VHA FORMULARY MANAGEMENT PROCESS

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

2. SUMMARY OF MAJOR CHANGES. This is a new VHA Handbook which incorporates aspects of the formulary management process previously found in a variety of VHA Directives and Policy Manuals. The most significant changes are:

a. The inclusion of guidance on Inventory Management, Compounding of Non-Sterile Pharmaceutical Preparations, Compassionate Use of Nutriceuticals, Tablet Splitting, and Cosmetic and Enhancement Drugs.

b. The abolishment of all Veterans Integrated Service Network (VISN) Formularies.

3. RELATED DOCUMENTS. VHA Handbook 1761.2.

4. RESPONSIBLE OFFICE. The Office of Patient Care Services, Pharmacy Benefits Management Service (119), is responsible for the contents of this Handbook. Questions may be addressed to the Chief Consultant at (202) 461-7326.

5. RESCISSIONS: VHA Manual M-2, Part VII, Chapter 2; VHA Manual M-2, Part VII, Chapter 9; VHA Manual M-2, Part I, Chapter 3; VHA Directive 2001-044; and VHA Directive 2003-060, are rescinded.

6. RECERTIFICATION: This VHA Handbook is scheduled for recertification on/or before the last working day of February 2014.

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DISTRIBUTION: CO: E-mailed 2/27/09
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 2/27/09

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VHA FORMULARY MANAGEMENT PROCESS

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides policy, procedures, and responsibilities for the management of the Department of Veterans Affairs (VA) National Formulary (VANF).

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 using more than 170 individual drug formularies to assist in the management of pharmacotherapy, to a formulary process that would result in a single VANF. This process involved overlaying Veterans Integrated Service Network (VISN) Formularies to the existing facility formularies, then overlaying a VANF to the facility and VISN formularies. In 2001, VA abolished medical center formularies, leaving only VISN Formularies and the VANF to guide management of drug therapy. 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.

3. DEFINITIONS

a. **Adverse Drug Event (ADE).** An 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. **Biological Product**. A biological product is any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.

c. Do Not Substitute. "Do Not Substitute" is a listing of drugs for which another manufactured drug may not be substituted. The determination of which product will be used is based on clinical or contractual considerations. VA's "Do Not Substitute" listing is posted on the VA Pharmacy Benefits Management Service (PBM) Internet Web site at http://www.pbm.va.gov/NationalFormulary.aspx.

d. **Inservice.** Inservice refers to instructional programs designed to increase knowledge, and eventually competency, by assisting staff in acquiring, maintaining, improving, and increasing skills and knowledge relevant to fulfilling the requirements of the position for which the individual has been hired.

e. **Medical Advisory Panel (MAP).** MAP is a panel of practicing VA physicians, PBM clinical pharmacists and Department of Defense (DOD) clinical personnel that provides oversight to the VA Formulary Management process.

f. **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 VISN Formulary Leaders (VFL).

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

h. **Pharmacy Benefits Management (PBM).** PBM 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 law related to pharmacy operations. This program office works with MAP and VFL to facilitate and coordinate the VANF process.

i. **Pharmaceutical Industry Representative.** A pharmaceutical industry representative is anyone acting on behalf of a manufacturer (e.g., pharmaceutical, supply, 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 medical supplies, nutritional supplements, and similar commodities managed under the VA formulary process.

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

k. **Reorder Point (ROP).** ROP is the minimum level at which time additional inventory is to be ordered.

l. **Reorder Quantity (ROQ).** ROQ is the quantity of a given product that is ordered when stock levels reach the reorder point.

m. **Restriction.** Restriction refers to criteria established to guide the use of drugs or supplies that require close monitoring to ensure appropriate use. Restrictions are evidence-based and allow prescribing by authorized providers (with recognized expertise) when clinical conditions warrant drug use.

n. **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).

