

## VHA FORMULARY MANAGEMENT PROCESS

**1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive provides procedures for the management of the VA National Formulary (VANF) Process.

### 2. SUMMARY OF MAJOR CHANGES:

a. Amendment, dated August 29, 2019, includes the addition of a note in paragraphs 4, 5.j, 5.n.3, and 6.s.6 describing the exception to the process in this directive (see VHA Directive 1108.15, Continuation of Mental Health Medications Initiated by Department of Defense Authorized Providers, dated August 2, 2019).

b. The most significant changes are the inclusion of a Prior Authorization policy for select VANF drugs and supplies; new United States (US) Food and Drug Administration (FDA) approved drug interpretations; the inclusion of guidance on Inventory Management and significant changes in the paragraphs on tablet splitting and nutraceuticals; revised responsibilities, and the addition of Consolidated Mail Outpatient Pharmacy (CMOP) Director responsibilities.

**3. RELATED ISSUES:** VHA Handbook 1108.04, VHA Handbook 1761.02, and VHA Handbook 1108.10, VHA Directive 1108.15.

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

**5. RESCISSIONS:** VHA Directive 2012-029, dated October 5, 2012, VHA Directive 2010-002, dated January 11, 2010, and VHA Handbook 1108.08, dated February 26, 2009 are rescinded.

**6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of November 2021. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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## VHA FORMULARY MANAGEMENT PROCESS

### 1. PURPOSE

This Veterans Health Administration (VHA) directive provides 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

a. 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 VANF. This process evolved through the consolidation of VA medical facility formularies, into 21 Veterans Integrated Service Network (VISN) Formularies, and then overlaying a VANF to the VISN formularies. In 2001, VA abolished medical facility formularies, leaving only VISN formularies and the VANF to guide management of drug therapy. In 2009, VA finished the transition to the VANF when VISN Formularies were suspended. The migration to regional and national formularies has allowed VA to rely more uniformly on evidence-based drug evaluations. The new formulary 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.

b. The Office of Inspector General (OIG) Report No. 08-01322-114, "Audit of Veterans Health Administration's Management of Non-Controlled Drugs," dated June 23, 2009, concluded that VHA needed to improve its ability to account for its non-controlled drug inventories in order to reduce the risk of waste and diversion. As a result, the following two activities were enacted.

(1) Regular facility-based inventory audits are to be performed for specific drugs identified as potentially high risk for diversion. The OIG included recommendations for improved inventory management, and establishing some standard triggers of concern (e.g., discrepancy rate, etc.). **NOTE:** *These audits will continue until the VistA Pharmacy software has an enhanced inventory management function incorporated and activated.*

(2) Pharmacy personnel must consistently record information on transactions in Veterans Health Information and Technology Architecture (VistA), such as pharmacy stock transfer, drug dispensing, and drug returns.

### 3. DEFINITIONS

a. **Adverse Drug Event.** An adverse drug event (ADE) is harm caused by the use of a drug or simply harm caused by a drug or the inappropriate use of a drug.

b. **Drug Standardization List.** The VA 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 interchange may compromise therapeutic response or patient safety.

c. **Medical Advisory Panel.** The Medical Advisory Panel (MAP) is a panel of practicing VA physicians, National PBM Clinical Pharmacy Program Managers, and Department of Defense (DoD) clinical personnel that provides oversight to the VA Formulary Management process. MAP members are VISN nominated with the call for nominations announced through the Deputy Under Secretary for Health for Operations and Management (10N). Those Subject Matter Expert (SME) positions that are not represented on the MAP membership will be identified by the Committee Chair after consultation with the PBM, Offices of the respective clinical specialty, field advisory committees (FACs) and Quality Enhancement Research Initiative (QUERI) centers. Once appointed, they are consulted on an AdHoc basis for those specialty areas that require input when VA National Formulary issues of interest are being discussed (e.g., dietitian/nutritionist, podiatrist, dentist, etc.). ***NOTE: Both MAP members and SMEs are required to provide Conflict of Interest declarations on an annual or AdHoc basis.***

d. **Medical Food.** Medical food is food that has been specially formulated to be orally consumed or administered enterally, used under medical supervision, and requiring 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 VA pharmacy's perspective, 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 will be considered in a similar manner to nutraceuticals by the MAP and VISN Pharmacist Executives (VPE) committee. Examples of medical foods include: Metanx, Deplin, Axona, Limbrel, and Sentra AM, etc. ***NOTE: The FDA does not approve dietary supplements or medical foods for use or determine their safety or effectiveness.***

e. **No Buy.** 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 MAP and VPE committees.

f. **Non-Formulary.** Non-formulary refers to drugs or supplies that are defined as commercially available products, but are not included on the VANF.

g. **Non-Formulary Request.** A non-formulary request is a request for a drug that is not listed on the VANF. The request must be submitted in a written or electronic format. ***NOTE: VA medical facilities should use an electronic non-formulary request process.***

h. **Nutraceutical.** Nutraceuticals are products intended to supplement the diet. They contain one or more dietary ingredients including 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."

i. **Orphan Drug.** An orphan drug is a drug product that is FDA approved for Orphan Drug Status after it goes through the New Drug Application (NDA) process for its approved use. However, it is not classified as an FDA-approved drug product. Such

drugs are used for the limited patient population that meets the criteria for its indicated use.

j. **Pharmacy Benefits Management Services.** Pharmacy Benefits Management (PBM) Services is a program office aligned under the Office of Patient Care Services, which is comprised of senior pharmacy leaders with expertise in clinical pharmacy practice, prescription benefits management, VA regulations, and federal laws related to pharmacy operations. This program office works with the MAP and VPE committees to facilitate and coordinate the VANF process.

k. **Pharmaceutical Sales Representative.** A pharmaceutical sales representative is anyone acting on behalf of a manufacturer (e.g., pharmaceutical, a pharmaceutical supply item, etc.) or its business partners, for the expressed purpose of promoting the use of its products. These products primarily include drugs and to a lesser extent drug related supplies, nutritional supplements, and similar commodities managed under the VANF process.

l. **Placebo.** A placebo is an inert or innocuous substance without pharmacologic properties.

m. **Re-order Point.** The re-order point (ROP) is the minimum stock level of an item or product at which time additional inventory is to be ordered.

n. **Re-order Quantity.** The re-order quantity (ROQ) is the quantity of a given item or product that is ordered when stock levels reach the reorder point.

o. **Restriction.** Restriction refers to criteria established to guide the use of select drugs, or drug related supplies, that require close monitoring to ensure appropriate use. Restrictions are evidence-based and allow for prescribing by authorized providers (with recognized expertise) when clinical conditions warrant their use. **Note:** *Criteria-for-use and prior authorization are restrictions.*

p. **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).

q. **Therapeutic Interchange.** Therapeutic interchange (TI) is the authorized exchange of a therapeutic (drug) alternative that is available on the National Formulary, in accordance with pre-established, written guidelines.

