Department of Veterans Affairs **VHA DIRECTIVE 2001-044**
Veterans Health Administration
Washington, DC 20420 **July 24, 2001**

VA NATIONAL FORMULARY PROCESS

1. PURPOSE: This Veterans Health Administration (VHA) Directive states policy, procedures, and responsibilities for the maintenance of the Department of Veterans Affairs (VA) National Formulary (VA NATIONAL FORMULARY) process.

2. BACKGROUND: Drug formularies in VA date back to the mid-1950s. Beginning in 1996, VA moved from using more than 170 individual drug formularies to assist in the management of pharmacotherapy, to a formulary process that has as its core the VA NATIONAL FORMULARY. The VA NATIONAL FORMULARY is augmented by 22 Veterans Integrated Service Network (VISN) FORMULARIES. The migration to regional and national formularies has allowed VA to rely more uniformly on evidence-based drug evaluations. The new formulary process has enabled VA to focus on the goals of improved patient safety, appropriate use of drugs, improved access to pharmaceuticals, promoting a uniform pharmacy benefit, and lastly, to reduce the acquisition cost of drugs when clinically feasible. ***NOTE:*** *For definitions see Attachment A.*

3. POLICY

a. As an integral part of VA's comprehensive health care delivery process, VA provides high quality and best value pharmaceutical products while assuring the portability and standardization of the pharmacy benefit to eligible veterans enrolled for VA medical care.

b. Items listed on the VA NATIONAL FORMULARY must be made available throughout the VA health care system and must not be made non-formulary at the VISN level.

c. 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 VISN FORMULARY, but will be made available through the non-formulary process when medically necessary.

d. In therapeutic classes or therapeutic sub-classes where national standardization contracts are not awarded, additional items may be added to the VISN FORMULARY.

e. The VISN FORMULARY and VA NATIONAL FORMULARY are the only drug formularies authorized for use in VA. The use of local drug formularies at individual medical care facilities is prohibited.

f. Restrictions can be established at both the national and VISN levels for VA NATIONAL FORMULARY items that require close monitoring to ensure appropriate use. In the case of anti-infectives, facility level restrictions intended to prevent resistance and/or to promote appropriate use are also permissible. Restrictions may include evidence-based guidelines and/or prescribing privileges for providers with certain expertise. Restrictions

shall not be based solely on economic issues and shall not be so limiting as to prevent patients with legitimate medical needs from receiving VA NATIONAL FORMULARY medications.

g. If a patient has pharmacotherapy initiated by an authorized VA provider at one VA medical care facility and transfers his or her care to a second VA medical facility, the pharmacotherapy will be continued when clinically appropriate, regardless of differences in VISN FORMULARIES. There will be no administrative action to change the pharmacotherapy exclusively due to differences in VISN FORMULARIES. As always, the prescriber must use his or her best clinical judgment when selecting the most appropriate pharmacotherapy for a specific patient in a specific clinical situation.

h. VA NATIONAL FORMULARY recommendations will be based on reviews of drug products approved by the Food and Drug Administration (FDA). Requests for drug or drug class reviews may be made by VISN Formulary Committees, the VISN Formulary Leaders Committee, the Medical Advisory Panel (MAP), VHA Chief Consultants, or VHA Chief Officers. Pharmacy Benefits Management (PBM) staff will conduct drug reviews for New Molecular Entities approved by the FDA in a timely manner. The reviews will emphasize safety and efficacy of the drugs in patient populations similar to the veteran population. VISNs will not add New Molecular Entities to the VISN FORMULARY until a national review is completed.

i. Drugs shall not be added to the VA NATIONAL FORMULARY solely for the purpose of performing a clinical trial; however, the VA NATIONAL FORMULARY is not intended to hinder the use of any pharmaceutical agent in legitimate scientific studies.

j. Each VISN shall have a non-formulary drug approval process in place that addresses local needs in an expeditious manner.

