated by Department of Defense Authorized Providers, dated August 2, 2019; VHA Directive 1169, National Pharmacy, Prosthetics, and Logistics Committee, dated April 14, 2017; VHA Directive 1761, Supply Chain Management Operations, dated December 30, 2020; VHA Handbook 1108.04, Investigational Drugs and Supplies, dated February 29, 2012.

**4. RESPONSIBLE OFFICE:** 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-PCSAction@va.gov](mailto:VHA12-PCSAction@va.gov).

**5. RESCISSIONS:** VHA Directive 1108.08(1), VHA Formulary Management Process, dated November 2, 2016, is rescinded.

**6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of July 2027. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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

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

**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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## VHA FORMULARY MANAGEMENT PROCESS

### 1. PURPOSE

This Veterans Health Administration (VHA) directive states policy, procedures and responsibilities for the management of the Department of Veterans Affairs (VA) National Formulary (VANF). **AUTHORITY:** 38 U.S.C. § 7301(b).

### 2. BACKGROUND

Drug formularies in VA date back to the mid-1950s. Beginning in 1996, VA began an evolutionary process to move from a system of using more than 170 individual locally managed drug formularies to a formulary process that would result in a single national formulary (VANF). The migration to VANF has allowed VA to rely uniformly on evidence-based drug evaluations. The VANF process enables VA to focus on the goals of improved patient safety, appropriate drug use, improved access to pharmaceuticals, promotion of a uniform pharmacy benefit and reduction in the acquisition cost of drugs when feasible.

### 3. DEFINITIONS

a. **Adverse Drug Event.** An adverse drug event (ADE) is an injury resulting from the use of a drug by a patient.

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 Pharmacy Benefits Management (PBM) website: <https://www.pbm.va.gov>. **NOTE:** *Exceptions may be applied at the local level for operational reasons.*

c. **Drug-Related Supplies.** For the purposes 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. Drug-related supplies 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.*

d. **Drug Standardization List.** VA's Drug Standardization List is a listing of pharmaceutical products for which substitution is not permitted under normal circumstances. The intent is to provide the Veteran with a consistent and reliable drug product in instances where interchanging drugs from different manufacturers may compromise therapeutic response or patient safety. **NOTE:** *See paragraph 6.p. for rare*

circumstances when substitution may be allowed. See VA's Drug Standardization List (under National Formulary) at <https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/SitePages/Home.aspx>. This is an internal VA website that is not available to the public.

e. **Electronic Health Record.** Electronic health record (EHR) is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA) and Cerner platforms. **NOTE:** *The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

f. **Medical Food.** Medical food is food that has been specially formulated to be orally consumed or administered enterally, used under medical supervision, and requires a prescription. Medical food is intended for the management of a disease or condition for which there are distinctive nutritional requirements. For the purposes of this directive, medical food products that are in the form of a tablet, capsule, pill, liquid or powder and intended for the management of a disease or condition are considered in a similar manner to nutraceuticals by the VANF Committee. Examples of medical foods include: Metanx, Deplin, Axona, Limbrel and Sentra AM. **NOTE:** *The U.S. Food and Drug Administration (FDA) does not review or evaluate dietary supplements or medical foods for use or determine their safety or effectiveness.*

g. **New Molecular Entity.** A new molecular entity (NME) is a drug product containing an active ingredient that has never received FDA approval.

h. **Non-Formulary.** Non-formulary 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.

i. **Non-Formulary Request.** A non-formulary request is a request for a drug that is not listed on VANF.

j. **Nutraceuticals.** Nutraceuticals are products intended to supplement the diet. They contain one or more dietary ingredients such as vitamins, minerals, herbs or other botanicals, amino acids or other substances; are taken by mouth in the form of a capsule, tablet, pill or liquid; and labeled on the front panel as a "dietary supplement."

k. **Pharmaceutical Company Representative.** A pharmaceutical company representative is any individual employed by or contracted to represent a pharmaceutical manufacturer or retailer.

l. **Prior Authorization.** Prior authorization (also known within VA as Prior Authorization Drug Request (PADR) or PADR consult) is the process in which select VANF drugs are reviewed for appropriateness of use prior to prescribing to ensure their safe and proper use for Veterans receiving drugs or drug-related supplies within VA.

Prior authorization adjudications are completed at the national, Veterans Integrated Services Network (VISN) or VA medical facility level, depending on the established drug designation by the VANF Committee.

m. **Therapeutic Class.** Therapeutic class is a grouping of individual drugs with similar therapeutic uses, but not necessarily similar pharmacologic activity (e.g., an Antilipemic Therapeutic Class could contain 3-Hydroxy-3-Methylglutaryl Coenzyme A (HMG-CoA) Reductase Inhibitors (RI), Bile Acid Sequestrants, Fibric Acid Derivatives, and Nicotinic Acid).

n. **Therapeutic Interchange.** Therapeutic interchange (TI) is the authorized exchange of a prescribed drug with a therapeutic drug alternative that is available on the VANF, in accordance with pre-established, written guidance.

o. **Therapeutic Sub-class.** Therapeutic sub-class is a grouping of drugs with similar pharmacologic activity (i.e., the therapeutic class of Antihyperlipidemics would include the therapeutic subclass of HMG- CoA RI).

p. **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>.

#### 4. POLICY

It is VHA policy that the formulary management process provides pharmaceutical and supply products of the highest quality and best value, while ensuring the portability and standardization of this benefit to all eligible Veterans. It is VHA policy that VANF is the only drug formulary authorized for use in VHA; the use of VISN formularies or local drug formularies at individual VA medical facilities is prohibited. **NOTE:** *This directive does not apply to transitioning Service members for whom it is clinically appropriate to continue their mental health medications. See VHA Directive 1108.15, Continuation of Mental Health Medications Initiated by Department of Defense Providers, dated August 2, 2019, for details about these circumstances.*

#### 5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall compliance with this directive.

b. **Assistant Under Secretary for Health for Patient Care Services.** The Assistant Under Secretary for Health for Patient Care Services is responsible for:

(1) Supporting PBM Services with implementation and oversight of this directive.