r. **Therapeutic Subclass.** Therapeutic subclass 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).

s. **VA National Formulary.** VA National Formulary (VANF) is a listing of products (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.

t. **VA Provider.** A VA provider is a health care professional who performs specific professional medical services. For the purpose of this directive a VA provider refers to a licensed individual practitioner (e.g., physician, dentist, physician's assistant, pharmacist, nurse practitioner, etc.), with prescriptive authority within VHA.

u. **VISN Restriction.** 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 facility-specific restrictions. VISN restrictions must be evidence-based and allow for prescribing by authorized providers (with recognized expertise) when clinical conditions warrant their use.

v. **VISN Formulary Committee.** A VISN Formulary Committee is comprised of VISN based clinical personnel. 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 MAP and VPE committees for consideration as an essential component of the VANF process.

w. **VISN Pharmacist Executives.** VISN Pharmacist Executives (VPEs) are pharmacist leaders charged by their VISN Directors and VISN Chief Medical Officers with the task of chairing or co-chairing the VISN Formulary Committee and serving as the VISN representative to the National VPE Committee.

x. **VISN Pharmacist Executive Committee.** The VPE Committee is comprised of pharmacists representing each VISN and one Medical Advisory Panel member. They provide clinical, strategic, and operational input to the PBM on VANF and Pharmacy Benefits Management issues. ***NOTE: VPEs are required to provide conflict of interest declarations on an annual or ad hoc basis.***

#### 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. The VANF is the only drug formulary authorized for use in VHA and the use of VISN formularies or local drug formularies at individual VA medical facilities is prohibited. ***NOTE: This policy does not apply to transitioning Servicemembers 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. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health Operations and Management (10N) is responsible for providing the necessary operational direction and support to secure VISN adherence

to the VANF process and to ensure that health care operations within VHA support its use.

b. **Assistant Deputy Under Secretary for Health for Clinical Operations (ADUSH-CO)**. The Assistant Deputy Under Secretary for Health for Clinical Operations (10NC) collaborates with PBM on various formulary initiatives of strategic importance to VA.

c. **Medical Advisory Panel**. The MAP is responsible for:

(1) Identifying, requesting, and reviewing drugs and drug related supplies for listing to, or removal from, the VANF. **NOTE:** *The MAP, in cooperation with the VISN Formulary Committees, reviews 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 9).*

(2) Prioritizing all U.S. FDA-approved New Molecular Entities (NME) for review based on their relevance to the Veteran population and the availability of comprehensive, clinically relevant, information. **NOTE:** *When these criteria are met, completion of NME reviews ordinarily do not exceed 1 year.*

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

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

(5) Establishing pharmacological management guidelines for specific disease states as required;

(6) Providing oversight for the preparation of drug monographs for NME approved by the FDA, in a timely manner;

(7) Providing oversight for performing evidence-based, therapeutic drug class reviews, that may or may not lead to a national standardization contract initiatives; and

(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).

d. **National Pharmacy, Prosthetics, and Logistics Committee**. The National Pharmacy, Prosthetics, and Logistics Committee (NPPLC) is established for the purpose of clarifying the responsibility for the management and provision of non-drug products. The coordinated efforts of the committee's membership are intended to improve the consistency of care associated with provision of those select products throughout VA. The mission of the NPPLC is to determine the type of product (e.g., device, biologic, implant, etc.) and the responsible service; after careful consideration of multiple factors. The committee deliberates over factors including, but not limited to, VA purchasing regulations and Veteran convenience to standardize responsibility for these

products across the system. The NPPLC is not responsible for determining formulary status, clinical merit, comparative effectiveness, product standardization or appropriate use of the products reviewed. It is expected that each VA medical facility have a local Clinical Products Review Committee (CPRC) in place to review and implement the NPPLC's determinations for nondrug items.

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

- (1) Managing the VANF listing, based on decisions by the MAP and VPE Committees;
- (2) Standardizing drug and drug related supply items according to 38 U.S.C. 8125;
- (3) Maintaining databases that reflect drug utilization;
- (4) Monitoring the use of select drugs and drug related supplies;
- (5) Identifying 10 non-controlled drugs that are high cost or at high risk for diversion each year.

(6) Posting the list of 10 non-controlled high risk / high cost drugs, on a yearly basis, for VA medical facility inventory adjudication by the Veterans Integrated Service Network (VISN) Pharmacy Executive Committee (VPEC), on the PBM Services Web site at:

[http://vaww.infoshare.va.gov/sites/vapharmacyinformatics/WIKI/INVENTORY\\_MANAGEMENT/List%20of%20High%20Cost%20High%20Risk%20Drug%202011.aspx](http://vaww.infoshare.va.gov/sites/vapharmacyinformatics/WIKI/INVENTORY_MANAGEMENT/List%20of%20High%20Cost%20High%20Risk%20Drug%202011.aspx). **NOTE:** *This is an internal Web site and is not available to the public.*

(7) Reviewing, on an annual basis, the list of 10 high cost or high risk drugs as well as the variance rate to determine needed updates or changes and posting such updates or changes as indicated above.

(8) Collaborating with the DoD Pharmacoeconomics Center (PEC) on joint contracts to standardize medication use, whenever possible, 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;

(10) Developing responses to Congressional inquiries in regard to drug therapy management issues;

(11) Maintaining the VANF database; and

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

f. **VISN Director.** The VISN Director is responsible for:



(1) Assigning a full-time VISN Pharmacist Executive to manage a VISN-Pharmacy Benefits Management Office and represent the VISN on the national VPE Committee. **NOTE:** *The VISN Director and/or Chief Medical Officer is encouraged to consult with the Chief Consultant, PBM, to ensure that candidates considered for this position possess the required knowledge, skills, and abilities. The position of VISN Pharmacist Executive refers to a single individual who promotes operational efficiency and provides the necessary attention to pharmacy related activities.*

(2) Assigning an appropriate complement of VISN pharmacy resources (financial and staffing) to support an expanded scope of services for the VISN Pharmacist Executive. **NOTE:** *These expanded services include an ongoing review of operations, preparation for the Joint Commission and other regulatory reviews, staffing assessments, etc. To accomplish this goal, consideration should be given to establishing a VISN-level Clinical Pharmacist Specialist, Pharmacoeconomics Specialist, and a PBM Data Manager or pharmacy administrative support.*

(3) Maintaining an active VISN Formulary Committee;

(4) Ensuring that the VANF is consistently implemented and all guidance (e.g., Criteria-for-Use) enforced throughout the VISN;

(5) Ensuring that VISN guidelines for the prescribing of VANF products meet the intent of this directive;

(6) Ensuring that a non-formulary approval process is in place to address specific patient requirements in a timely manner and that this process is functioning in all VISN medical facilities;