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

p. **Therapeutic Subclass.** Therapeutic subclass is a grouping of drugs with similar pharmacologic activity (e.g., the therapeutic class of Antihyperlipidemics would include the therapeutic subclass of HMG- CoA RI).

q. **VA National Formulary (VANF).** VANF is a listing of products (drugs and supplies) that must be available for prescription at all VA facilities, and cannot be made non-formulary by a VISN or individual medical center. Regarding chemical or biological entities that by law must be submitted to the United States (U.S.) Food and Drug Administration (FDA) for pre-marketing approval, only those entities that actually have been approved by FDA using New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or biologics license, may be added to the VANF.

r. **VA Provider.** A VA Provider is a health care professional who performs specific professional medical services. For the purpose of this Handbook a VA Provider refers to a licensed individual practitioner (e.g., Physician, dentist, pharmacist, nurse practitioner etc., or a physician's assistant), with prescriptive authority within VHA.

s. **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; however, those restrictions must be clinically driven. 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.

t. **VISN Formulary Committee.** A VISN Formulary Committee is a group within each VISN comprised of clinical personnel. Their function is to provide clinical oversight and guidance for the formulary review process; coordinate VANF initiatives at the VISN and facility levels; and communicate VISN-specific submissions to the PBM and MAP for consideration as part of the VANF process.

u. **VISN Formulary Leaders (VFL).** VFL are physicians or pharmacists 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 VFL Committee.

v. **VFL Committee.** The VFL Committee is a group comprised of pharmacists and physicians representing each VISN. They provide clinical, strategic, and operational input to the PBM on VANF management issues.

w. **VISN Pharmacy Benefits Management (VISN PBM).** The VISN PBM is an individual or group that provides VISN-level leadership for pharmacy benefits and formulary management. Additional activities may include data management, compliance with governing regulations, and operations management.

4. SCOPE

Formulary management is an integral part of VA's comprehensive health care delivery process. The VANF is the only drug formulary authorized for use in VHA. The use of VISN formularies or local drug formularies at individual medical care facilities is prohibited. The formulary management process must provide pharmaceutical and supply products of the highest quality and best value, while ensuring the portability and standardization of this benefit to all eligible Veterans.

5. THE RESPONSIBILITIES OF THE DEPUTY UNDER SECRETARY FOR HEALTH OPERATIONS AND MANAGEMENT

The Deputy Under Secretary for Health Operations and Management (10N) is responsible for the operational direction and support to the VISNs necessary to implement the VANF process and to ensure that health care operations within VHA support its use.

6. THE RESPONSIBILITIES OF THE MEDICAL ADVISORY PANEL (MAP)

The MAP is responsible for:

a. Identifying, requesting and reviewing drugs for listing to or removal from the VANF; ***NOTE:*** *The MAP, in cooperation with the VISN Formulary Committee, 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 par. 19).*

b. 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.*

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

d. Establishing criteria-for-use for VANF drugs and certain non-formulary agents, when appropriate;

e. Establishing pharmacological management guidelines for specific disease states as required;

f. Oversight for preparing drug monographs for NME approved by the FDA, in a timely manner;

g. Oversight for performing evidence-based, therapeutic drug class reviews, that may or may not lead to a national standardization contract initiative; and

h. Providing guidance to VISNs regarding TI when required as a result of a VANF initiative (i.e., drug shortage or drug recall).

7. THE RESPONSIBILITIES OF THE CHIEF CONSULTANT, PHARMACY BENEFITS MANAGEMENT (PBM) SERVICE

The Chief Consultant, PBM Service, is responsible for:

a. Managing the VANF listing, based on decisions by the MAP and VISN Formulary Leaders Committee;

b. Standardizing drug and supply items according to the Veteran's Benefits and Services Act of 1988, Public Law 100-322;

c. Maintaining databases that reflect drug utilization;

d. Monitoring the use of select medications;

e. Collaborating with the DOD Pharmacoeconomic Center (PEC) to standardize medication use whenever possible among VA medical centers and DOD Medical Treatment Facilities (MTFs);

f. Assessing drug-related safety projects in collaboration with the VA National Center for Patient Safety;

g. Developing responses to Congressional inquiries into drug therapy management issues; and

h. Maintaining the VANF database.

