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Report to the Ranking Minority Member, Committee on Veterans' Affairs, U.S. Senate

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VA HEALTH CARE

VA's Management of Drugs on Its National Formulary

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GAO

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Health, Education, and
Human Services Division

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December 14, 1999

The Honorable John D. Rockefeller IV
Ranking Minority Member
Committee on Veterans' Affairs
United States Senate

Dear Senator Rockefeller:

The Department of Veterans Affairs (VA) spent over $1.8 billion (11 percent of its health care budget) to provide pharmacy benefits to veterans in fiscal year 1999. To help manage its pharmacy benefit, VA maintains a list of drugs that its physicians are expected to use when prescribing drugs for veterans, known as the national formulary. A formulary is a list of drugs, grouped by therapeutic class, that a health care organization prefers that its physicians prescribe. VA provides outpatient pharmacy services free to veterans receiving medications for the treatment of service-connected conditions and to veterans whose income does not exceed the maximum VA pension, regardless of the drugs' formulary status. Other veterans may be charged $2 for each 30-day supply of medication.

You expressed interest in knowing how VA manages its national formulary and how drugs other than those on the national formulary are made available to veterans.[1] In performing our work to address these issues, we met with VA officials responsible for managing the national formulary, reviewed program guidance and operating procedures, and visited with pharmacy managers in two VA medical centers. We also spoke with officials from the Institute of Medicine concerning their study of VA's formulary. We performed our work between April 1999 and November 1999 in accordance with generally accepted government auditing standards.

Results in Brief

VA's national formulary is administered by the Pharmacy Benefits Management Strategic Healthcare Group (PBM), a strategy modeled after one commonly used in private health care systems. PBM adds drugs to, and deletes drugs from, the national formulary on the basis of a review of current literature related to drugs' safety and efficacy and the

[1]We are continuing to examine how VA's national formulary may affect providers' ability to prescribe needed medications and other formulary issues and will report on these matters at a later date. In addition, the Institute of Medicine has work under way to address (1) the effect of the national formulary on the cost and quality of VA's health care, (2) the restrictiveness of VA's national formulary, and (3) how the national formulary compares with private and other government formularies. These issues will not be part of our continuing evaluation.

contributions they can make in treating veterans. The PBM also performs drug class reviews that determine which drugs are therapeutically interchangeable—essentially equivalent in terms of efficacy, safety, and outcomes. This determination allows VA to obtain better prices for one or more of these drugs by using competitively bid contracts. Finally, PBM safeguards against inappropriate use by requiring that clinical guidelines be followed when some drugs are used; limiting prescribing privileges in certain cases to specially trained physicians; and, in other cases, requiring consultation with a specialist before a drug can be prescribed.

Drugs not on the national formulary may be available to veterans through independent formularies maintained by Veterans Integrated Service Networks (VISN) and some medical centers. These formularies are designed to provide local facilities flexibility by giving physicians access to additional drugs that meet the special needs of their patients. In addition, if prescribers believe that a patient needs a drug that is not on the national, VISN, or medical center formulary, they may request a nonformulary drug waiver, which would allow the prescriber to provide the nonformulary drug. New drugs may be added to VISN and medical center formularies immediately upon Food and Drug Administration (FDA) approval. However, VA policy states that new drugs generally may not be added to the national formulary until they have been on the U.S. market for at least 1 year because VA believes veterans may be exposed to potential side effects that are not identified during the drug review and approval process. This potentially allows veterans treated in some facilities to benefit from new drugs before veterans in other locations, but, according to some VA officials, it may also expose them to any side effects that are identified within the first year of a drug's general use.

Background

In fiscal year 1999, VA's Veterans Health Administration (VHA) provided primary and specialty medical care to about 3.3 million veterans at a cost of approximately $17 billion. A pharmacy benefit that provides prescriptions, medically necessary over-the-counter drugs, and medical and surgical supplies is an important component of this care. VA provides outpatient pharmacy services free to veterans receiving medications for treatment of service-connected conditions and to veterans whose incomes do not exceed the maximum VA pension, regardless of the drugs' formulary status. Other veterans who have prescriptions filled by VA may be charged $2 for each 30-day supply of medication.

Formularies are generally used in the health care industry to help control pharmacy costs and improve quality of care by (1) limiting the number of drugs available; (2) using financial incentives such as variable copayments to encourage the use of formulary drugs; (3) using compliance programs, such as prior authorization, that encourage or require physicians to prescribe formulary drugs; and (4) developing clinical guidelines for prescribing drugs.