(2) Announcing Medical Advisory Panel (MAP) member nominations on behalf of PBM Services.

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 VISNs.

(2) Assisting VISN Directors to resolve 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 by collaborating with the Assistant Under Secretary for Health for Patient Care Services and the Executive Director, PBM Services.

d. **Deputy Assistant Under Secretary for Health for Operations.** The Deputy Assistant Under Secretary for Health for Operations is responsible for collaborating with PBM Services on various formulary initiatives of strategic importance to VA.

e. **Executive Director, Pharmacy Benefits Management Services.** The Executive Director, PBM Services or designee (Deputy Chief Consultant, Formulary Management) provides oversight and monitoring that VANF drugs and drug-related supplies are uniformly available at VA medical facilities. The Executive Director is responsible for:

(1) Providing operational direction and support to secure VISN adherence to the VANF process and to ensure health care operations within VHA support its use, as necessary.

(2) Managing VANF, based on decisions by the VANF Committee for additions and status changes, including responding to requestors who submit requests for VANF changes within 30 days of receipt or request to acknowledge receipt and provide a targeted date for review of request. **NOTE:** *For further details regarding requests for change in VANF status and required documentation, see paragraph 6.i.*

(3) Appointing the Deputy Chief Consultant, Formulary Management and MAP Chair to oversee VANF Committee activities and ensuring that VANF Committee members and subject matter experts (SME) provide conflict of interest declarations at least annually. **NOTE:** *The VANF Committee is comprised of the VISN Pharmacist Executive (VPE) Committee and MAP. See paragraph 5.f.*

(4) Developing a procurement request after VANF status is established, and subsequently submitting the request to the National Contract Service.

(5) Maintaining databases that reflect drug utilization.

(6) Monitoring the use of select drugs and drug-related supplies.

(7) Reviewing non-formulary request data and provider-initiated appeals reported by VA medical facilities on a quarterly basis. For further details, see paragraph 6.n.

(8) Whenever possible and mutually beneficial, collaborating with the Department of Defense (DoD) Pharmacy Operations Division on joint contracts to standardize medication use among VA medical facilities and DoD medical treatment facilities.

(9) Assessing drug-related safety projects in collaboration with the VA National Center for Patient Safety, VHA Center for Medication Safety and VPEs.

(10) Developing responses to Congressional inquiries regarding drug therapy management issues with support from the VPE.

(11) Maintaining and updating formulary content to the VA Pharmacy Product System/National Drug File.

(12) Implementing and maintaining national business rules for managing drugs and drug-related supplies designated as Formulary-Prior Authorization National (PA-N) in accordance with paragraph 6.n.

(13) Maintaining VA's Drug Standardization List. For further details see paragraph 6.o.

(14) Supporting the VANF Committee Chairs in planning committee meeting agendas, chair meetings and other administrative tasks.

f. **Chairs, VA National Formulary Committee.** The VANF Committee is comprised of the national VPE Committee and MAP. The national VPE Committee consists of pharmacists that provide clinical, strategic and operational input to PBM Services on VANF and PBM issues. MAP is a national panel of practicing VA physicians and PBM National Clinical Pharmacy Program Managers that oversee VHA's Formulary Management process. MAP members are nominated by VISN leadership (e.g., VISN Director, Chief Medical Officer (CMO), Chief Nursing Officer (CNO)). The Deputy Chief Consultant, Formulary Management and MAP Chair co-chair the VANF Committee and are responsible for ensuring that the VANF Committee completes the following:

(1) Identifying, requesting and reviewing drugs, nutraceuticals (in accordance with paragraph 7 of this directive), and general categories of drug-related supplies (the VANF Committee does not routinely evaluate or determine specific brands of drug-related supplies) for listing to, or removal from, VANF. **NOTE:** *This includes reviewing formulary restrictions and approval infrastructure to ensure that agents commonly used for purposes not considered medically necessary are appropriately scrutinized and not prescribed. Examples include those drugs used solely for cosmetic purposes (see paragraph 8).*

(2) Prioritizing all FDA-approved and marketed NME and reviewing them based on their relevance to the Veteran population and the availability of comprehensive and clinically relevant information. **NOTE:** *When these criteria are met, NME reviews are ordinarily completed within 1 year from the time the product is marketed.*



(3) Reviewing data and national reports on non-formulary utilization and access to VANF products and taking appropriate action when necessary.

(4) Establishing criteria-for-use for VANF, selected non-formulary drugs and criteria for prior authorization drugs, when appropriate.

(5) Establishing pharmacological management guidance for VA providers for specific disease states as required.

(6) Overseeing the preparation of drug monographs for NME approved by FDA, based on internal PBM workload prioritization.

(7) Overseeing the performance of evidence-based, therapeutic class reviews that may or may not lead to national standardization contract initiatives.

(8) Providing national guidance regarding TI when required as a result of a VANF initiative (e.g., in instances of drug shortage or drug recall).

(9) Working with the Executive Director, PBM Services to plan VANF Committee meeting agendas, chair meetings and perform other administrative committee tasks.

(10) Identifying SME positions who are not VANF Committee members after consultation with PBM Services, offices of the respective clinical specialty, field advisory committees (FAC) and Quality Enhancement Research Initiative centers. **NOTE:** *SMEs are consulted on an ad hoc basis for those specialty areas that require input when VANF issues of interest are being discussed (e.g., dietitian/nutritionist, podiatrist, dentist).*

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

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Assigning a full-time VPE to manage a VISN PBM Office, chair or co-chair the VISN Pharmacy & Therapeutics (P&T) Committee and represent the VISN on the VANF Committee. **NOTE:** *The VISN Director or VISN CMO/CNO is encouraged to consult with the Executive Director, PBM Services, to ensure that candidates considered for this position possess the required knowledge, skills and abilities. The position of VPE refers to a single individual who promotes operational efficiency and provides the necessary attention to pharmacy-related activities. See paragraph 5.h. for VPE responsibilities.*

(3) Maintaining an active VISN P&T Committee. See paragraph 5.i. for further information.