8. THE RESPONSIBILITIES OF THE VISN DIRECTOR

The VISN Director is responsible for:

a. Assigning a full-time VISN Pharmacist Executive to manage a VISN-PBM Benefits Management Office and serve as the VISN Formulary Leader, representing the VISN on the national VFL Committee. ***NOTE:*** *The VISN 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 terms VISN Pharmacist Executive, VISN PBM Manager, and VISN Formulary Leader can refer to a single individual or to multiple individuals, depending on how the duties are assigned. It is recommended, but not required, that these duties be assigned to a single individual to provide the necessary focus and promote operational efficiency.*

b. Assigning an appropriate compliment 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, Pharmacoeconomic Specialist, a PBM Data Manager, and pharmacy administrative support.*

c. Maintaining an active VISN Formulary Committee;

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

e. Ensuring that VISN guidelines for prescribing of VANF products meet the intent of this Handbook;

f. 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 centers and clinics;

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

h. 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 centers; and

i. Tracking both approved and denied requests.

9. THE RESPONSIBILITIES OF THE VISN PHARMACIST EXECUTIVE

The VISN Pharmacist Executive is responsible for:

a. Serving as, or supervising, the position of VISN PBM Manager or Formulary Leader;

b. Data management utilizing local, VISN, and National databases to track patient outcomes, pharmacy costs, etc; and

c. Providing minutes of VISN Formulary Committee meetings and medical center Pharmacy and Therapeutic Committee meetings when requested by the PBM.

10. THE RESPONSIBILITIES OF THE VISN FORMULARY COMMITTEE

The VISN Formulary Committee is responsible for:

a. Identifying and requesting drugs for listing to or removal from the VANF;

b. Widely disseminating draft and final Drug Monographs, Criteria-for-use Statements, Pharmacologic Management Guidelines, and other material necessary to manage the formulary process;

c. Effectively communicating VANF decisions to facility Pharmacy and Therapeutics Committees and all clinical staff;

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

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

f. Monitoring split medications for ADEs, tracking those ADEs and submitting an annual report to the PBM;

g. Assessing clinical outcomes related to medications being split (e.g., using laboratories and vital signs);

h Providing a copy of the VISN TI plan to the PBM as requested, when required by a VANF initiative;

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

j. Monitoring and trending of ADEs throughout the VISN.

11. RESPONSIBILITIES OF THE VISN PBM MANAGER OR VISN FORMULARY LEADER

The VISN PBM Manager or VISN Formulary Leader is responsible for:

a. Serving as co-chair of the VISN Formulary Committee and coordinating its activities;

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

c. Providing operational support for the VANF processes that includes coordination of pharmacy benefit activities for the VISN;

d. Attending and participating in quarterly VFL meetings with PBM and national contracting representatives;

e. Participating on scheduled monthly conference calls;

f. Collecting and collating drug-related survey information from local VISN facilities when requested by the PBM;

g. Providing input to the PBM regarding the impact of VANF decisions on VISN operations;

h. Reporting VISN restrictions to the PBM, as requested;

i. Reviewing clinical evidence compiled by the MAP and making informed determinations regarding VANF issues;

j. Assessing and evaluating national, VISN, and local drug utilization for the VISN formulary committee;

k. Representing the VISN on VANF drug and pharmacy policy decisions;

l. Widely disseminating draft Drug Monographs, Criteria-for-Use statements, and Pharmacologic Management Guidelines to appropriate VISN clinicians, and providing feedback related to these documents, as requested by the PBM or MAP; and

m. Assisting the PBM to develop responses to Congressional inquiries into drug therapy management issues.

12. RESPONSIBILITIES OF THE FACILITY DIRECTOR

The Facility Director is responsible for ensuring that a written medical center policy:

a. States all items listed on the VANF are available, and

b. Addresses the business relationships between VA medical center personnel and representatives from the pharmaceutical industry.

13. RESPONSIBILITY OF THE FACILITY CHIEF OF STAFF

The facility Chief of Staff is responsible for establishing a system to receive and adjudicate any physician-initiated appeals of a disapproved non-formulary drug request.