Pharmacy Costs as a Percentage of VHA's Budget Nearly Doubled in Last 9 Years

VHA's cost of providing pharmacy services to veterans has more than doubled over the past 9 years and has accounted for an increasing share of total costs. As table 1 shows, in fiscal year 1990, VHA spent approximately $716 million, or 6 percent of its total budget, on pharmacy services, but by fiscal year 1999, the amount had climbed to $1.8 billion, or about 11 percent of its budget.

Table 1: Total VHA Budget and Pharmacy Expenditures, Fiscal Years 1990-99

Dollars in thousands

Fiscal year	Total VHA budget	Pharmacy expenditures	Percentage of total VHA budget
1990	$11,499,879	$715,879	6
1991	12,400,326	795,114	6
1992	13,682,060	881,593	6
1993	14,612,138	912,531	6
1994	15,400,526	924,482	6
1995	16,125,957	1,054,961	7
1996	16,372,856	1,101,056	7
1997	17,149,463	1,337,487	8
1998	17,441,079	1,548,424	9
1999	17,306,000	1,844,742	11

VHA officials believe that the more rapid cost increase in VHA's pharmacy benefit from 1996 to the present is attributable, in part, to VHA's shift from primarily inpatient care to outpatient care, the high cost of new drugs entering the market, and the growing need for expensive drug treatments for chronic diseases such as heart disease and chronic obstructive pulmonary disease. These upward cost trends are expected to continue, and pharmacy costs are expected to consume an increasing percentage of the VHA budget over the foreseeable future.

VA's Use of Formularies

VA medical centers began using formularies as early as 1955 to manage their pharmacy inventories, and until recently each of VA's 173 medical centers maintained its own formulary. Because of the mobility of VA patients, VHA officials believed that moving from uncoordinated, facility-specific formularies to a national formulary should improve veterans' continuity of care. In September 1995, VA established the PBM, a centralized group to manage its pharmacy benefit nationwide.

In November 1995, in concert with the establishment of VISNs,[2] the Under Secretary of Health directed each VISN to develop and implement a networkwide formulary and a mechanism for ensuring integration of medical center and VISN formulary decisions. The process for developing these formularies was left to the discretion of VISN directors, assisted by VISN formulary leaders.[3] However, on the basis of suggested guidance from a VHA directive, networks generally combined existing medical center formularies. VISN formularies became effective on April 30, 1996.

In 1996, also recognizing the effect of veterans' increasing mobility on their access to care, the Congress required VA to improve veterans' access to care regardless of the region of the United States in which they live. As one response, on June 1, 1997, VA implemented a national drug formulary by combining the core set of drugs common to the newly developed VISN formularies. The national formulary contained only drug items until December 1997, when VA added medical and surgical supplies. By virtue of an item's listing on the national formulary, VA requires that it be made available to veterans throughout VA's health care system, if the item is medically appropriate.

The benefits of establishing a national formulary in VA include (1) standardizing drug availability among its facilities, (2) increasing continuity of care by decreasing variations in practice among VA facilities by using clinical guidelines, (3) standardizing the processes for evaluating evidence on safety and efficacy in selecting drugs, and (4) helping to manage the cost growth in the pharmacy benefit. VA also uses its formulary to comply with Joint Commission for the Accreditation of Health Care Organizations standards that require VA to develop and maintain an appropriate selection of medications prescribers may use in treating their patient populations.

[2]In fiscal year 1996, VA shifted management authority for basic decision-making and budgetary duties from its headquarters to 22 new regional networks called VISNs.

[3]VISN formulary leaders appointed by VISN directors are the liaisons between VISN management and VA officials responsible for managing the national formulary.

Drugs are usually grouped by class, depending on their mechanism of action and therapeutic effect. VA's national formulary is composed of 304 classes of drugs and supplies used to treat similar illnesses or conditions. Of the 304 classes, 251 include drugs used to treat a wide variety of illnesses. The remaining 53 classes include medical and surgical supply items, such as diabetic supplies and bandages. Approximately 1,100 different drugs are included in VA's 251 drug classes. When counting all forms and dosage levels of all drugs represented, the national formulary includes approximately 7,500 drug items. About 125 items are included in VA's 53 medical and surgical supply classes.[4]

VISNs and their associated medical centers are allowed to maintain and manage their own independent formularies, which include drugs in addition to those on the national formulary. VISNs may add or delete drugs on their formularies without seeking approval from VA headquarters. While PBM does not track the contents of VISN formularies, PBM estimates that the 22 VISN formularies include approximately 5,500 forms and dosages of medications that are not on the national formulary. The only prohibition placed on VISNs and medical centers in adding or deleting drugs on their formularies is that they may neither delete drugs listed on the national formulary nor add drugs to those classes for which there are national committed-use contracts—contracts for drug purchases that require VA to agree to use primarily the products chosen in exchange for lower prices.