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

(8) Enforcing the existing requirement that the VISN collect and analyze the non-formulary drug data to determine if the process is implemented appropriately and effectively in their medical facilities; and

(9) Tracking both approved and denied non-formulary requests.

g. **VISN Pharmacist Executive.** The VISN Pharmacist Executive is responsible for:

(1) Serving as co-chair of the VISN Formulary Committee and coordinating its activities;

(2) Guiding VISN-level formulary management activities including implementation of national formulary decisions, national contracts, cost avoidance initiatives, and evidenced based prescribing;

(3) Providing operational support for the VANF processes that includes coordination of pharmacy benefit activities for the VISN;

(4) Attending and participating in monthly VPE Committee conference calls and quarterly VPE face-to-face meetings with PBM and national contracting representatives;

(5) Participating in scheduled VISN Formulary meetings at least quarterly;

(6) Collecting and collating drug-related survey information from local VISN facilities when requested by the PBM;

(7) Providing input to the PBM regarding the impact of VANF decisions on VISN operations;

(8) Reporting VISN restrictions to the PBM, as requested. **NOTE:** *In some instances, it may also be appropriate for VISNs to further institute 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. Restrictions are not to be based solely on economic issues and be so limited as to prevent patients with legitimate medical needs from receiving needed medications.*

(9) Reviewing clinical evidence compiled by the MAP and making informed determinations regarding VANF issues;

(10) Assessing and evaluating national, VISN, and local drug utilization for the VISN Formulary Committee;

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

(12) Widely disseminating draft drug monographs, criteria-for-use statements, and pharmacologic management guidelines to appropriate VISN clinicians for comment as requested by the PBM or MAP;

(13) Assisting the PBM in developing responses to congressional inquiries into drug therapy management issues;

(14) Data management utilizing local, VISN, and national databases to track patient outcomes, pharmacy costs, etc; and

(15) Providing minutes of VISN Formulary Committee meetings and VA medical facility Pharmacy and Therapeutic Committee meetings when requested by the PBM.

h. **VISN Formulary Committee.** The VISN Formulary Committee is responsible for:

(1) Identifying and requesting drugs for listing to or removal from the VANF;

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

(3) Effectively communicating VANF decisions to facility Pharmacy and Therapeutics Committees and all clinical staff;

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

(5) Developing a VISN tablet splitting policy to ensure appropriate procedures are in place, listing drugs that are candidates for tablet splitting, and reviewing that list on an annual basis;

(6) Monitoring split medications for ADEs and reporting those ADEs to the VA Adverse Drug Event Reporting System (VA ADERS);

(7) Reporting, monitoring, and trending of ADEs throughout the VISN by utilizing VA ADERS.

(8) Assessing, when necessary, clinical outcomes related to medications being split (e.g., using laboratory data and vital signs);

(9) Providing a copy of the VISN TI plan to the PBM as requested, when required by a VANF initiative; and

(10) Reviewing data provided to the PBM on the formulary status designation of drugs within the VISN and ensuring their accuracy with the VANF designation.

i. **VA Medical Facility Director.** The VA medical facility Director is responsible for pharmacy operations and ensuring that all the requirements of this directive are implemented and adhered to. The medical facility Director must also ensure a written medical facility policy:

(1) States that all items listed on the VANF are available;

(2) Requires the use of VistA Automatic Replenishment/Ward Stock software, or equivalent third party software, to document movement of drug inventory from one VA medical facility location to another;

(3) Ensures that the Pharmacy Product System/National Drug File software patches are installed into VistA accounts in a timely manner and local VistA Drug Files are mapped to the updated medication terms;

(4) Limits the number of individuals with access to the VistA Outpatient label reprint function;

(5) Establishes a Clinical Products Review Committee (CPRC) to review and implement the NPPLC's determinations for nondrug items (see paragraph 5.c.); and

(6) Addresses the business relationships between VA medical facility personnel and pharmaceutical sales representatives to assure compliance with VHA Handbook 1108.10, Promotion of Drugs and Drug-Related Supplies by Pharmaceutical Company

Representatives, at

[http://vaww.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=2852](http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=2852). **NOTE:** *This is an internal VA Web site that is not available to the public.*

j. **Medical Facility Chief of Staff.** The medical facility Chief of Staff is responsible for establishing a system to receive and adjudicate any provider-initiated appeals of a disapproved non-formulary drug request. **NOTE:** *This does not apply to transitioning Servicemembers for whom it is clinically appropriate to continue their mental health medications. See VHA Directive 1108.15 for details about these circumstances.*

k. **Medical Facility Chief of Pharmacy Service.** The medical facility Chief of Pharmacy Service, or designee, is responsible for:

(1) Procuring emergently needed non-formulary medications expeditiously. **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 requests within 96 hours of submission of a completed request. **NOTE:** *This does not apply to transitioning Servicemembers for whom it is clinically appropriate to continue their mental health medications. See VHA Directive 1108.15 for details about these circumstances;*

(3) Informing the medical facility Director of concerns related to business relationships between VA medical facility personnel and pharmaceutical sales representatives;

(4) Educating pharmaceutical sales representatives regarding VHA policy on business relationships with VA medical facility personnel;

(5) Providing to each sales representative visiting the VA medical facility a copy of the local medical center policy on business relationships between VA medical facility personnel and pharmaceutical sales representatives. **NOTE:** *A signed receipt procedure must be established to document that each pharmaceutical sales representative, visiting the medical facilities, has received a copy.*

(6) Ensuring that all tablet splitting guidelines in this directive are closely adhered to (see paragraph 10);

(7) Complying with national contracts that are based on requirements;

(8) Ensuring, along with all VA medical facility providers, that non-VA supplied medications are maintained as a subcategory in the patient medication profile, in addition to active and inactive VA pharmacy dispensed medications;

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

(10) Ensuring that any drug or supply designated as "No Buy" is not procured;

(11) Ensuring that all drug transfers from the VA medical facility to a remote storage areas (e.g., Community Based Outpatient Clinic (CBOC), etc.) is documented using the Automatic Replenishment/Ward Stock software.

(12) Assigning the pharmacy manager who is responsible for:

(a) Selecting, on an annual basis, five non-controlled drug line items from the VISN VPEC listing (originating from the list of ten high-cost or high-risk drugs posted by the Chief Consultant, PBM Services [see paragraph 10.e.]) and monitoring accountability of these items on a quarterly basis, beginning April 1<sup>st</sup> of each year.

(b) Using Drug Accountability software, Prime Vendor reports, annual wall-to-wall inventory results, or the Controlled Substances Software to track inventory and monitor utilization of any specific drug identified as being at high risk for diversion.