k. In some instances, the PBM-MAP review of a New Molecular Entity may result in a recommendation that the drug not be added to the VA NATIONAL FORMULARY, while also permitting individual VISNs to add it to their VISN FORMULARIES. In these cases, if ten or more VISNs eventually add such a drug to their VISN FORMULARIES, the PBM will conduct a re-review of that drug for consideration for VA NATIONAL FORMULARY listing.

l. The PBM/Medical Advisory Panel (MAP) will perform evidence-based therapeutic drug class reviews that may or may not lead to national standardization contract initiatives.

m. In cases where the Therapeutic Interchange (TI) of drugs is required as a result of a VA NATIONAL FORMULARY initiative, the PBM will provide guidance to VISNs regarding essential conversion process elements.

n. Final decisions for VA NATIONAL FORMULARY listing will be made by consensus of MAP and the VISN Formulary Leaders Committee. In situations where consensus cannot be reached, the recommendation of the MAP will prevail.

o. The PBM/MAP will maintain a list of proprietary pharmaceutical products for which generic dispensing is not permitted. Such products will be published as the "VA Negative Formulary" on the PBM web site (http://www.pbm.med.va.gov). Currently, the VA Negative Formulary contains the following products: Coumadin®, Dilantin®, Lanoxin®, and Tegretol®.

4. ACTION

a. Responsibilities

(1) The VA Deputy Under Secretary for Health is responsible for assuring that the intent and letter of this Directive is carried out.

(2) The VISN Director is responsible for:

(a) Assuring that a VISN Formulary Committee is in place and that no less than one-third of the voting members are practicing physicians and no less than one-half of all voting members are practicing physicians or non-physician prescribers. A simple majority of voting members is required to conduct Formulary Committee business.

(b) Identifying a VISN Formulary Committee representative to serve as liaison to the PBM VISN Formulary Leaders Committee.

(c) Implementation of the VISN FORMULARY and VA NATIONAL FORMULARY at all facilities within the VISN.

(d) Assuring that VISN restrictions for VA NATIONAL FORMULARY products meet the intent of this Directive.

(e) Assuring that a non-formulary approval process is functioning in all VISN medical centers and clinics.

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

(3) The VISN Formulary Leader is responsible for:

(a) Providing operational support for VISN FORMULARY processes. Activities often include coordination of pharmacy benefit activities for the VISN.

(b) Attending and participating in quarterly VISN Formulary Leaders meetings with the PBM and national contracting officials and participating on monthly conference calls.

(c) Collecting and collating drug-related survey information from local VISN facilities if requested by the PBM.

(d) Communicating their VISN FORMULARY COMMITTEE decisions and actions to VISN and pharmacy leadership within their VISN.

(e) Using the template provided, providing information to the PBM on all drugs added to the VISN FORMULARY.

(f) Providing input to the PBM regarding the impact of VA NATIONAL FORMULARY decisions on VISN operations.

(g) Reporting VISN restrictions to the PBM if requested.

(h) Assessing and evaluating national and local drug utilization for the VISN formulary committee.

(i) Representing the VISN on VA NATIONAL FORMULARY and drug policy decisions, i.e., the liaison can vote for the VISN on a policy or assist in writing a policy.

(j) Widely disseminating draft Drug Class Reviews, Criteria for Use Statements, Pharmacologic Management Guidelines, and other material necessary to manage the formulary process and solicit feedback for the PBM, MAP, and other reviewers.

(4) The VISN Formulary Committee is responsible for:

(a) Identifying and requesting drugs for listing on or removal from the VA NATIONAL FORMULARY.

(b) Widely disseminating draft and final Drug Class Reviews, Criteria for Use Statements, Pharmacologic Management Guidelines, and other material necessary to manage the formulary process.

(c) Effectively communicating VA NATIONAL FORMULARY decisions to facility Pharmacy and Therapeutics Committees and clinical staff.

(d) Reviewing PBM reports and data on non-formulary utilization, access to VA NATIONAL FORMULARY products and variation between the VISN FORMULARY and the VA NATIONAL FORMULARY, and taking appropriate action when necessary.