(4) Assigning an appropriate complement of VISN pharmacy resources (financial and staffing) to support an expanded scope of services for the VPE. **NOTE:** *These expanded services include an ongoing review of operations, preparation for*

*accreditation and regulatory reviews and staffing assessments. To accomplish this goal, consideration should be given to establishing a VISN-level Clinical Pharmacist Practitioner, Pharmacoeconomics Specialist, a PBM Data Manager and pharmacy administrative support.*

(5) Ensuring that VANF is consistently implemented and all guidance (e.g., criteria-for-use) enforced throughout the VISN.

(6) Ensuring that the VPE updates VISN guidelines for the prescribing of VANF products to meet the intent of this directive.

(7) Ensuring that a non-formulary request process is in place to address specific patient requirements within 96 hours of a request, and that this process is functioning in all VA medical facilities within the VISN. **NOTE:** See paragraph 6.m. for further information regarding expectations for this process.

(8) Ensuring that local forums exist where formulary issues can be discussed with Veterans Service Organization representatives on a continuous and ongoing basis.

(9) Ensuring that VA medical facilities follow national reporting processes for non-formulary request data and provider-initiated appeals; collecting and analyzing the data to determine if the process is implemented appropriately and effectively in their VA medical facilities. For reporting details see paragraph 6.o.

(10) Tracking both approved and disapproved non-formulary requests.

h. **Veterans Integrated Services Network Pharmacist Executive.** The VPE is responsible for:

(1) Serving as chair or co-chair of the VISN P&T Committee and coordinating its activities; serving as the VISN representative to the VANF Committee.

(2) Participating in scheduled VISN P&T Committee meetings at least quarterly.

(3) Assessing and evaluating national, VISN and local drug utilization for the VISN P&T Committee.

(4) Guiding VISN-level formulary management activities including implementation of VANF decisions, national contracts, cost avoidance initiatives and evidenced-based prescribing; updating VISN guidelines for the prescribing of VANF products to align with this directive and national guidance.

(5) Providing operational support for VANF processes including coordination of pharmacy benefit activities for the VISN.

(6) Attending and participating in monthly joint VANF Committee conference calls and quarterly face-to-face or virtual meetings with PBM Services.

(7) Collecting and collating drug-related information from VA medical facilities within the VISN when requested by PBM Services.

(8) Providing input to PBM Services regarding the impact of VANF decisions on VISN operations.

(9) Reporting VISN restrictions to PBM Services, as requested. **NOTE:** *In the absence of national guidelines, reasonable restrictions may be imposed at the VISN level. In some instances, it may also be appropriate for VISNs to further institute VA medical facility-specific restrictions; however, those restrictions must be clinically driven. National restrictions such as criteria-for-use and prior authorization criteria may not be altered by the VISN or VA medical facility. VISN restrictions must be evidence-based and allow for prescribing by authorized VA providers (with recognized expertise) when clinical conditions warrant their use. Restrictions may be based on economic issues if safety and efficacy are equivalent. Restrictions must not be so limited that patients with legitimate medical needs are prevented from receiving needed medications.*

(10) Reviewing clinical evidence compiled by the VANF Committee and making informed determinations regarding VANF issues.

(11) Representing the VISN on VANF drug and pharmacy policy decisions.

(12) Widely disseminating draft drug monographs, criteria-for-use statements and pharmacologic management guidance to appropriate VISN clinicians for comment as requested by the VANF Committee.

(13) Assisting PBM Services in developing responses to Congressional inquiries into drug therapy management issues.

(14) Overseeing drug-related data management utilizing local, VISN and national databases to track issues including patient outcomes and pharmacy costs.

(15) Providing minutes of VISN meetings and VA medical facility P&T Committee meetings when requested by PBM Services.

(16) Implementing and maintaining VISN business rules for managing drugs and drug-related supplies designated as Formulary-Prior Authorization VISN (PA-V) in accordance with paragraph 6.n.

(17) Completing conflict of interest declarations on an annual and ad hoc basis.

(18) Serving as a liaison between local and VISN medication safety efforts and national safety efforts.

i. **Chair, Veterans Integrated Services Network Pharmacy & Therapeutics Committee.** A VISN P&T Committee (formerly referred to as the VISN Formulary Committee) is comprised of VISN-based clinical personnel and generally chaired by the VPE or a physician appointed by the VISN Director or VISN CMO/CNO. The

committee's function is to provide clinical oversight and guidance for the formulary review process, coordinate VANF initiatives at the VISN and VA medical facility levels and communicate VISN-specific submissions to the VANF Committee for consideration as an essential component of the VANF process. The VISN P&T Committee Chair is responsible for:

(1) Identifying and requesting drugs for listing to or removal from VANF for review at the national level by the VANF Committee. See paragraph 6.i. for required documentation for VANF requests.

(2) Widely disseminating draft and final drug monographs, criteria-for-use statements, pharmacologic management guidance and other material necessary to manage the formulary process.

(3) Communicating VANF decisions to VA medical facility P&T Committees and all clinical staff.

(4) Reviewing PBM reports and VA medical facility data on non-formulary utilization or access to VANF products and, when necessary, taking appropriate action.

(5) Reviewing and trending reports of ADEs throughout the VISN by utilizing the VA Adverse Drug Event Reporting System (ADERS).

(6) Assessing, when necessary, clinical outcomes related to medications being split (e.g., using laboratory data and vital signs). Further information regarding tablet splitting is located at (under Other Documents and Resources):

<https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/SitePages/Home.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

(7) Developing the VISN TI plan and providing a copy of it to the Executive Director, PBM as requested, when required by a VANF initiative. For further details regarding the VISN TI plan, see paragraph 6.p.

(8) Reviewing data provided to the Executive Director, PBM Services on the formulary status designation of drugs within the VISN and ensuring their accuracy with the VANF designation.

(9) Ensuring VISN P&T Committee members and subject matter experts provide conflict of interest declarations at least annually.