(c) Auditing procurement and dispensing records for each of the selected drug items at least quarterly.

l. **The Consolidated Mail Outpatient Pharmacy Director.** The Consolidated Mail Outpatient Pharmacy (CMOP) Director, or designee, is responsible for:

(1) Selecting, on an annual basis, five non-controlled drug line items from the VISN VPEC listing (originating from the list of ten high-cost or high-risk drugs posted by the Chief Consultant, PBM Services [see paragraph 10.e.]) and monitoring accountability of these items; and

(2) In addition, designate another 3 medications for the detailed inventory monitoring.

m. **Medical Facility Pharmacy and Therapeutics Committee.** The Pharmacy and Therapeutics (P&T) Committee, or similar authorized body, at a VA medical facility must be chaired by a physician. The committee is responsible for:

(1) Performing all functions required in the most current Joint Commission Accreditation Manual for Hospitals and the American Society of Health-System Pharmacists (ASHP) Statements on the P&T Committee and the formulary system;

**NOTE:** *The ASHP statement on the P&T Committee can be found at:*

<http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/FormularyManagement.aspx>.

(2) Implementing, supporting, and monitoring compliance with VANF initiatives;

(3) Monitoring non-formulary use and providing the information to the VISN Formulary Committee;

(4) Providing input to the VISN Formulary Committee regarding the impact of VANF decisions on medical facility operations;

- (5) Ensuring compliance with access to VANF items in closed therapeutic classes and sub-classes or select therapeutic classes and sub-classes;
- (6) Ensuring that the VISN Formulary Committee is properly informed of any problems or concerns regarding VANF or prescribing;
- (7) Ensuring compliance with the VISN TI plan when required by a VANF initiative;
- (8) Evaluating all protocols concerned with the use of investigational drugs on human subjects (see VHA Handbook 1108.04, Investigational Drugs and Supplies at [http://vaww.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=2497](http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=2497)). **NOTE:** *This is an internal VA Web site that is not available to the public.;*
- (9) Ensuring that the use of a placebo is strictly prohibited, except when used as part of an Institutional Review Board approved research protocol with informed consent;
- (10) Reviewing and approving requests for additions to the VANF from providers and forwarding any approved requests to the VISN Formulary Committee;
- (11) Meeting as often as necessary, but at least 4 times each calendar year;
- (12) Maintaining detailed minutes of all proceedings at every meeting, including subcommittee reports. **NOTE:** *Minutes are prepared by the Chief of Pharmacy Services, or pharmacy designee, who acts in the capacity of Executive Secretary.*
- (13) Forwarding committee minutes to the Medical Executive Committee (MEC) or other approving body according to local medical facility policy, for review following approval by the P&T committee;
- (14) Ensuring that VANF status designations and drug pricing in the local drug files are up to date and accurate;
- (15) Effectively communicating, implementing, and enforcing VANF decisions to all VA medical facility clinical staff;
- (16) Reviewing and forwarding requests for VANF addition or removal of drugs and drug related supplies to the VISN Formulary Committee, which may submit the request to the PBM for consideration by the MAP and VPE committees;
- (17) Reviewing non-formulary drug requests for appropriateness and the percentage of approvals and disapprovals;
- (18) 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;
- (19) Ensuring that the medical facility has a mechanism in place that complies with the drug usage evaluation and medication indicator requirements of The Joint Commission;

(20) Reviewing all ADE reports for the medical center on a quarterly basis and assessing all relevant data to identify trends and determine if actions can be taken to prevent future occurrences;

(21) Utilizing the VA Adverse Drug Event Reporting System (VA ADERS) to report and monitor ADE activity and surveillance;

(22) Including ADE report reviews as a standing agenda item at meetings and forwarding any process or system improvements to the VISN Formulary Committee; and

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

n. **VA Providers.** VA Providers are responsible for:

(1) Ensuring that all non-VA patient medications are communicated to pharmacy so they can be maintained 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. **NOTE:** *Except in situations where clinical judgment mandates otherwise. Exceptions include transitioning Servicemembers 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; and

(5) Reporting ADEs in accordance with local medical facility policy.

## 6. PROCEDURES

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

b. VISNs and VA medical facilities are not permitted to modify PBM/MAP/VPE criteria-for-use documents.

c. The VANF Drug Listing must be grouped according to the VA Classification System or other nationally developed or licensed classification system adopted by the PBM and updated when changes are required.

d. Individual VA medical facilities are prohibited from not listing or marking VANF drugs and drug related supplies as non-formulary in their local drug file as a means to enforce restrictions or control utilization.

e. Products with FDA approval in a category that is not regulated by FDA are to be given priority consideration for addition to the VANF over non-FDA approved products,

unless the MAP and VPE Committees make an alternative decision that is evidence-based.

f. All decisions for VANF listing are made by consensus of the MAP and VPE Committees. In situations where consensus cannot be reached, the recommendation of the MAP prevails.

g. A determination, made by consensus of the MAP and VPE Committees, 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, or VISN or local level. The level at which adjudication is performed will be part of the decision to designate a product as formulary with prior authorization.

h. When consensus is reached by the MAP and VPE Committees regarding a given agent, the contracting requirements (as determined by PBM) are sent to the National Acquisition Center to issue a solicitation, receive all bids, and make an award.

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

j. Drugs and supplies are not added to the VANF solely for the purpose of performing a clinical trial; however, the 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 the PBM by a VISN Formulary Committee, the VPE Committee, the MAP, VHA Chief Medical Consultants, or VHA Chief Medical Officers.

l. A request for change in VANF status may be submitted to the PBM by a VISN Formulary Committee, the VPE Committee, the MAP, a VHA Chief Medical Consultant, or VHA Chief Medical Officer. **NOTE:** *An individual or group of physicians may submit a request for VANF addition through their VISN Formulary Committee(s).*

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

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

(b) Literature citations that support the recommendation.

(2) All requests for addition to the VANF must contain:

(a) Completion of an Abbreviated Review with: drug name, dosage form, indication(s), safety, dosing and administration, monitoring parameters, efficacy outcomes, advantages over current VANF products, literature citations, current utilization of the product as well as potentially competing products as indicated, price comparisons, conclusions, and intended use or place in therapy specific to the Veteran population;



(b) Disclosure, by the parties presenting the drug for formulary addition, of any financial or other relationship with the pharmaceutical manufacturer of the requested product or other pharmaceutical company that has a competing product; and

(c) The signature of the VISN Pharmacist Executive, Chief Medical Officer, or VHA Chief Medical Consultant. **NOTE:** *Requests are to be forwarded to: Pharmacy Benefits Management Service (119D), P.O. Box 126, Hines, IL 60141.*

(3) All completed requests for change in VANF status must be maintained by the Associate Chief Consultant, PBM Service, Hines, IL.

m. Requests for the change of VANF status, with regard to pharmacy-dispensed medical and surgical supplies, may be initiated by the medical facility's Commodity Standards Committee, but must be submitted to the VISN Formulary Committee for review prior to receipt by the PBM for consideration by the MAP and VPE Committees.