(e) Providing a copy of the VISN Therapeutic Interchange plan when a VA NATIONAL FORMULARY initiative requires TI. The TI Plan will include examples of patient and provider communication and education materials and a general description of how TI will be accomplished. Reporting to the PBM will be completed within 90 days of implementation of the VA NATIONAL FORMULARY initiative.

(f) Reviewing data provided to the PBM on the formulary status designation of drugs by facilities within the VISN and assuring the accuracy of the designation.

(g) Adding drugs to or removing drugs from the VISN FORMULARY where permissible.

(5) Although facility-level formularies are no longer utilized by VA, medical care facilities' Pharmacy and Therapeutics Committees or similar authorized bodies continue to have responsibilities for:

(a) Implementing and supporting VISN FORMULARY and VA NATIONAL FORMULARY initiatives.

(b) Assuring that the formulary status designations and drug pricing in the local drug file are up to date and accurate.

(c) Widely disseminating draft and final PBM-MAP Drug Class Reviews, Criteria for Use Statements, Pharmacologic Management Guidelines, and other material necessary to manage the formulary process.

(d) Effectively communicating VISN FORMULARY and VA NATIONAL FORMULARY decisions to medical care facility clinical staff.

(e) Monitoring non-formulary use and providing the information to the VISN Formulary Committee.

(f) Providing input to the VISN Formulary Committee regarding the impact of VISN FORMULARY and VA NATIONAL FORMULARY decisions on facility operations.

(g) Assuring compliance with access to VA NATIONAL FORMULARY items in closed therapeutic classes and sub-classes and selected therapeutic classes and sub-classes and keeping the VISN Formulary Committee informed of any problems or concerns.

(h) Assuring compliance with the VISN Therapeutic Interchange plan when a VA NATIONAL FORMULARY initiative requires TI.

(6) In consultation and collaboration with the MAP and VISN Formulary Leaders (VFLs) Committee, the PBM is responsible for:

(a) Supporting, implementing, maintaining, and updating the VA NATIONAL FORMULARY. The VA NATIONAL FORMULARY is available on the PBM web site, http://vaww.pbm.med.va.gov.

(b) Monitoring non-formulary use and providing utilization data and reports to the VISN Formulary Committees.

(c) Monitoring drug utilization variation among VISNs and providing data and reports to the affected VISN Formulary Committees.

(d) Recommending to the MAP necessary actions identified while conducting drug utilization analyses.

(e) Monitoring compliance with access to VA NATIONAL FORMULARY items in closed therapeutic classes and sub-classes and selected therapeutic classes and sub-classes by facilities and reporting variation to VISN Directors, VISN Clinical Managers, and VISN Formulary Committees for action.

(f) Providing VISN Formulary Committees with data on the drug formulary status designations for drugs in the facility drug files.

(g) Developing and distributing criteria for addition of drugs to and removal of drugs from VISN FORMULARIES.

(h) Developing a template for quarterly VISN Formulary Committee reporting of drugs added to or removed from the VISN FORMULARY and non-formulary approvals and disapprovals by VISNs.

(i) Developing a system-wide approach for TI when a VA NATIONAL FORMULARY initiative requires TI. The PBM will identify the important aspects of TI that must be included in each VISN's TI Plan. Such elements will include patient selection criteria, patient and provider communication, patient and provider education, monitoring of any conversion-related Adverse Drug Events, and identification of clinically acceptable conversion methods.

b. **Procedures**

(1) **Request for change in VA NATIONAL FORMULARY status:** Requests may be made by VISN Formulary Committees, the VISN Formulary Leaders Committee, the Medical Advisory Panel (MAP), VHA SHG Chief Consultants, or VHA Chief Officers. Requests should be forwarded to: Pharmacy Benefits Management Strategic Health Group (119D), P.O. Box 126, Hines, IL 60141.