National Formulary Management Process

In September 1995, before implementing a national formulary, VA established its PBM, modeled after a strategy commonly used in the private sector, to manage the cost, use, outcomes, and distribution of pharmaceuticals. PBM centralized the management of VA's pharmacy benefit and, working in conjunction with VA's National Acquisition Center (NAC), seeks to obtain the drugs needed to treat veterans at the best price. PBM (1) facilitates the addition and deletion of drugs on the national formulary on the basis of safety and efficacy data; (2) determines which drugs are therapeutically interchangeable,[5] in order to purchase drugs through competitive bidding; and (3) develops safeguards to protect veterans from the inappropriate use of certain drugs.

[4]The list of drugs on VA's national formulary is available at Internet address www.dppm.med.va.gov

[5]Therapeutic interchange is the clinically appropriate replacement of one drug with another drug having the same pharmacological or therapeutic effect.

Process for Adding and Deleting Drugs

VA's process for considering the addition and deletion of drugs on its national formulary begins with a request from a senior official in one of VA's Strategic Healthcare Groups (an organizational unit within VA responsible for a particular continuum of care for a specific patient population), a PBM consultant, or a recommendation from the Medical Advisory Panel.[6] Requests may also come from VISN formulary committees that, in turn, may have originated from requests made to those committees by medical center pharmacy and therapeutics committees.[7]

A request for formulary review is submitted to PBM. A clinical pharmacist then evaluates the current literature on the drug and prepares a document reviewing the pharmacology, indications for use, a comparison with drugs currently on the formulary, adverse effects, and cost and utilization data. This document is forwarded to the Medical Advisory Panel for its consideration. After receiving input from other clinicians, the Panel makes the final decision about whether the drug should be added to the national formulary. VA has added 26 and deleted 6 drugs on the national formulary since it was established in 1997.

According to PBM officials, cost is not a major consideration during the initial phase of reviewing a drug. Decisions to add or delete drugs on the national formulary are made using criteria similar to those used by pharmacy benefit managers in the private sector—safety and effectiveness. Purchasing the drug at the lowest price possible is the responsibility of VA's NAC, which uses several purchasing techniques, including competitive bidding for drugs available from multiple sources. VA officials believe this two-phased process ensures that the drugs on the national formulary include those representing the "best value"—the most effective treatment at the least cost—rather than simply the least expensive drug available.

Determination of Therapeutic Interchange Allows VA to Obtain Better Prices

Drugs on the national formulary are assigned to one of VA's 251 drug classes—groups of drugs similar in chemistry, method of action, or purpose of use. After performing drug class reviews, VA decided that some drugs in 4 of its 251 drug classes are therapeutically interchangeable and

[6]The Medical Advisory Panel is a working group made up of 11 practicing physicians who are currently on staff at VA medical centers and 1 practicing Department of Defense physician. Members are appointed for a 2-year term. Its mission is to help manage VA's national formulary and to assist in developing evidence-based clinical practice guidelines. The Medical Advisory Panel is organizationally part of the PBM.

[7]Pharmacy and therapeutics committees are composed of physicians, pharmacists, and other health care professionals who address formulary issues and establish drug treatment policies.

therefore limited the number of similar drugs in these classes. These four classes are known as "closed" classes. VA has not made a clinical decision regarding therapeutic interchange in the remaining 247 drug classes, and it does not limit the number of drugs that can be added to these classes. These are known as "open" classes.

A closed class usually contains drugs that either have a high volume of use or are high cost; this therefore presents an opportunity to obtain a lower price through competitive bidding. To close a class, VA evaluates the clinical evidence to determine whether the drugs in that class are basically equivalent in terms of efficacy, safety, and outcomes and therefore generally have the same therapeutic effect. The clinician responsible for the review prepares a report on the extent to which the drugs in the class are therapeutically interchangeable and, in conjunction with a Medical Advisory Panel representative, makes a recommendation as to whether the class should be closed and competitive contracts considered. The drug class report is submitted to the Panel for its deliberation, comments, and modification. The report then goes to VISN directors and pharmacy officials in the VISNs and medical centers for comment. The final report, incorporating all agreed-upon changes, is returned to the Panel, which makes a final decision.