n. The PBM must send an acknowledgement of receipt of the request to the submitting committee or individual within 30 days of receipt of a request for change in formulary status or review of a drug class. This response must be in writing and if a national review is to be conducted, must identify the target date for completion.

o. The PBM must notify the VPEs of requests received, and seek evidence-based feedback from all VISN Formulary Committees before any decision regarding VANF addition or deletion is made. **NOTE:** *If a review is conducted, a draft is distributed to VISN Formulary Committees for wide dissemination and comment.*

p. 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 the VANF, but when medically necessary are to be made available through the non-formulary process.

q. A non-formulary request process must exist at each VA medical facility to ensure that:

(1) Decisions are evidence-based and timely;

(2) Urgent requests for non-formulary agents are immediately addressed by individual(s) identified in local medical facility policy; and

(3) 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 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.*

r. 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 P&T Committee.

s. Non-formulary drugs are only to be approved when:

(1) A documented contraindication exists to the formulary agent(s);

(2) The patient has had a documented adverse reaction to the formulary agent(s);

(3) The patient has had a documented therapeutic failure to formulary therapeutic alternatives;

(4) No formulary alternative exists;

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

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

t. All provider-initiated appeals of a non-formulary drug request are received and adjudicated by the facility Chief of Staff, except for Prior Authorization requests designated to the VISN or national levels. **NOTE:** *Prior authorization appeals at the VISN or national levels will be adjudicated as outlined in paragraph 7.f.(3).*

u. An orphan drug must enter the non-formulary request process for consideration and approval; restricted to its FDA-approved use.

v. There will be no administrative action taken to discontinue pharmacotherapy 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 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.

w. 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 facility.

x. For selected non-formulary approvals, VISN Formulary Committees or local 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.

y. Each VISN must establish a process to analyze, trend, and report non-formulary utilization data at the local facility level. Reported information must include:

- (1) The number of non-formulary requests received;
- (2) The number of non-formulary requests approved;
- (3) The number of non-formulary requests disapproved;
- (4) The number of non-formulary requests not completed within 96 hours; and

(5) 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 transmitted on a quarterly basis to PBM Hines.*

z. Each VISN must establish a process to analyze, trend, and report provider-initiated appeals of non-formulary drug request data at the local facility level. Reported data must include:

(1) The number of provider-initiated appeals for non-formulary drug requests received;

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

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

(4) The number of provider-initiated appeals for non-formulary drug requests not completed within 96 hours; and

(5) 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 transmitted on a quarterly basis to PBM Hines.*

aa. Since VHA policy is to always dispense generically equivalent drugs when they are available, the PBM must maintain a list of pharmaceutical products for which substitution is not permitted. Such products are published as the "VA Drug Standardization List" (see paragraph 3.c.). In most instances, this is accomplished by awarding a mandatory national contract. Products are added to this list by vote of the MAP and VPE Committees. Decisions are based on reviews of therapeutic equivalency and/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. Providers must be alerted by a designated individual in pharmacy services when it is necessary to dispense an alternative product. The VA Drug Standardization List is available on the PBM web site at:

<https://vaww.cmopnational.va.gov/cmop/PBM/default.aspx>. **NOTE:** *This is an internal VA Web site not available to the public.*

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

(1) The MAP and VPE Committees 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) A review of VADERS data for all ADEs associated with the implementation phase of the interchange; and

(2) The PBM provides guidance to each VISN regarding essential process conversion elements.

cc. The TI Plan must include examples of patient and provider communication instruments, education materials, and a general description of how TI will be accomplished. Reporting to the PBM must be completed within 90 days of implementation of the VANF initiative.

dd. 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, facility level restrictions intended to prevent resistance are permissible. Restrictions may include evidence-based guidelines or prescribing privileges for providers with specific expertise. Restrictions are not to be based solely on economics, nor are they to be so limiting as to prevent patients with legitimate medical needs from receiving these medications and supplies.

## 7. PRIOR AUTHORIZATION

a. The MAP and VPE committees will designate all drugs and supplies submitted for formulary consideration as either formulary or non-formulary. A subset of the formulary agents, as determined by the aforementioned committees, will be designated as prior authorization medications requiring review and approval through the following established processes prior to dispensing. Prior authorization determinations will be completed at the national, VISN, or VA medical facility level, depending on the established drug designation.

b. For those medications designated as "Formulary Prior Authorization" at the facility level (PA-F) the Chief of Pharmacy Services, or designee, must implement and maintain a PA-F standard operational procedure.

c. For those medications designated as "Formulary Prior Authorization" at the VISN level (PA-V) the VISN Pharmacist Executive, or Designee, must implement and maintain a VISN Prior Authorization (PA-V) standard operational procedure.

d. For those medications designated as "Formulary Prior Authorization" at the national level (PA-N) the Chief Consultant, PBM Services, or designee, must implement and maintain a PA-N standard operational procedure.

e. 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 pharmacy service to ensure communication and coordination for PA-N requests. **NOTE:** *It is highly recommended that facilities populate this directory with an Outlook e-mail group versus assigning responsibility to one person.*

f. The PA-N standard operating procedure specifies and governs the business and technical details of PA-N inter-facility requests (IFCs), such as the:

- (1) Submission of PA-N drug request by the provider;
- (2) Review of the submission;
- (3) Adjudication of provider appeals;
- (4) Communication of all determinations to the originating provider; and
- (5) Monitoring of response times and outcomes.

g. Every effort must be made to process requests for prior authorization within 96 hours of submission of a provider's completed request; in alignment with non-formulary requests in this directive. Only on rare occasions, such as the receipt of a request for prior authorization on Friday prior to a Holiday weekend, will any leeway be permitted. **NOTE:** *A new request for prior authorization approval 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 facility.*

## 8. NUTRACEUTICALS, DIETARY SUPPLEMENTS AND MEDICAL FOODS

a. The MAP and VPE Committees have determined that certain dietary supplements, also known as nutraceuticals or medical foods, may 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); and

(3) PBM Services will identify and give preference to those manufacturers who:

(a) Comply with Title 21 Code of Federal Regulations (CFR) part 111, which requires manufacturers of dietary supplements to comply with current good manufacturing practices (cGMP);

(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; and **NOTE:** *PBM Services will give 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, etc.) providing oversight of manufacturing and product quality in terms of identity, purity, strength and composition of the product produced; and*

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

b. A PBM National Clinical Program Manager or the requesting VISN, following a comparable procedure for reviewing requests for formulary addition (if recommended to do so by the MAP and VPE Committees), will review the available evidence for both safety and efficacy for the product and present the findings to the a-for-mentioned committees.

c. To determine if a product is acceptable for use in VA, both the MAP and VPE Committees must:

(1) Review all clinical evidence collected by the PBM National Clinical Program Manager or the requesting VISN;

(2) Make a determination of the products efficacy based on the presented published information;

(3) Consider 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, etc.);