(a) All requests must contain: Minutes of the VISN Formulary Committee or other meeting in which action was taken on the product (if applicable); literature citations that support the recommendation; and for additions to VA NATIONAL FORMULARY, the requestor or requesting body must supply criteria for drug use that address indications, monitoring, and any efficacy or safety outcomes specific to the veteran population. The request must include the signature of the VISN Formulary Leader, SHG Chief Consultant, or Chief Officer.

(b) Within 30 days of receipt of the request, the requestor will be notified in writing by the PBM if a national review will be conducted, and if so, the target date for completion of the review. The PBM will advise the VISN Formulary Leaders of requests received, and seek evidence-based feedback from all VISN Formulary Committees before any decision regarding VA NATIONAL FORMULARY additions or deletions are made. If a review is conducted, a draft will be distributed to VISN Formulary Committees for wide dissemination and comment.

(2) **Non-formulary requests**

(a) A non-formulary request process must exist at each VA medical treatment facility. The process should assure that decisions are evidence-based and timely.

(b) Normally, non-formulary requests will be reviewed and the requestors will be notified of the approval or disapproval decision within 96 hours of the receipt of a complete non-formulary request by individuals identified in local VA medical center policy.

(c) Emergency requests for non-formulary drugs will be immediately addressed by individuals identified in local VA medical center policy.

(d) Non-formulary drugs should be approved under the following circumstances:

1. Contraindication(s) to the formulary agent(s).

2. Adverse reaction to the formulary agent(s).

3. Therapeutic failure of all formulary 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.

6. Other circumstances having compelling evidence-based clinical reasons.

(e) Non-formulary requests will not be required for patients who have had pharmacotherapy started at one VA facility, and whose care has been transferred to another VA facility where the existing pharmacotherapeutic agent is considered non-formulary.

(f) Individual medical care facilities are prohibited from marking VA NATIONAL FORMULARY and VISN FORMULARY drugs as non-formulary in the local drug file as a means to enforce restrictions or control utilization.

(g) For selected non-formulary approvals, VISN Formulary Committees or Local Pharmacy and Therapeutics Committees should require a reevaluation of the approval based upon clinical response.

(h) Each VISN will establish a process to analyze and trend non-formulary utilization data at the VISN and local facility levels. Reported information will include the number of non-formulary requests received, the number of non-formulary requests approved and denied, and the average time taken to approve requests.

(3) **VA NATIONAL FORMULARY Database Maintenance**

(a) The VA NATIONAL FORMULARY database will be maintained by the PBM.

(b) VA NATIONAL FORMULARY drug listings will be grouped according to the VA Classification System.

(c) The VA NATIONAL FORMULARY will be updated by the PBM when changes are made. The FORMUALRY is available on the PBM web site, http://vaww.pbm.med.va.gov.

5. REFERENCES

a. VHA Directive 10-95-111. Implementation of Veterans Integrated Service Network Formularies. November 7, 1995.

b. JCAHO Comprehensive Accreditation Manual for Hospitals, November 2000, TX.3.1, TX.3.2.

c. Best Practices for Health-System Pharmacy, Position and Practice Standards of the ASHP, 1999-2000.

d. Veterans Health Services and Research Administration Manual M-2, "Clinical Affairs" Part VII, Pharmacy Service.

e. Institute of Medicine Report *"Description and Analysis of the VA National Formulary"*, http://www.nap.edu.books/0309069866/html/

f. United States General Accounting Office Report to the Ranking Minority Member, Committee on Veterans' Affairs, U.S. Senate. *"VA's Management of Drugs on Its National Formulary,"* GAO/HEHS-00-34. December 1999.

g. United States General Accounting Office Report to the Ranking Member, Committee on Veterans' Affairs, U.S. Senate *"Better Oversight Is Required, but Veterans Are Getting Needed Drugs,"* GAO-01-183. January 2001.

h. Principles of a Sound Drug Formulary System. The Formulary Principles Coalition. October 2000. http://vaww.pbm.med.va.gov/pbm/formularyprinciples.pdf

6. FOLLOW-UP RESPONSIBILITY: The Chief Consultant, Pharmacy Benefits Management, Strategic Healthcare Group (119), is responsible for the content of this Directive.