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

(1) Managing pharmacy operations and ensuring implementation and compliance with all requirements of this directive.

(2) Ensuring that a physician is appointed to chair the VA medical facility P&T Committee.

(3) Ensuring that the VA medical facility has a non-formulary request process consistent with paragraph 6.m.

(4) Ensuring written VA medical facility procedures require that:

(a) All items listed on VANF are available. **NOTE:** *Not all drugs and drug-related supplies on VANF must be in stock; however, there must be local processes in place to obtain items as needed such as through ordering or transmitting to the Consolidated Mail Outpatient Pharmacy.*

(b) Pharmacy Product System/National Drug File software patches are installed into EHR accounts as close to the time as the patches are released as feasible and that local drug files are mapped to the updated medication terms.

(c) All business relationships between VA medical facility personnel and pharmaceutical company representatives must comply with VHA Directive 1108.10, Promotion of Drugs and Drug-related Supplies by Pharmaceutical Company Representatives, dated June 13, 2018.

k. **VA Medical Facility Chief, Pharmacy Service.** The VA medical facility Chief, Pharmacy Service (or designated associate chiefs or supervisors) is responsible for:

(1) Procuring emergently needed non-formulary or prior authorization medications. **NOTE:** *Requests for urgently or emergently needed non-formulary medications (e.g., antimicrobials) are to be reviewed immediately and, if approved, promptly procured so as not to adversely affect the patient.*

(2) Adjudicating routine non-formulary drug requests and PADR within 96 hours of submission of a completed request. See paragraphs 6.m. and 6.n. for further information. **NOTE:** *This does not apply to transitioning Service members for whom it is clinically appropriate to continue their mental health medications. See VHA Directive 1108.15 for details about these circumstances.*

(3) Educating pharmaceutical company representatives regarding VHA policy on business relationships with VA medical facility personnel. **NOTE:** *For further details see VHA Directive 1108.10.*

(4) Complying with competitively bid national contracts for pharmaceuticals or related services that are based on purchase volume requirements.

(5) Ensuring, along with all VA providers, that non-VA supplied medications are maintained as a subcategory in the patient's EHR medication profile, in addition to active and inactive VA pharmacy dispensed medications.

(6) Ensuring that all drugs and drug-related supplies on VANF are in the local drug file and available for prescribing.

(7) Ensuring VANF status designations and drug pricing in the local drug files are up to date and accurate where there is no enterprise-level drug file. **NOTE:** *This is not applicable to VA medical facilities using the Cerner EHR as Cerner has one enterprise-level drug file that is controlled at the national level.*

(8) Ensuring that any drug or supply designated as “No Buy” by the VANF Committee is not procured. Current drugs and supplies designated as “No Buy” can be found on VHA PBM SharePoint at (under National Formulary): <https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/SitePages/Home.aspx>. **NOTE:** *This is an internal VA website that is not available to the public. No Buy is the term utilized to identify when the purchase of a specific drug or supply is prohibited, due to law or such designation by the VANF Committee.*

(9) Implementing and maintaining the non-formulary request process and VA medical facility business rules for drugs and drug-related supplies designated as Prior Authorization-Facility (PA-F) in accordance with paragraph 6.n.

(10) Assigning a Prior Authorization point of contact (POC) at the VA medical facility. See paragraph 6.n.

(11) Ensuring that pharmacy staff review non-formulary utilization data for errors before it is reported to PBM Services. For reporting see paragraph 6.o.

I. **Chair, VA Medical Facility Pharmacy and Therapeutics Committee.** The VA medical facility P&T Committee, or similar authorized body, must be chaired by a physician appointed by the VA medical facility Chief of Staff or Director. The Chair, VA medical facility P&T Committee is responsible for:

(1) Performing all functions required by health care accreditation standards and the American Society of Health-System Pharmacists (ASHP) Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System, available at: <https://www.ashp.org/pharmacy-practice/policy-positions-and-guidelines/browse-by-topic/formulary-management>.

(2) Identifying medication-related problems and implementing measures to improve medication safety, in conjunction with the appropriate department or service line representatives.

(3) Approving a list of non-approved abbreviations to be avoided during the act of prescribing in compliance with health care accreditation standards.

(4) Implementing, supporting and monitoring compliance with VANF initiatives.

(5) Monitoring non-formulary utilization from the EHR or Corporate Data Warehouse and providing the information to the VISN P&T Committee when requested.

(6) Providing input to the VISN P&T Committee regarding the impact of VANF decisions on VA medical facility operations and ensuring it is informed of any problems or concerns regarding VANF or prescribing.

(7) Ensuring compliance with access to VANF items in closed therapeutic classes and sub-classes or select therapeutic classes and sub-classes.

(8) Ensuring compliance with the VISN TI plan when required by a VANF initiative. See paragraph 6.q. for further details regarding the VISN TI plan.

(9) Evaluating all protocols concerned with the use of investigational drugs on human subjects. **NOTE:** *For more information, see VHA Handbook 1108.04, Investigational Drugs and Supplies, dated February 29, 2012.*

(10) Approving non-formulary medications prescribed for humanitarian or compassionate use (e.g., an investigational new drug) prior to use.

(11) Ensuring that the use of a placebo is strictly prohibited, except when used as part of an Institutional Review Board-approved research protocol with the informed consent of all research participants. **NOTE:** *A placebo is an inert or innocuous substance without pharmacologic properties.*

(12) Establishing a course of action for the review of an investigational drug under emergency use or treatment investigational new drug use, to ensure protocol adherence when existing procedures must be expedited.

(13) Evaluating all protocols concerned with the use of investigational drugs for impact on pharmacy services in an effort to assure appropriate drug management.

(14) Approving non-medication protocols such as nutritional supplementation and wound care. **NOTE:** *More information on non-medication protocols is available in VHA Directive 1108.07(1), Pharmacy General Requirements, dated March 10, 2017. Additionally, more information on nursing medication and non-medication protocols is available in VHA Directive 1108.13(1), Provision and Use of Nursing Medication Management Protocols in Outpatient Team-Based Practice Settings, dated February 6, 2019.*

(15) Approving non-patient-specific medications that can be transported and administered by VA medical facility staff.