(4) Determine if there is a need for criteria-for-use to be developed; and

(5) Recommend VANF status.

d. Once VANF status has been established and application of the requirements in paragraphs 8.a. and 8.b. have been completed, the assigned contracting officer must:

(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; and

(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.

e. The contracting officer must review all available product information to determine:

(1) If the product meets any criteria (e.g., specific contract requirements) set forth by the solicitation and recommended by the MAP and VPE committees;

(2) The best price available;

(3) How the needs of VA, with regard to product supply, will be met; and

(4) The manufacturer's proof of adherence to cGMP standards and producing a high quality product (i.e., Seal-of-approval or certification by third-party company that provides oversight or produced in a FDA approved manufacturing facility).

f. The following procedures must be followed in all instances when a product is being considered:

(1) A request for consideration of nutraceuticals or medical foods is to be submitted by a VPE, or other approved requesting official or group, for concurrence by both the MAP and VPE committees to review the product requested based upon the perceived need of VA patients;

(2) As with pharmaceuticals, the PBM assigns a PBM clinician or VISN representative to review the requested nutraceutical or medical food or, alternatively, the VISN requesting consideration of the product will prepare and present the review;

(3) The PBM clinician or VISN representative will review the peer-reviewed, published literature and develop a review/monograph. **NOTE: This review is similar to that performed for any FDA approved pharmaceutical;**

(4) Upon review of the evidence, the MAP and VPE committees will determine if there is sufficient evidence supporting its use and a recognized need for the product in the VA population;

(5) The MAP and VPEs will determine formulary status and whether criteria-for-use are needed; and

(6) For product selection, preference will be given to manufacturers whose product carries a seal-of-approval or certification from a reputable third-party company (e.g., Consumer Lab, USP Verified, etc.) validating compliance with the FDA's Final Rule (see paragraph 8.a.(3)) and those manufacturing their product in a FDA approved manufacturing facility.

## 9. COSMETIC AND ENHANCEMENT DRUGS

a. Cosmetic and enhancement drugs can be provided only for the purpose of improving a patient's physical or mental health.

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 following is a list of conditions where cosmetic drugs are utilized for non-medically necessary conditions: **NOTE: This listing is not intended to be all-inclusive.**

(1) Minoxidil, finasteride, or pimecrolimus for hair re-growth;

(2) Oral and topical antifungal drugs used to treat onychomycosis only for cosmetic purposes; and

(3) Botulinum toxin or retinoids for wrinkles.

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

e. The following is a list of conditions where enhancement drugs are utilized for non-medically necessary conditions: **NOTE: This listing is not intended to be all-inclusive.**

(1) Anabolic steroids, testosterone, or any drug used for the purpose of bodybuilding or improving athletic performance;

(2) Phosphodiesterase inhibitors used for erectile enhancement in a patient without a diagnosis of erectile dysfunction;

(3) Growth hormone used in a patient who has normal or near normal (age adjusted) growth hormone levels; and

(4) Drugs used to support transgender surgical procedures prior to gender alteration.  
**NOTE: This would not apply in conditions where it has been determined that the well-being of the patient is at risk.**

## 10. TABLET SPLITTING

a. VISNs are permitted to establish tablet splitting programs for both inpatients and outpatients; however, tablets are to be split for inpatients only when the required dosage is not available in a commercial package.

b. Determination of patient suitability for a tablet splitting program must be individualized according to a patient's unique capabilities. Patients who express a desire not to participate in a tablet splitting program must be permitted to receive full tablet doses.

c. All patients in a tablet splitting program must be provided a tablet splitter and must be educated regarding its use.

d. Tablets are not to be split into more than two pieces, unless specifically designed for that purpose.

e. To ensure appropriateness, all VA medical facility tablet splitting programs must be approved by the VISN's Formulary Committee.



f. Tablets may be split outside of a formal tablet splitting program to achieve an intermediate dose not available with marketed strengths, or at the request of an individual provider.

g. The following requirements must be followed whenever tablet splitting is instituted.

(1) Tablets that must not be split are:

(a) Sustained release preparations (unless scored and designed to allow tablet splitting);

(b) Enteric coated tablets;

(c) Products with a narrow therapeutic index, unless required for therapeutic reasons, or titration, or where the required dose is not commercially available; and

(d) Products in which tablet splitting would result in the destruction of the release mechanism of the individual drug.

(2) Any patient who is otherwise able, but is unwilling to participate in a tablet splitting program, must be provided whole tablets if they are commercially available.

**NOTE:** *Patients with caregivers who have similar reservations also need to be provided whole tablets.*

(3) The patient or caregiver needs to be able to demonstrate:

(a) An understanding of the purpose for splitting medication;

(b) An understanding of the intended dose and treatment regimen; and

(c) The physical ability (e.g., coordination, adequate vision, etc.) to easily and accurately split the tablet.

(4) Medications eligible for tablet-splitting must have an associated message tagged in the master drug file that alerts the provider that the dose is being provided as a split tablet, unless otherwise ordered. This message must appear on the screen in the computerized patient record system when one of the tagged medications is selected for prescription.

(5) Tablet splitting is to be considered only when it is clinically appropriate and after determination of patient suitability and willingness to participate.

(6) If the patient is not willing or is unable to split tablets utilizing the intended device, the provider must notify the pharmacy of the need to dispense whole tablets.

(7) Patients must be provided tablet splitting devices, free of charge, as often as necessary. Written instructions on its use must be provided with the first splitter and when a new style splitter is introduced.

(8) Directions on the prescription label must reflect the exact product and dosing instructions. To avoid misunderstanding, providers need to prescribe the medication strength and dose in milligrams (mg) (e.g., simvastatin 40 mg. tablet. Take one-half tablet daily (for a 20mg dose). **NOTE:** *One-half is to be spelled out on the label to avoid misreading "1/2" as 1-2 tablets.*

(9) When the dose of a previously prescribed drug required it to be split (as stated in paragraph 10.g.(8)) and the dosage is changed by the provider, such that the new dose requires a whole dosage form (e.g., simvastatin 40mg. tablet), the new dose must be clearly explained in writing to the patient by pharmacy. **NOTE:** *This is to ensure the patient does not continue to split a tablet if it is no longer warranted.*

(10) The dosage strength of the whole tablet is to be printed on the label as part of the product name.

h. If tablets are to be split for inpatients, the pharmacy must split the tablet to be dispensed in the most ready to administer dose for the nurse, doctor, pharmacist, or other health care team member approved to administer the medication.

i. Split tablets for inpatient use must be bar coded in order to be recognized as the appropriate final dose in the barcode medication administration (BCMA) system.