14. RESPONSIBILITIES OF THE FACILITY CHIEF OF PHARMACY SERVICE

The Facility Chief of Pharmacy Service is responsible for:

a. 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.*

b. Adjudicating routine non-formulary requests within 96 hours of submission of a completed request;

c. Informing the Facility Director of concerns related to business relationships between VA medical center personnel and representatives from the pharmaceutical industry;

d. Educating pharmaceutical industry representatives regarding VHA policy on business relationships with VA medical center personnel;

e. Providing to each industry representative visiting the facility a copy of the local medical center policy on business relationships between VA medical center personnel and representatives from the pharmaceutical industry; ***NOTE:*** *A signed receipt procedure must be established to*

document that each pharmaceutical industry representative, visiting the medical center's facilities, has received a copy.

f. Ensuring that all tablet splitting guidelines in this Handbook are closely adhered to;

g. Complying with PBM contracts that are based on percentage utilization;

h. Ensuring, along with providers, that all non-VA supplied medications are maintained as a subcategory in the patient medication profile, in addition to active and inactive medications;

i. Ensuring that all medications and supplies on the VANF are in the local drug file and available for prescribing;

j. Ensuring that all procured drugs have been approved by the FDA using NDA, ANDA, or biologics license; and

k. Ensuring that any drug or supply designated as "No Buy" is not procured.

15. RESPONSIBILITIES OF THE PHARMACY AND THERAPEUTICS (P&T) COMMITTEE

The P&T Committee, or similar authorized body, at VA medical centers is responsible for:

a. Performing all functions required in the most current Joint Commission Accreditation Manual for Hospitals and the American Society of Health-System Pharmacists (ASHP) Statement on the P&T Committee; ***NOTE:*** *The ASHP statement on the P&T Committee can be found at* *http://www.ashp.org/sashp/docs/files/BP07/FormStPTComm.pdf* .

b. Implementing, supporting, and monitoring compliance with VANF initiatives;

c. Monitoring non-formulary use and providing the information to the VISN Formulary Committee;

d. Providing input to the VISN Formulary Committee regarding the impact of VANF decisions on medical center operations;

e. Ensuring compliance with access to VANF items in closed therapeutic classes and sub-classes or select therapeutic classes and sub-classes;

f. Ensuring that the VISN Formulary Committee is properly informed of any problems or concerns;

g. Ensuring compliance with the VISN TI plan when required by a VANF initiative;

h. Complying with the FDA's MedWatch process for documenting ADEs;

i. Trending ADEs to identify opportunities for future avoidance, and providing relevant timely information to support the FDA's MedWatch program (see http://www.fda.gov/medwatch/index.html);

j. Evaluating all protocols concerned with the use of investigational drugs on human subjects (see VHA Handbook 1108.04);

k. Ensuring that the use of a placebo is strictly prohibited, except when used as part of an Institutional Review Board (IRB)-approved research protocol with informed consent;

l. Reviewing and approving requests for addition to the VANF from providers and forwarding any approved requests to the VISN Formulary Committee;

m. Meeting as often as practicable, but at least six times each calendar year;

n. 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 Executive Secretary.*

o. Forwarding committee minutes to the Medical Executive Committee (MEC) or other approving body according to local medical center policy, for review following approval by the P&T committee;

p. Ensuring that the National formulary status designations and drug pricing in the local drug files are up to date and accurate;

q. Effectively communicating, implementing, and enforcing VANF decisions to VA medical center clinical staff;

r. Reviewing and forwarding requests for the formulary addition of drugs and supplies to the VISN Formulary Committee, which may submit the request to the PBM for consideration by the MAP and VFL committees;

s. Reviewing non-formulary drug requests for appropriateness and percentage of approvals and disapprovals;

t. Establishing an emergency mechanism for the review of an investigational drug under emergency use or treatment investigational new drug use when existing procedures must be expedited, to ensure protocol adherence;

u. Ensuring that the medical center has a mechanism in place that complies with the drug usage evaluation and medication indicator requirements of The Joint Commission;

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

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

x. Including ADE report reviews as a standing agenda item at meetings and forward any process or system improvements to the VISN Formulary Committee; and

y. Evaluating all protocols concerned with the use of investigational drugs for impact on pharmacy services and to assure appropriate drug management.