Once VA has determined that a class will be closed, the drugs that have been determined therapeutically interchangeable are referred to NAC for contracting purposes. VA then contracts for one or more of these therapeutically interchangeable drugs using competitively bid national committed-use contracts. By committing to use these drugs to treat veterans throughout its health care system, VA can assure the drug companies a high volume of use and drug companies in turn are more likely to offer a lower price.

VA's four closed classes may also contain drugs that are not therapeutically interchangeable. These drugs have different mechanisms of action and represent alternative agents for treating the same conditions. Table 2 lists the four closed classes, the diseases the drugs in the classes generally treat, and the specific drug(s) in the classes for which VA has awarded committed-use contracts.

Table 2: National Formulary Closed Classes and Drugs With Committed-Use Contracts

Drug class (VA class code)	Disease treated	Drug(s) with committed-use contracts
Antineoplastic Hormones (AN500)	Prostate cancer	Goserelin acetate implant syringe
Antilipemic Agents (CV350)	High cholesterol	Gemfibrozil, Lovastatin, Simvastatin
ACE Inhibitors (CV800)	High blood pressure	Captopril, Fosinopril, Lisinopril
Gastric Medications (GA900)	Stomach ulcers	Lansoprazole

In fiscal year 1999, prescriptions for the drugs in the closed classes represented 10 percent of all filled prescriptions written by VA prescribers and 13 percent of VA's pharmaceutical expenditures. VA reports that compliance with national committed-use contracts exceeds 94 percent. Once the class has been designated closed, VISNs and medical centers are not allowed to add items to those classes on their own formularies.

VA's remaining 247 drug classes are designated as open, meaning that VA has not made a decision to award committed-use contracts for drugs in these classes. Open classes may contain several drugs, and VA may purchase the drugs in these classes using a variety of contracting instruments to obtain the best possible price. If a class is open, VISNs and medical centers may add items to it on their own formularies.

Safeguards Developed to Protect Veterans From Inappropriate Drug Use

Because of the unique characteristics of certain drugs, VA's national formulary places some restrictions or controls on their use. VA has applied restrictions to 123 drugs listed on the national formulary. Restrictions are generally placed on the use of a drug if it has the potential for inappropriate use, making it ineffective or high risk. For example, restrictions are placed on the use of antibiotics because organisms can develop resistance to them, making them ineffective in treating disease. Because they are high-risk drugs, acyclovir, used to treat HIV/AIDS, and interferon, used to treat hepatitis C, are restricted by guidelines established by subject matter experts.

Controls to restrict drug use include applying clinical guidelines, limiting prescribing privileges to specially trained physicians, and requiring the prescriber to consult with a specialist before a drug can be prescribed. VA has adopted clinical guidelines for the treatment of 10 common diagnoses associated with its patient population. These guidelines assist

practitioners in making decisions about the diagnosis, treatment, and management of specific clinical conditions, such as congestive heart failure, depression, and hypertension. Clinical experts inside, as well as outside, VA developed these guidelines. Recommendations for the use of certain drugs as a part of the management of these clinical conditions are identified in each guideline. The use of these drugs may be restricted to comply with these guidelines.

In addition, VA has adopted clinical guidelines to assist practitioners in making decisions about the appropriate use of specific drugs. These guidelines help standardize treatment, improve the quality of patient care, and promote the cost-effectiveness of prescriptions. The guidelines specifically address the role of the drug in managing VA patients and include appropriate dosing guidelines and monitoring parameters.

Access to Drugs Not Limited to Those on the National Formulary

The effect of a formulary on the prescribers' choice of drugs depends on how difficult it is to provide drugs that are not listed on the formulary. Formularies that do not impose additional charges on their patients if their physicians prescribe drugs other than those on the formulary are often described as "open."[8] Open formularies are often used in conjunction with compliance programs that are used to make physicians aware of which drugs are on the formulary. Open formularies are often referred to as "voluntary" because beneficiaries are not penalized financially if their physicians prescribe nonformulary drugs.

In addition to drugs listed on VA's national formulary, physicians may also prescribe drugs listed on formularies developed and maintained independently by VISNs and some medical centers. VISN and medical center formularies are designed to provide flexibility and allow physicians to meet the special needs of their patients. In addition, if a prescriber believes that a patient needs a drug that is not included on the national, VISN, or medical center formularies, he or she may request a waiver, which, if approved, allows the nonformulary drug to be prescribed. Although new drugs may be added to VISN and medical center formularies immediately upon FDA approval, such drugs generally may not be added to the national formulary until they have been on the U.S. market for 1 year. This creates discrepancies across VA's health care system, allowing veterans treated in some VA facilities to possibly benefit from new drugs sooner than veterans treated in other locations. At the same time, these veterans are exposed to

[8]Prescription Drug Benefits: Implications for Beneficiaries of Medicare HMO Use of Formularies (GAO/HEHS-99-166, July 20, 1999).

the risk of possible side effects that may be identified within the first year of general use of a drug, while other veterans are provided a greater margin of safety, according to VA officials.