(16) Ensuring the VA medical facility P&T Committee meets as often as necessary, but at least four times each calendar year.

(17) Maintaining detailed minutes of all proceedings at every meeting, including subcommittee reports. **NOTE:** *Minutes are prepared by the VA medical facility Chief, Pharmacy Service, or pharmacy designee, who acts in the capacity of Executive Secretary.*

(18) Forwarding VA medical facility P&T Committee minutes to the Medical Executive Committee or other approving body according to VA medical facility procedures, for review following approval by the P&T Committee.

(19) Effectively communicating, implementing and enforcing VANF decisions related to formulary designations to all VA medical facility clinical staff.

(20) Reviewing and forwarding requests for VANF addition or removal of drugs and drug-related supplies to the VISN P&T Committee, which may submit the request to the Executive Director, PBM Services for consideration by the VANF Committee.

(21) Performing periodic reviews for non-formulary prescribing trends including appropriateness of use and percentages for approvals and disapprovals.

(22) Ensuring that the VA medical facility has a mechanism in place that complies with the drug usage evaluation and medication indicator requirements of health care accreditation standards.

(23) Evaluating and assessing ADEs as reported through VA ADERS, medication error and close call reports for the VA medical facility at each VA medical facility P&T committee meeting, or a minimum of quarterly, to identify trends and determine what actions can be taken to prevent future occurrences.

(24) Including ADE report reviews as a standing agenda item at meetings and forwarding any process or system improvements to the VISN P&T Committee.

(25) Approving the addition of any controlled substances in the VA medical facility self-medication program.

(26) Ensuring VA medical facility P&T Committee members and subject matter experts provide conflict of interest declarations at least annually.

(27) Establishing a system to receive and adjudicate any provider-initiated appeals of a disapproved non-formulary drug request or PADR. **NOTE:** *This does not apply to transitioning Service members for whom it is clinically appropriate to continue their mental health medications. See VHA Directive 1108.15 for details about these circumstances.*

m. **VA Providers.** For the purposes of this directive, a VA provider is a licensed independent practitioner (e.g., physician, dentist, physician's assistant, pharmacist, nurse practitioner) with prescriptive authority within VHA. VA providers are responsible for:

(1) Ensuring all non-VA patient medications not in the drug file are communicated to the pharmacy so providers can document and maintain all non-VA medications as a subcategory in the patient medication profile.

(2) Prescribing by generic drug name (official chemical or non-proprietary).



(3) Prescribing medications in accordance with VANF requirements and established criteria-for-use, except in situations in which clinical judgment mandates otherwise.

**NOTE:** *Exceptions include transitioning Service members for whom it is clinically appropriate to continue their mental health medications. See VHA Directive 1108.15 for details about these circumstances.*

(4) Prescribing medications in accordance with VHA treatment guidelines.

(5) Submitting written or electronic non-formulary drug requests or PADRs, as needed. **NOTE:** *For further details regarding the non-formulary and PADR processes, see paragraphs 6.m. and 6.n.*

(6) Reporting ADEs in accordance with VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, dated May 15, 2020, and VA medical facility procedures.

(7) Adhering to standards in VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry, dated November 24, 2014, and VHA Directive 1108.10 related to financial relationships and procedures for interacting with pharmaceutical company representatives.

## 6. PROCEDURES

a. VANF is the sole drug formulary used in VA.

b. VISNs and VA medical facilities are not permitted to modify criteria-for-use or formulary designations approved by the VANF Committee.

c. VANF contents must be grouped according to the VA Classification System or other nationally developed or licensed classification system adopted by PBM Services and updated when changes are required. Current VA drug classes are listed on the VANF file (Excel Spreadsheets under National Formulary) at:

<https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/SitePages/Home.aspx>.

**NOTE:** *This is an internal VA website that is not available to the public.*

d. Individual VA medical facilities must list VANF drugs and drug-related supplies in the EHR and are prohibited from marking VANF agents as non-formulary in their local drug file as a means to enforce restrictions or control utilization.

e. Products with FDA approval are to be given priority consideration for addition to VANF over non-FDA approved products, unless the VANF Committee makes an alternative decision that is evidence-based.

f. All decisions for VANF are made by majority vote of the VANF Committee. In situations where consensus cannot be reached, the MAP recommendation prevails.

g. A determination, made by consensus of the VANF Committee, may result in the designation of a drug or drug-related supply as formulary with prior authorization. The adjudication of requests for these VANF items may be done at the national (PA-N),

VISN (PA-V) or VA medical facility (PA-F) level. The level at which adjudication is performed is part of the decision to designate a product as formulary with prior authorization.

h. When consensus is reached by the VANF Committee regarding a given drug or drug-related supply, the contracting requirements (as determined by PBM Services) are sent to the National Acquisition Center by assigned PBM staff to issue a solicitation, receive all bids and make an award, when applicable.

i. All NME reviews must emphasize safety and efficacy in patient populations similar to the Veteran population.

j. Drugs and drug-related supplies are not added to VANF solely for the purpose of performing a clinical trial; however, VANF is not intended to impede the use of any pharmaceutical agent in legitimate scientific studies.

k. A request for drug or drug class review may be submitted to [AskPBMFormulary@va.gov](mailto:AskPBMFormulary@va.gov) by a VISN P&T Committee, a member of the VANF Committee or a VHA Central Office national program director.

l. **Requests for Change in VA National Formulary Status.** A request for change in VANF status may be submitted to [AskPBMFormulary@va.gov](mailto:AskPBMFormulary@va.gov) by a VISN P&T Committee, a member of the VANF Committee, a VHA Chief Medical Consultant, VHA (National) CMO or CNO, VHA FAC or a VHA Technical Advisory Group (TAG). All completed requests for change in VANF status must be maintained by the Executive Director, PBM Services, through the VANF Committee minutes. **NOTE:** *An individual or group of clinicians may submit requests for VANF changes through their VISN P&T Committee(s) after discussion and approval by their VA medical facility P&T Committee.*

(1) All requests for addition or change in VANF status must contain:

(a) Minutes of the VANF Committee or other acknowledged meeting in which action was taken on the product (if applicable).