16. RESPONSIBILITIES OF THE VA PROVIDERS

VA Providers are responsible for:

a. Ensuring that all non-VA patient medications are communicated to pharmacy so they can be maintained as a subcategory in the patient medication profile, in addition to active and inactive medications;

b. Prescribing by generic drug name (official Chemical or non-proprietary);

c. Prescribing medications in accordance with VANF requirements and established Criteria-for-Use; ***NOTE:*** *Except in situations where clinical judgment mandates otherwise.*

d. Prescribing medications in accordance with VHA treatment guidelines; and

e. Reporting Adverse Drug Events in accordance with local medical center policy.

17. PROCEDURES

a. Effective January 15, 2009, all VISN Formularies are abolished. VANF is the sole drug formulary used in VA.

b. VISNs are not permitted to modify PBM-MAP 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 is updated when changes are required.

d. Individual VA medical centers are prohibited from marking VANF drugs and supplies as non-formulary in their local drug file as a means to enforce restrictions or control utilization.

e. VANF recommendations are based on the review of <u>only</u> those drug products approved by the FDA.

f. Products with FDA approval in a category that is not regulated by FDA are to be preferentially selected for addition to the VANF over non-FDA approved products.

g. All decisions for VANF listing are made by consensus of the MAP and VFL Committee. In situations where consensus cannot be reached, the recommendation of the MAP prevails.

h. When consensus is reached by the MAP and VFL committee regarding a given agent, the contracting requirements (as determined by PBM) are sent to the National Acquisition Center (NAC) 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. Requests for drug or drug class reviews may be submitted to the PBM by a VISN Formulary Committee, the VFL Committee, the MAP, VHA Chief Medical Consultants, or VHA Chief Medical Officers.

l. Requests for change in VANF status may be submitted to the PBM by a VISN Formulary Committee, the VFL 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 VFL Committee or other acknowledged meeting in which action was taken on the product (if applicable).

(b) Literature citations that support the recommendation.

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

(a) Criteria for drug use that addresses indications, monitoring, and any efficacy or safety outcomes specific to the Veteran population;

(b) Completion of VA Form 10-0450, VHA National Formulary Request for Formulary Review (see App. A);

(c) Completion of VA Form 10-0451, Conflict of Interest Disclosure Form, by the parties presenting the drug for formulary addition (see App. B); and

(d) The signature of the VISN Formulary Leader, VHA Chief Medical Consultant, or Chief Medical Officer. ***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 center's Commodity Standards Committee, but must be submitted to the VISN Formulary Committee for review prior to forwarding to the PBM for consideration by the MAP and VFL Committees.

n. The PBM must send on 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 VFL 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 center. This process needs to ensure that decisions are evidence-based and timely. Routine requests for non-formulary agents are reviewed and the requestor notified of the decision within 96 hours of receipt of a completed non-formulary request. Emergency requests for non-formulary agents are immediately addressed by individual(s) identified in local VA medical center policy. ***NOTE:*** *If the degree of urgency or emergency is in question, the drug needs to be provided immediately and the nature of the urgency or emergency reviewed afterwards.*

r. Non-formulary drugs that have received FDA approval are only to be approved when:

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

(2) A documented adverse reaction occurred to the formulary agent(s);

(3) A documented therapeutic failure to formulary therapeutic alternatives exists;

(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.

s. All physician-initiated appeals of a non-formulary drug request are received and adjudicated by the facility Chief of Staff.

t. There will be no administrative action taken to discontinue pharmacotherapy initiated by an authorized provider at one VA medical center, when a patient transfers their care to a second VA medical center or when care is transferred back to the primary facility. However, VA providers need to exercise good clinical judgment to discontinue a medication started at a different VA medical center when they have determined that it is not the best agent for a given clinical situation.

u. A new non-formulary request is not required for patients who have had pharmacotherapy initiated on a non-formulary agent at one VA facility, if their care has been transferred to another VA facility, or when care is transferred back to the primary facility.

v. 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.