## 11. INVENTORY MANAGEMENT

a. Since inventory control is an integral part of formulary management, VA pharmacy inventory managers, purchasing agents, and their supervisors must be fully acquainted with VHA Handbook 1761.02, VHA Inventory Management, at [http://vaww.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=2100](http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=2100) and follow all requirements. **NOTE:** *This is an internal VA Web site that is not available to the public.* The following are items of particular importance:

(1) The pharmaceutical prime vendor must be used as the primary source of all contract pharmaceutical purchases whenever possible;

(2) When needed, inventory management staff may request training manuals and on-site training from the pharmaceutical prime vendor;

(3) Demand forecasting, in which weighting factors are applied to past purchases, must be utilized to factor trends into the calculation of both the re-order point (ROP) and re-order quantity (ROQ) for more accurate inventory management;

(4) Bar Code shelf labels containing the product name, item number, ROP, and ROQ must be affixed to all stock locations;

(5) A hand held barcode reader, provided by the prime vendor, will be used for scanning the shelf label for items whose schedule dictates a reorder is required;

(6) All received invoices must be uploaded into the Veterans Health Information System and Technology Architecture (VistA) drug accountability software;

(7) End-of-year purchases make pharmaceutical inventories increasingly difficult to manage and need to be avoided; and

(8) An annual wall to wall inventory of all pharmacy items must be completed by February 28<sup>th</sup> of each calendar year and sent by each VA medical facility to PBM Services, Hines, IL, by March 31<sup>st</sup> of the same calendar year. There must be a clear separation of duties to minimize the risk of fraud or loss of property. Assignment of duties, such as: authorizing, approving, and recording of all transactions; receiving assets; approving cardholder statements; making payments; certification of funding; and reviewing or auditing, need to be assigned to separate individuals to the greatest extent possible. **NOTE:** *For clarification purposes, one person cannot be the cardholder and approving official for the same transaction. An individual that places a purchase order cannot receive and check-in the same order.*

b. "Specialty Distributed" drugs are not available through the prime vendor's normal process. They have an ordering process specific to the manufacturer and are distributed through a specialty distribution company or a third-party distributor. Reasons for specialty distribution include: patient safety, limited manufacturing capacity, and the need for educating providers and pharmacies to ensure appropriate use. **NOTE:** *The PBM maintains a Web site with a list of specialty distribution drugs and the process for ordering under the heading "Documents and Lists" at: <http://vaww.pbm.va.gov/pbm/closeddist.htm>. This is an internal VA Web site not available to the public.*

c. The ABC inventory analysis method must be utilized to manage pharmacy medications and supplies. The "A" items (approximately 70 percent of the inventory dollars and 10 percent of the products) are to be monitored closely to reduce total inventory carrying cost. The "B" items (approximately 20 percent of the inventory dollars and 20 percent of products) can be managed less aggressively. The "C" items (approximately 10 percent of the inventory dollars and 70 percent of the products) can be managed least aggressively and the ordering process for these items can be streamlined to reduce daily workload requirements for these items. **NOTE:** *When drug shortages influence product availability this inventory analysis method can be omitted for those specific products effected.*

d. Five non-controlled drug line items are to be selected, on an annual basis, from the VISN VPEC listing (originating from the list of ten high-cost or high-risk drugs posted by the Chief Consultant, PBM Services at: [http://vaww.infoshare.va.gov/sites/vapharmacyinformatics/WIKI/INVENTORY\\_MANAGEMENT/List%20of%20High%20Cost%20High%20Risk%20Drug%202011.aspx](http://vaww.infoshare.va.gov/sites/vapharmacyinformatics/WIKI/INVENTORY_MANAGEMENT/List%20of%20High%20Cost%20High%20Risk%20Drug%202011.aspx)). **NOTE:** *This is an internal VA Web site that is not available to the public.* They are to be monitored with an accountability of these items performed on a quarterly basis, beginning April 1<sup>st</sup> of each year.

(1) A manual count of each drug item selected must be completed and compared to the inventory level from the Drug Accountability Software, prime vendor reports or other tools decided by local pharmacy management. This count must include all sizes for a specific generic drug and strength.

(2) The variance between the actual and predicted amount on hand for the reporting period must be calculated. Variances greater than 5 percent require an in-depth review and analysis.

(3) The actual balance must be adjusted to ensure accurate inventory once the cause of the discrepancy has been resolved.

(4) The assigned pharmacy manager will report the results of the inventory reviews to facility management through the quality assurance process on a quarterly basis.

(5) The assigned pharmacy manager will provide quarterly and annual summary reports to the VPEC indicating the results of the review and any follow-up actions taken.

e. VA pharmacies must not restock into inventory, nor reissue to another patient, any CMOP or locally-dispensed prescription medication that has been returned as undeliverable.

f. Each CMOP will select, on an annual basis, five non-controlled drug line items from the VISN VPEC listing (originating from the list of ten high-cost or high-risk drugs posted by the Chief Consultant, PBM Services) and monitor the accountability of these items.

(1) Monitoring, reporting and review by the CMOP Purchasing and Inventory Committee (CMOP PIC) will be on a monthly basis, with a report sent to the CMOP Executive Leadership Committee (CMOP ELC) monthly.

(a) Each CMOP will compute the actual on hand inventory of the chosen drugs taking into account active stock, warehouse stock, unpacked items on production line, and returns to stock.

(b) The CMOP will then compute a theoretical ending inventory based on the previous months actual inventory. **NOTE:** *The CMOP will take into account monthly receipts, monthly dispensing totals and any product marked for destruction.*

(c) Each CMOP will conduct a physical inventory of all stock on hand and calculate the variance between the calculated and actual inventory counts. **NOTE:** *Both the total variance and the total amount dispensed (in individual units) is to be reported to the CMOP PIC and recorded on a Dashboard report that is reviewed monthly. If a drug review evidences two consecutive positive or negative variances greater than 0.5% (which constitutes a 50 unit loss or gain per 10,000 units dispensed) or if the year to date variance is greater than 0.5% the respective CMOP will be required to submit an action plan to the CMOP PIC.*

(2) The Dashboard report reviewed by the CMOP PIC is presented monthly at the CMOP ELC.