(b) Completion of VHA National Formulary Request form. See VA Form 10-313, VHA National Formulary Request for Formulary Review Form for Addition or Removal Requests by VHA Leadership. The form for requests by VA providers is available on VHA PBM SharePoint (National Formulary > General Documents) at <https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/SitePages/Home.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.* The form must contain the following information:

1. Drug name.
2. Dosage form.
3. Indication(s).

4. Safety.

5. Dosing and administration.

6. Monitoring parameters.

7. Efficacy outcomes.

8. Advantages over current VANF products.

9. Literature citations that support the recommendations.

10. Current utilization of the product as well as potentially competing products as indicated.

11. Price comparisons.

12. Conclusions and intended use or place in therapy specific to the Veteran population.

(c) Disclosure, by the parties presenting the drug or drug-related supplies for VANF addition or change, of any financial or other relationship with the pharmaceutical manufacturer of the requested product or other pharmaceutical company that has a competing product.

(d) The signature of the VPE, VANF Committee member or a VHA Chief Medical Consultant, VHA (National) Chief Consultant, VHA FAC or a VHA TAG. **NOTE:** Requests are to be forwarded to: [AskPBMFormulary@va.gov](mailto:AskPBMFormulary@va.gov).

(2) With regard to pharmacy-dispensed drug-related supplies, requests for a change of VANF status may be initiated by the VA medical facility's Clinical Product Review Committee and must be submitted to the VISN P&T Committee for review prior to receipt by the Executive Director, PBM Services for consideration by the VANF Committee. **NOTE:** *The VANF Committee does not routinely evaluate or determine specific brands of drug-related supplies. Refer to VHA Directive 1169 for additional information regarding determination of the responsible service for management and provision of non-drug supplies.*

(3) In therapeutic classes or therapeutic sub-classes where national standardization contracts have been awarded, additional items from the same class or sub-class may not be added to VANF; however, when medically necessary, they are to be made available through the non-formulary process.

m. **Non-Formulary Request Process.**

(1) A non-formulary request process must exist at each VA medical facility to ensure all of the following:

(a) Decisions are evidence-based and timely.

(b) Urgent requests for non-formulary agents are immediately addressed by individual(s) identified in VA medical facility procedures.

(c) Non-urgent requests, with all necessary information for non-formulary agents, are reviewed and the requestor notified of the decision within 96 hours of receipt of the submission. **NOTE:** *The requestor should make every effort to include the necessary information needed to evaluate non-formulary requests. For non-urgent requests, if the necessary information is not received in a timely manner, the reviewer will work with the VA provider to complete the request within 96 hours. If the information is not provided, the reviewer will discontinue the request. The requestor may resubmit a new non-formulary request once the necessary information is available. Pharmacy staff utilizing CPRS are not required to adhere to the consult standards that prohibit the use of the “discontinue” function for administrative consult requests stipulated in VHA Directive 1232(4), Consult Processes and Procedures, dated August 24, 2016. Instead, consults with [space]PADR in the title may use the “discontinue” function as described above.*

(2) If the non-formulary request’s degree of urgency or emergency is in question, the drug is to be provided immediately and the nature of the urgency or emergency reviewed afterwards by the VA medical facility P&T Committee.

(3) Non-formulary drugs are only to be approved when one or more of the following applies:

(a) A documented contraindication exists to the formulary agent(s).

(b) The patient has had a documented adverse reaction to the formulary agent(s).

(c) The patient has had a documented inadequate therapeutic response to formulary therapeutic alternatives.

(d) No formulary alternative exists.

(e) The patient has previously responded to a non-formulary agent and serious risk is associated with a change to a formulary agent.

(f) Other circumstances having compelling evidence-based clinical reasons. **NOTE:** *These circumstances include transitioning Service members for whom it is clinically appropriate to continue their mental health medications. See VHA Directive 1108.15 for details.*

(4) All provider-initiated appeals of non-formulary drug requests are received and adjudicated by the Chair, VA medical facility P&T Committee.

(5) No administrative action will be taken to discontinue pharmacotherapy when initiated by an authorized provider at one VA medical facility, when a patient transfers their care to a second VA medical facility or when care is transferred back to the primary

VA medical facility. However, VA providers need to exercise good clinical judgment to discontinue a medication once the determination is made that it is not the best agent for a given clinical situation.

(6) A new approval for prior authorization or non-formulary use is not required for patients who have previously received approval for the agent, if their care has been transferred to another VA medical facility or when care is transferred back to the primary VA medical facility.

(7) For selected non-formulary approvals, VISN P&T Committees or VA medical facility P&T Committees need to require a reevaluation of the approval based upon clinical response, new clinical findings or after a pre-determined period of time has elapsed.

n. **Prior Authorization Drug Request Process.** The VANF Committee designates all drugs and drug-related supplies submitted for formulary consideration as either formulary or non-formulary. A subset of formulary agents, as determined by the Committee, is designated as prior authorization drugs requiring review and approval through the following established processes prior to dispensing. ***NOTE: Prior authorization determinations are completed at the national, VISN or VA medical facility level, depending on the established prior authorization designation (i.e., PA-N, PA-V or PA-F).***

(1) All formulary agents designated as prior authorization require Prior Authorization Drug Request (PADR) approval prior to dispensing. ***NOTE: VA medical facilities may use multiple options for implementing PA-F requirements such as PADR consult, local order sets or drug file messaging.***

(2) For drugs and drug-related supplies designated as Formulary PA-F, business rules must be established and maintained at the local VA medical facility level.

(3) For drugs and drug-related supplies designated as Formulary PA-V, business rules must be established and maintained for submitting and adjudicating requests.