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

(1) The number of non-formulary requests received;

(2) The number of non-formulary requests approved and denied; and

(3) The average time taken to approve completed requests (reported in hours). ***NOTE:*** *This information is sent, on a quarterly basis, to the PBM Hines.*

x. Since VHA policy is to always dispense generically equivalent drugs when they are available, the PBM and MAP must maintain a list of pharmaceutical products for which substitution is not permitted. Such products are published as the "VA Do Not Substitute." ***NOTE:*** *This listing is available on the PBM Web site at, http://vaww.pbm.va.gov.* ***NOTE:*** *This is an internal VA link not available to the public.*

y. TI of drugs is permissible when required as a result of a VANF initiative and according to the following:

(1) The MAP and VFLs Committee 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 total cost impact for conversion in the estimation of cost savings; and

(d) A review of Veterans Adverse Drug Event Reporting System (VADERS) for all ADEs associated with the implementation phase of the interchange.

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

z. 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.

aa. 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.

bb. All Blanket Purchase Agreements (BPA) must be negotiated at a National level by the PBM. BPAs that require national participation must be approved by the VISN Formulary Leaders Committee. VISN participation in a BPA that does not require national participation is determined by the VISN Pharmacist Executive in consultation with the VISN Formulary Committee.

18. COMPASSIONATE USE OF NUTRICEUTICALS

a. MAP members and VFL have determined that only dietary supplements, where an FDA-approved pharmaceutical has not been proven to be safe and effective may be considered for the VANF and for use on VA patients. The dietary supplements meeting this criterion are referred to as "nutriceuticals." If a dietary supplement meets this definition, it must also meet other rigorous criteria to be considered for use in VA which includes:

(1) Possessing scientific evidence supporting its safe and effective use in a particular disease state. ***NOTE:*** *The evidence must come from well-designed, randomized controlled trials, providing level 1A evidence and published in recognizable peer-reviewed journals.*

(2) Meeting compendium standards for the particular nutriceutical (if standards exist for the product). ***NOTE:*** *The PBM must review the manufacturing standards to ensure the product's consistency of formulation. If compendium standards do not exist for a nutriceutical, the PBM must review all available manufacturing information to satisfy the concern.*

(3) Utilizing Good Manufacturing Practice (GMP) standards as recommended by FDA to ensure a product's purity; and

(4) Prohibiting any product considered to be a food or beverage.

b. Products meeting all of the aforementioned criteria for a nutriceutical, may then be reviewed by both the MAP and VFL Committee, who can recommend formulary status and develop Criteria-for-Use. To determine if the product meets these criteria both the MAP and VFL Committee must:

(1) Review all clinical evidence collected by the PBM clinical staff;

(2) Make a determination of whether or not the supplement meets the VA definition of a nutriceutical;

(3) Recommend the need to develop Criteria-for-Use for the nutriceutical;

(4) List the factors or advantages in which they are interested (e.g., fish oils: product with a lower number of capsules needed to meet required intake) to assist in product selection; and

(5) Recommend VANF status.

c. Once VANF status has been recommended, the assigned contracting officer must:

(1) Develop a solicitation to request bids from manufacturers of the specific nutriceutical;

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

(3) Review manufacturer documentation pertaining to consistency regarding the quantity of ingredients contained in a product; and

(4) Review all manufacturer documentation of GMP standards and evidence that the manufacturer is currently practicing these standards.

d. The contracting agent must review all available product information to determine:

(1) The best price available;

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

(3) The product consistency related to the quantity of ingredients contained in a product; and

(4) The manufacturer's GMP standards.

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

(1) Nutriceuticals may be submitted for review by the MAP and VFL Committee as a Dietary Supplement or based on a perceived need for VA patients.