## 12. COMPOUNDING OF NON STERILE PHARMACEUTICAL PREPARATIONS

- a. Medical facilities must ensure that all non-sterile compounded preparations (NSCP) are prepared and stored in accordance with the standards established within the United States Pharmacopoeia (USP) Chapter 795 (USP<795>) “Pharmaceutical Compounding - Non Sterile Preparations” (Revision Bulletin: Official January 1, 2014), USP Chapter 1075 “Good Compounding Practices”, and USP Chapter 1160, “Pharmaceutical Calculations in Prescription Compounding.”
- b. VA medical facility Pharmacy Services must assess their capability to compound preparations that are not commercially available based on an evaluation of available equipment, resources, and expertise to prepare the compounded product.
- c. The requested NSCP’s intended use must be within the scope of practice or specialty of the prescriber to justify its medical necessity.
- d. The requested NSCP must not represent a formulation that combines commercially-available FDA-approved products, absent the existence of evidence from published studies to support the safety, efficacy, stability, and cost effectiveness of NSCP formulation.
- e. The pharmacist, or designated pharmacy personnel, under the supervision of the pharmacist, is responsible for compounding preparations of acceptable strength, quality, and purity in accordance with USP compendial standards and current scientific principles. The finished product must also have the appropriate packaging and labeling in accordance with these standards.
- f. NSCPs may be prepared in batched quantities but can only be dispensed pursuant to a prescription or inpatient order; labeled for that specific patient. Upon receipt of a request for a NSCP, the pharmacist must first recommend use of a commercially available product or commercially-prepared alternative therapeutic regimen available on the VANF. In the absence of a VANF alternative, a non-formulary commercially available product is to be considered. **NOTE: In this instance the non-formulary approval process must be followed to secure the drug product.**
- g. The request for a NSCP would be considered if an equivalent product (or therapeutic alternative) is not commercially available and there exists a specific medical need for the prescribed NSCP formulation (e.g., the patient has a confirmed allergy to one or more of the excipients, inactive ingredients, or dyes in the commercially available product; there are changes in strength, dosage form, or delivery mechanism that are considered therapeutically necessary for a specific patient, etc.).
- h. Any NSCP provided to a patient must conform to the requirements as outlined in the provisions specified for USP compendial standards (see paragraph 12.a).
- i. The pharmacist must ensure that any NSCP, when prepared, is:
- (1) An article in the USP/National Formulary monograph;
  - (2) FDA-approved (if no USP monograph exists); or

(3) Supported by evidence of safety from published studies (supplied by the prescriber for labeled or unlabeled use).

j. A pharmacist must ensure that the prescription order for the NSCP specifies the quantity of each active ingredient. The active ingredient(s) used in the NSCP must be effectively absorbed, either locally or systemically according to the prescribed purpose, preparation, and route of administration.

k. The requested NSCP must not present demonstrable difficulties in compounding (e.g., require a sophisticated drug delivery system, present concerns regarding dosage uniformity in bioavailability, a complex compounding process, sophisticated facilities or equipment, or highly-technically trained personnel). **NOTE:** *For additional guidance, refer to Reference 13.j.*

l. If compounding a NSCP presents significant difficulty (as previously stated), and the Chief of Pharmacy Service, or designee, determines a need to outsource the NSCP to a traditional compounding pharmacy, the VA medical facility pharmacy will:

(1) Adhere to established local medical facility policy for non-formulary drug adjudication;

(2) Acquire the NSCP from a compounding pharmacy accredited by the Pharmacy Compounding Accrediting Board (PCAB) or equivalent;

(3) Require a pharmacist to inspect the outsourced NSCP for quality prior to patient administration;

(4) Consider a contractual arrangement if outsourcing is expected to be on a long term basis; and

(5) Verify that the outsourced compounding pharmacy has the necessary equipment and qualified personnel with appropriate practice experience to compound the NSCP.

m. The requested NSCP must not be a component in the FDA Negative List, or have been withdrawn from the market due to safety concerns. **NOTE:** *For additional guidance, refer to Reference 13.f.; (Pharmacy Compounding: Drug products withdrawn or removed from the market for reasons of safety or effectiveness).*

n. The pharmacist designee must ensure that the compounding process for NSCP(s) prepared in-house, or outsourced to a compounding pharmacy, is such that opportunities for error are reduced and product preparation is of the highest quality. Therefore, the pharmacist, when practical, must ensure that:

(1) The necessary calculations are performed to establish the correct amounts of ingredients to be added;

(2) The equipment required to compound the product is calibrated correctly;

(3) The compounding pharmacist and pharmacy technician/s adhere to procedural requirements for compounding (including proper attire);

(4) Only one NSCP is compounded at a time;

(5) A pharmacist examines and verifies each completed NSCP;

(6) All required information and instructions are included on the prescription container; and

(7) A record of all compounded products is maintained.

o. The provider will specify in the medication order of the patient's profile that the product prescribed and dispensed is a NSCP and inform the patient as necessary.

p. The pharmacist must provide patient counseling regarding the NSCP that includes (at a minimum), the beyond-use-date, appropriate administration, storage requirements and methods of detecting evidence of instability (e.g., visual changes, odor, etc.).

### 13. REFERENCES

a. 21 CFR 216.24.

b. 21 U.S.C. 301.

c. 38 U.S.C. 8125.

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

e. American Society of Hospital Pharmacists. ASHP Statement on the Pharmacy and Therapeutics Committee. American Journal Hospital Pharmacy. Aug 1992; 49(8):2008–2009.

f. FDA Compliance Policy Guides Manual on Pharmacy Compounding, Chapter 4, Sub Chapter 460; "Pharmacy Compounding;" Reissued: May 29, 2002.

g. FDA Drug Quality and Security Act (HR 3204); Sect. 503A, November 27, 2013. FDA Negative List: Federal Register, Volume 64, No. 44, March 8, 1999; Part 216, Pharmacy Compounding "Drug withdrawn or removed from the market for reasons of safety or effectiveness." Good Compounding Practices. (General Information Chapter <1075>. In: The United States Pharmacopoeia 36<sup>th</sup> rev and the National Formulary 31<sup>th</sup> ed. Rockville, MD: United States Pharmacopoeia Convention: 2013.

h. ISMP Medication Safety Alert. Tablet Splitting: Do it if you "Half" to, and Then do it Safely. May 18, 2006; 11(10): 2-3.

- i. McDevitt, J.T., et al. Accuracy of tablet splitting. *Pharmacotherapy*. 998; 18(1): 193-197.
- j. Pharmaceutical Calculations in Prescription Compounding. (General Information Chapter <11160>. In: The United States Pharmacopoeia 36<sup>th</sup> rev and the National Formulary 31<sup>th</sup> ed. Rockville, MD: United States Pharmacopoeia Convention: 2013.
- k. Pharmaceutical Compounding – Non-sterile Preparations. (General Information Chapter <795>. In: The United States Pharmacopoeia, Rockville, MD: United States Pharmacopoeia Convention: Revision Bulletin: Official; January 1, 2014.
- l. Sedrat, M., et al. Splitting tablets in half. *American Journal of Hospital Pharmacy*. 1994; 51” 548-550.
- m. Sian Carr-Lopez M., et al. The tablet splitter: Barrier to compliance or cost-saving instrument? *American Journal of Health-System Pharmacists*. 1995; 52:2707-2708. United States Pharmacopoeia Convention, Inc. USP Pharmacists' Pharmacopoeia. Rockville, MD: US Pharmacopoeial Convention, Inc.; 2008-2009.
- n. VHA Handbook 1108.04, Investigational Drugs and Supplies.
- o. VHA Handbook 1108.10, Promotion of Drugs and Drug-Related Supplies by Pharmaceutical Company Representatives.
- p. VHA Handbook 1761.02, VHA Inventory Management.