(4) For drugs and drug-related supplies designated as Formulary PA-N, business rules must be established and maintained. The business rules specify and govern the business rules and technical details of PA-N inter-facility requests, such as:

- (a) Submission of PA-N request by a VA provider.
- (b) Review of the submission.
- (c) Adjudication of VA provider appeals.
- (d) Communication of all determinations to the originating VA provider.
- (e) Monitoring of response times and outcomes.

(5) PADR adjudication processes must ensure:

(a) Decisions are evidence-based and timely.

(b) Urgent or emergent requests for prior authorization drugs and drug-related supplies are immediately addressed according to VA medical facility procedures to provide the drug immediately; the request's degree of urgency or emergency is reviewed afterwards by the VA medical facility P&T Committee, if needed.

(c) Non-urgent PADRs are reviewed and the requestor notified of the decision as soon as possible, ideally within 96 hours of the receipt of the submission. **NOTE:** *The requestor should make every effort to include the necessary information needed to evaluate the PADR. If the information is not provided, then the reviewer will discontinue the request. The requestor may resubmit a new PADR once the necessary information is available.*

(6) All provider appeals of PADRs are received and adjudicated by the Chair, VA medical facility P&T Committee, except for PADRs designated to the VISN or national levels. **NOTE:** *Prior authorization appeals at the VISN or national levels are adjudicated in accordance with business rules at the appropriate levels.*

(7) No administrative action will be taken to discontinue pharmacotherapy when initiated by an authorized provider at one VA medical facility, when a patient transfers their care to another VA medical facility or when the patient is transferred back to the primary VA medical facility. However, VA providers need to exercise good clinical judgment to discontinue a medication once the determination is made that it is not the best agent for a given clinical situation.

(8) A new approval for prior authorization is not required for patients who have previously received approval for the agent, if their care has been transferred back to another VA medical facility or when care is transferred back to the primary VA medical facility.

(9) For selected prior authorization approvals, the VISN or VA medical facility P&T Committees may require a reevaluation of the approval based upon clinical response, new clinical findings or after a pre-determined period of time has elapsed.

(10) A position entitled Prior Authorization POC has been added to the PBM phone directory and is to be assigned by each VA medical facility's Chief, Pharmacy Service to ensure communication and coordination for PA-N requests. **NOTE:** *It is highly recommended that VA medical facilities populate this directory with an Outlook email group versus assigning responsibility to one person.*

(11) Every effort must be made to process PADRs within 96 hours of submission of a VA provider's completed request, in alignment with non-formulary request requirements in this directive.

o. **Non-Formulary Reporting.**

(1) Each VISN must ensure that non-formulary utilization data at the VA medical facility level is reported and consistent with national guidance located at [https://dvagov.sharepoint.com/sites/VHAPBM/efficiency/PADR/Pages/PADR\\_Consult.aspx](https://dvagov.sharepoint.com/sites/VHAPBM/efficiency/PADR/Pages/PADR_Consult.aspx). **NOTE:** *This is an internal VA website that is not available to the public.* Reported information must include all of the following:

- (a) The number of non-formulary requests received.
- (b) The number of non-formulary requests approved.
- (c) The number of disapproved non-formulary requests.
- (d) The number of non-formulary requests not completed within 96 hours.

(e) A list of individual non-formulary requests not completed within 96 hours, including the actual number of hours, reason for the delay and outcome. **NOTE:** *This information is entered into the PBM database and is reviewed on a quarterly basis by the Executive Director, PBM Services with the VANF Committee.*

(2) Each VISN must ensure that provider-initiated appeals of non-formulary drug request data at the VA medical facility level is reported consistent with national guidance located at [https://dvagov.sharepoint.com/sites/VHAPBM/efficiency/PADR/Pages/PADR\\_Consult.aspx](https://dvagov.sharepoint.com/sites/VHAPBM/efficiency/PADR/Pages/PADR_Consult.aspx). **NOTE:** *This is an internal VA website that is not available to the public.* Reported data must include all the following:

(a) The number of provider-initiated appeals for non-formulary drug requests received.

(b) The number of provider-initiated appeals for non-formulary drug requests where there was concurrence with the original disapproval.

(c) The number of provider-initiated appeals for non-formulary drug requests where the original disapproval was overturned.

(d) The number of provider-initiated appeals for non-formulary drug requests not completed within 96 hours.

(e) A list of individual provider-initiated appeals for non-formulary drug requests not completed within 96 hours, including the actual number of hours, reason for delay and outcome. **NOTE:** *This information is reviewed on a quarterly basis to by the Executive Director, PBM Services.*

p. **VA Drug Standardization List.** Since VHA policy is to dispense generically equivalent drugs when they are available, the Executive Director, PBM Services must maintain a list of pharmaceutical products for which substitution is not permitted. Such products are published as the VA Drug Standardization List. In most instances, this is accomplished by awarding a mandatory national contract. Products are added to this list

by vote of the VANF Committee. Decisions are based on reviews of therapeutic equivalency or patient safety data. Substitution is allowed in rare circumstances when the Drug Standardization item is on back order or the patient has a documented intolerance to the standardized product. VA providers must be alerted by a designated individual in the VA medical facility Pharmacy Service when it is necessary to dispense an alternative product. The VA Drug Standardization List is available on the PBM Services website (under National Formulary) at:

<https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/SitePages/Home.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

q. **Therapeutic Interchange.** Therapeutic Interchange (TI) of drugs is permissible when required as a result of a VANF initiative and according to the following:

(1) The VANF Committee must consider the clinical consequences of any TI, including a review of:

(a) Laboratory reports to determine format, frequency, and outcome.

(b) The impact on clinical staff and clinic access.

(c) The cost impact for conversion including the estimated savings.

(d) The potential for medication errors.

(e) A review of VA ADERS data for all ADEs associated with the TI implementation phase.

(2) The Executive Director, PBM Services or designee provides guidance including on product conversion guidelines, and patient and VA provider information letters regarding TI to each VISN when deemed appropriate by the VANF Committee.