(2) As with pharmaceuticals, the PBM assigns a clinician to review the particular dietary supplement.

(3) The clinician determines if the supplement meets the VA definition for a nutriceutical. When a supplement does not meet the definition, the requestor is informed.

(4) If the supplement meets the VA definition of a nutriceutical, the clinician reviews the peer-reviewed, published literature to develop a review or monograph. This review is to be similar to that performed for any FDA-approved pharmaceutical.

(5) If the nutriceutical is covered in the U.S. Pharmacopeia, Homeopathic Pharmacopeia of the U.S., or the National Formulary, there must be evidence adequate to support a conclusion that the manufacturing process ensures that the product consistently meets the GMP standard.

(6) If the product is not covered by a compendium standard, there must be evidence demonstrating that a particular manufactured nutriceutical product contains a consistent quantity of the ingredients. However, if VA has doubts regarding consistency of the ingredients, the product can not be considered for addition to the VANF or for non-formulary approval.

(7) If a manufacturer's documentation is available as to its current GMP standards, this documentation may be considered in determining whether the product is free from contaminants and free from impurities introduced during the manufacturing process.

(8) If a product is to be considered for addition to the VANF or for non-formulary approval, both the MAP and VFL Committee must conclude that the product is free from such contaminants and impurities.

19. 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 drugs solely to improve normal physiologic function or to enhance body appearance is generally not considered medically necessary and therefore are 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) Phospodiesterase 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.*

20. 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 tablets.

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 medical center 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 that crumble easily;

(d) Products that cannot be split consistently into equal parts unless small fluctuations in the delivered dose do not alter clinical effect (i.e., some HMG-CoA RIs);

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

(f) Products in which tablet splitting would result in the destruction of the release mechanism of the individual drug; and

(g) Products that are not either scored or round in shape.

(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. Patients with caregivers with 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 (CPRS) when one of the tagged medications is selected for prescription.

(5) Tablet splitting is to be considered <u>only</u> 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 each splitter.

(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 20mg [one-half tablet] daily). 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 drug that is currently being split is changed, 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.

21. 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 1761.2 and follow all requirements. The following are items of particular importance:

(1) The pharmaceutical prime vendor must be used as the primary source of all 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 ROP and 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, must be used for scanning the shelf label for items whose schedule dictates reorder.

(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.

(8) An annual wall-to-wall inventory of all items must be sent by each facility to the PBM Service by February 28th of each calendar year.

b. 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 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. For clarification, one person cannot be the cardholder and approving official for the same transaction.

c. "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 at:* http://vaww.pbm.va.gov/pbm/closeddist.htm . ***NOTE:*** *This is an internal VA link not available to the public.*

d. 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.

22. COMPOUNDING OF NON STERILE PHARMACEUTICAL PREPARATIONS

a. Medical centers must ensure that all non-sterile compounded preparations (NSCP) are prepared and stored in a manner consistent with United States Pharmacopoeia (USP) Chapter 795 (entitled "Pharmaceutical Compounding - Non Sterile Preparations"), USP Chapter 1075 (entitled "Good Compounding Practices"), and USP Chapter 1160 (entitled "Pharmaceutical Calculations in Prescription Compounding"). ***NOTE:*** *The FDA guidance on pharmacy compounding is to be used.*

b. Pharmacy services must assess their capability to compound such preparations that are not commercially available based on equipment, resources, and expertise to evaluate and prepare the final preparation.

c. The requested NSCP must not represent a combination formulation consisting of commercially-available FDA-approved products, unless there exists evidence from published studies to support the safety, efficacy, stability, and, cost effectiveness of NSCP formulation.

d. The pharmacist, or designated pharmacy personnel under the supervision of the pharmacist, is responsible for compounding preparations of acceptable strength, quality, and purity with appropriate packaging and labeling in accordance with good pharmacy practices and current scientific principles.

e. All requests for NSCP must be pursuant to a valid VA prescriber's prescription (or medical order) for an identified patient. When the request for a NSCP is made, the pharmacist must first recommend an alternative therapeutic regimen from the VHA drug formulary to be given full consideration. If the recommended alternative drug product is non-formulary, appropriate procedures are to be followed to secure the drug product.