7. RESCISSIONS: VHA Directive 97-047 is rescinded. This VHA Directive will expire July 31, 2006.

S/Thomas L. Garthwaite, M.D.
Under Secretary for Health

Attachment

DISTRIBUTION: CO: E-mailed 8/2/2001
FLD: VISN, MA, DO, OC, OCRO, and 200 - FAX E-mailed 8/2/2001

VHA DIRECTIVE 2001-

(DATE)

ATTACHMENT A

DEFINITIONS

1. VA NATIONAL FORMULARY items are defined as any products listed on the VA NATIONAL FORMULARY. These products must be available at all VA facilities, and cannot be made non-formulary by a Veterans Integrated Service Network (VISN). This definition does not require that a physical inventory of VA NATIONAL FORMULARY items be maintained at all facilities; however, if a clinical need for a VA NATIONAL FORMULARY product arises in the course of treating a patient, then the VA NATIONAL FORMULARY product must be made available to the patient.

2. VISN FORMULARY products are defined as products listed on the VISN FORMULARY. All VA NATIONAL FORMULARY products must be included on the VISN FORMULARY. With the exception of instances where therapeutic classes or therapeutic subclasses have been closed through national standardization contracting, VISNs may add additional items to the VISN FORMULARY to meet patient care needs.

3. VA NATIONAL FORMULARY RESTRICTED medications are those that require close monitoring to ensure appropriate use. Restrictions may include implementing evidence-based guidelines and/or allowing prescribing privileges to providers with certain expertise. 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 will not be based solely on economic issues and should not be so limited as to prevent patients with legitimate medical needs from receiving needed medications.

4. NON-FORMULARY medications are defined as commercially available drug products not included on the VA NATIONAL or VISN FORMULARIES.

5. NEGATIVE FORMULARY items are proprietary VA NATIONAL FORMULARY products for which generic drug products not be dispensed. VA's Negative Formulary list will be maintained on the PBM intranet web site (http://vaww.pbm.med.va.gov).

6. The PHARMACY BENEFITS MANAGEMENT STRATEGIC HEALTH CARE GROUP (PBM) is comprised of clinical pharmacists, data analysts and administrative pharmacy personnel. In cooperation with the MAP and the VISN Formulary Leaders Committee, the PBM is responsible for facilitating and coordinating the VA NATIONAL FORMUALRY process.

7. MEDICAL ADVISORY PANEL (MAP) members provide physician oversight to the PBM on formulary management issues. MAP membership includes practicing VA physicians, one Department of Defense physician and PBM clinical pharmacist staff.

8. VISN FORMULARY LEADERS (VFLs) COMMITTEE members provide clinical, strategic and operational input to the PBM on VA NATIONAL FORMULARY management issues. The VFLs Committee is comprised of pharmacist and physician representatives from each of the 22 VISNs.

9. VISN FORMULARY LEADERS (VFLs) 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 their VISN's representative to the PBM VISN Formulary Leaders Committee.

10. VISN FORMULARY COMMITTEES are comprised of medical personnel from within a VISN. The function of the VISN Formulary Committee is to provide clinical oversight and guidance for the VISN FORMULARY process, coordinate VA NATIONAL FORMULARY initiatives at the VISN and facility levels and provide input to the PBM and MAP regarding the VA NATIONAL FORMULARY process.

11. THERAPEUTIC CLASSES are defined as groupings of individual drugs with similar therapeutic uses, but not necessarily similar pharmacologic activity (e.g., an Antilipemic Therapeutic Class could contain HMG-CoA RIs, Bile Acid Sequestrants as well as Fibric Acid Derivatives and Nicotinic Acid).

12. THERAPEUTIC SUBCLASSES are defined as groupings of drugs with similar pharmacologic activity (e.g., an HMG-CoA RI Therapeutic Subclass could contain all HMG-CoA RIs).

13. THERAPEUTIC INTERCHANGE: The authorized exchange of therapeutic alternates in accordance with previously established and written guidelines or protocols within a formulary system.