(3) VISN TI plans are developed by the VISN P&T Committee and must include examples of patient and VA provider communication instruments, education materials, and a general description of how TI will be accomplished. A copy of the VISN TI plan must be sent to the Executive Director, PBM Services if the information is requested.

r. **Restrictions.** Restrictions to prescribing can be established for VANF items that require close monitoring to ensure appropriate use. For example, in the case of anti-infectives, VA medical facility-level restrictions intended to prevent resistance are permissible. Restrictions may include evidence-based guidelines or prescribing privileges for VA providers with specific expertise. Restrictions may be based on economics if safety and efficacy are equivalent. Restrictions must not be so limiting that patients with legitimate medical needs are prevented from receiving medications and supplies.



## 7. NUTRACEUTICALS, DIETARY SUPPLEMENTS AND MEDICAL FOODS

a. The VANF Committee may determine that certain dietary supplements, also known as nutraceuticals or medical foods, can be considered for use in VA patients if the following conditions are met:

(1) The product possesses sufficient scientific evidence to support its safe and effective use in the treatment of a specified disease state or condition. **NOTE:** *The evidence must come from well-designed, randomized, controlled trials, providing level 1A evidence and published in peer-reviewed journals.*

(2) The product satisfies or supplements an unmet need in the treatment of a medical condition or offers an advantage over FDA-approved pharmaceuticals (e.g., based on safety, efficacy or cost).

(3) PBM Services identifies and gives preference to those manufacturers who:

(a) Comply with 21 C.F.R. part 111, which requires manufacturers of dietary supplements to comply with current good manufacturing practices.

(b) Provide evidence that these supplements or medical foods are produced in a quality manner, do not contain contaminants or impurities, and are accurately labeled. **NOTE:** *PBM Services gives preference to those manufacturers that are given a “seal of approval or certification” from a third-party evaluator (e.g., Consumer Lab, USP Verified, NPA’s TruLabel) providing oversight of manufacturing and product quality in terms of identity, purity, strength and composition of the product produced.*

(c) Maintain certification throughout the duration of the VA contract, if awarded, or alternatively manufacture their product(s) in an FDA-approved manufacturing facility. **NOTE:** *Consideration of any product intended as a food or beverage is prohibited.*

b. A PBM National Clinical Pharmacy Program Manager on the VANF Committee, or the requesting VISN, follows procedures as listed in paragraph 6.i. for requests for formulary change, reviews available clinical evidence for both safety and efficacy for the product and presents the findings to the VANF Committee. Specific to nutraceutical reviews and presentations, all factors or product advantages which are of interest (e.g., fish oil products with higher potency requiring a lower number of capsules to achieve desired dose) should be included. **NOTE:** *VHA Directive 1438, Clinical Nutrition Management and Therapy, dated September 19, 2019, and associated National Dietary Supplements Contract should be included in evaluations of these requests.*

c. Once the requirements in paragraph 7.a. and paragraph 7.b. have been completed and VANF status has been established for the dietary supplement, the Executive Director, PBM Services must develop a procurement request and submit it to the National Contract Service so that the following steps can be completed:

(1) Develop a solicitation to request bids from manufacturers of the specific nutraceutical or medical food.

(2) Provide a projected number of users of the product.

(3) Identify manufacturers, giving preference to those possessing a “seal of approval or certification” for their product or those manufacturers producing their product in an FDA-approved manufacturing facility.

## **8. COSMETIC AND ENHANCEMENT DRUGS**

a. Cosmetic and enhancement drugs (e.g., hair growth products, hair bleaching products) can be provided only for the purpose of improving a patient’s documented physical or mental health condition and treatment plan.

b. The use of drugs for cosmetic or enhancement purposes may be considered medically necessary when provided in connection with the treatment of a service-connected injury or other clinically indicated care.

c. The use of a drug solely to improve normal physiologic function or to enhance body appearance is generally not considered medically necessary; therefore, the drug is not to be prescribed.

## **9. TRAINING**

There are no formal training requirements associated with this directive.

## **10. 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 should be addressed to the appropriate Records Officer.

## **11. REFERENCES**

a. 38 U.S.C. §§ 7301(b), 8125.

b. 21 C.F.R. part 111.

c. VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, dated May 15, 2020.

d. VHA Directive 1108.07(1), Pharmacy General Requirements, dated March 10, 2017.

e. VHA Directive 1108.10, Promotion of Drugs and Drug-Related Supplies by Pharmaceutical Company Representatives, dated June 13, 2018.

f. VHA Directive 1108.13(1), Provision and Use of Nursing Medication Management Protocols in Outpatient Team-Based Practice Settings, dated February 6, 2019.

g. VHA Directive 1108.15, Continuation of Mental Health Medications Initiated by Department of Defense Authorized Providers, dated August 2, 2019.

h. VHA Directive 1169, National Pharmacy, Prosthetics, and Logistics Committee, dated April 14, 2017.

i. VHA Directive 1232(4), Consult Processes and Procedures, dated August 24, 2016.

j. VHA Directive 1438, Clinical Nutrition Management and Therapy, dated September 19, 2019.

k. VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry, dated November 24, 2014.

l. VHA Handbook 1108.04, Investigational Drugs and Supplies, dated February 29, 2012.

m. Criteria for Use. PBM Website. <https://www.pbm.va.gov>.

n. Prior Authorization Drug Review Reports Home Page. [https://dvagov.sharepoint.com/sites/VHAPBM/efficiency/PADR/Pages/PADR\\_Consult.aspx](https://dvagov.sharepoint.com/sites/VHAPBM/efficiency/PADR/Pages/PADR_Consult.aspx). **NOTE:** *This is an internal VA website that is not available to the public.*

o. VA Form 10-313, VHA National Formulary Request for Formulary Review Form for Addition or Removal Requests by VHA Leadership.

p. VA National Formulary. <https://www.pbm.va.gov/PBM/NationalFormulary.asp>.

q. VHA PBM Formulary Management SharePoint. <https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/SitePages/Home.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

r. American Society of Health System Pharmacists. ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System. Am J Health-Syst Pharm. 2021;78:907-918. <https://www.ashp.org/pharmacy-practice/policy-positions-and-guidelines/browse-by-topic/formulary-management>.