f. The request for a NSCP would be considered if it is not available commercially and there exists a specific medical need which renders NSCP as significantly different (e.g., the patient is

allergic to one or more of the excipients, inactive ingredients, or dyes in the commercially available product, and there are changes in strength, dosage form, or delivery mechanism that would be considered unique for the NSCP).

g. Any NSCP provided to the patient must conform to the requirements as outlined in the USP provisions (see subpar. 22a).

h. The pharmacist must ensure that the NSCP, if prepared, is:

(1) An article in the USP monograph;

(2) FDA-approved (if no USP monograph exists); or

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

i. A pharmacist must determine if each active ingredient in the requested NSCP is identifiable as to its quantity and quality. 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.

j. The requested NSCP must not present demonstrable difficulties in compounding (e.g., sophisticated drug delivery system, dosage uniformity in bioavailability, complex compounding process, sophisticated facilities or equipment, or highly-technically trained personnel).

k. When compounding a NSCP presents significant difficulty as stated previously, the Chief of Pharmacy Service may consider a contractual arrangement with a compounding pharmacy provided:

(1) The contract pharmacy has the necessary equipment and qualified personnel with appropriate practice experience to compound the NSCP; and

(2) The contract pharmacy is a certified member of the Pharmacy Compounding Accreditation Board. ***NOTE:*** *The Web site for the Pharmacy Compounding Accreditation Board is http://www.pcab.info.*

l. The requested NSCP's intended use must be within the scope of practice or specialty of the prescriber to justify its medical necessity.

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.

n. The pharmacist must ensure that the compounding process of the NSCP is ensured to minimize error and maximize the prescriber's intent for the patient. Specifically, the pharmacist must ensure that:

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

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

(3) The proper attire and procedures are followed by the pharmacist or technician during compounding;

(4) Only one prescription product is compounded at a time;

(5) A log of all compounding is maintained;

(6) A pharmacist checks and verifies each NSCP; and

(7) All required information and instructions are included on the prescription container.

o. Both the prescriber (by the prescription) and the patient (by the label) must be aware that a NSCP is being dispensed.

p. The pharmacist is to provide patient counseling regarding the NSCP to include: its beyond-use date, storage, and on any evidence of instability (e.g., visual changes, odor, etc.) that may be observed.

23. REFERENCES

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NOTE: *The preceding listed references are foundational documents used when first establishing VA formulary policy.*

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

g. Pharmaceutical Compounding – Non-sterile Preparations. (General Information Chapter <795>. In: The United States Pharmacopoeia 29th rev and the National Formulary 24th ed. Rockville, MD: United States Pharmacopoeia Convention: 2006.

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j. 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." ***NOTE:*** *This reference is a foundational document used when first establishing VA formulary policy.*

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

l. United States Pharmacopeia Convention, Inc. USP Pharmacists' Pharmacopeia. Rockville, MD: US Pharmacopeial Convention, Inc.; 2005.

m. Veteran's Benefits and Services Act of 1986, Public Law 100-322.

n. VHA Handbook 1108.04, Investigational Drugs and Supplies.

o. VHA Handbook 1761.2, Inventory Management.

VA FORM 10-0450, VHA NATIONAL FORMULARY REQUEST FOR FORMULARY REVIEW

Department of Veterans Affairs (VA) Form 10-0450, VHA National Formulary Request for Formulary Review, can be found on the VA Forms web site at: http://vaww.va.gov/vaforms/. ***NOTE:*** *This is an internal VA link not available to the public.*

VA Form
10-0450-fill.pdf

VA FORM 10-0451, CONFLICT OF INTEREST DISCLOSURE FORM

Department of Veterans Affairs (VA) Form 10-0451, Conflict of Interest Disclosure Form, can be found on the VA Forms web site at: http://vaww.va.gov/vaforms/. ***NOTE:*** *This is an internal VA link not available to the public.*

VA Form
10-0451-fill.pdf