VISN and Medical Center Formularies Supplement the National Formulary

Each of VA's 22 VISNs is allowed to add drugs to its formulary in addition to the drugs on the national formulary. Although each VISN may make formulary decisions on the basis of slightly different steps and procedures, VISNs generally follow processes similar to the one used to add drugs to the national formulary. Requests for a drug's consideration may come from a VISN's pharmacy and therapeutics committee or from such committees located in any of the VISN's individual facilities. VA requires the VISN committee members to review literature and evidence from clinical trials to assess efficacy, safety, and outcomes before the VISN may add a drug to its formulary.

VISNs have reported to VA's PBM that they have added 268 drugs to open classes on their individual formularies since the national formulary began in June 1997. These formulary drugs are available for use by medical center prescribers only in the VISNs where they were added. Between June 1997 and June 1999, VISNs added drugs to their formularies at varying rates, ranging from as few as 2 (VISN 8—Bay Pines) to as many as 87 (VISN 20—Portland) (see table 3). During that same period, 26 drugs were added to the national formulary. VISN formularies have been a significant source of growth in the number of drugs available for VA prescribers and their patients.

Table 3: Drugs Added to VISN Formularies, 1998 and 1999

VISN	1998	Jan.-June 1999	Total
1 (Boston)	8	5	13
2 (Albany)	10	6	16
3 (Bronx)	20	2	22
4 (Pittsburgh)	21	0	21
5 (Baltimore)	6	10	16
6 (Durham)	22	6	28
7 (Atlanta)	50	9	59
8 (Bay Pines)	2	0	2
9 (Nashville)	15	0	15
10 (Cincinnati)	12	3	15
11 (Ann Arbor)	10	9	19
12 (Chicago)	13	9	22
13 (Minneapolis)	30	3	33
14 (Omaha)	5	1	6
15 (Kansas City)	13	18	31
16 (Jackson)	6	3	9
17 (Dallas)	18	8	26
18 (Phoenix)	7	1	8
19 (Denver)	16	3	19
20 (Portland)	52	35	87
21 (San Francisco)	19	5	24
22 (Long Beach)	36	18	54
Total	391	155	546
Unduplicated total[a]	215	53	268

Note: No drugs were added to VISN formularies in 1997.

[a]Represents total unduplicated count of drugs (more than one VISN could have added the same drug to its formulary).

In some cases, medical centers also add drugs to their formularies if the drugs are needed to meet the special needs of their patients. For example, a medical center that has a large population of patients with mental illness added Celexa[R], a new medication used to treat depression, to its formulary. Just as VISN formulary drugs are only available in the applicable VISN, medical center formulary drugs are only available at that facility.

VA's process for moving drugs from VISN formularies to the national formulary has relied primarily on requests from VISN formulary leaders. However, VISN formulary leaders have little incentive to request that drugs on their formularies be added to the national formulary because their prescribers already have access to those drugs.

Without a process for systematically reviewing the drugs added to VISN formularies and considering their addition to the national formulary, the proportion of prescriptions written for national formulary drugs could decline over time, while the proportion written for VISN formulary drugs could increase. Consequently, the benefits of a national formulary—more standardized drug availability and review processes, for example—could be eroded. Moreover, opportunities for savings that VA might realize in contracting for larger drug purchases could be reduced.

In October 1999, with the approval of the formulary leaders, PBM announced that it was implementing a process whereby any drug that has been added to 10 or more VISN formularies will be considered automatically for inclusion on the national formulary. However, as of that date, only 1 of the 268 different drugs that VISNs had added to their formularies was listed by 10 or more VISNs.

Waiver Process Allows Access to Nonformulary Drugs

If a prescriber believes that a patient needs a drug that is not included on the national, VISN, or local formularies, he or she may request the use of a nonformulary drug. Each VA medical facility is required to have a process in place, known as a nonformulary waiver, for prescribers to obtain approval for the use of nonformulary drugs. Waivers are generally approved if there are contraindications to the use of formulary drugs; a patient has an adverse reaction to a formulary drug; all formulary alternatives are therapeutic failures; no formulary alternative exists; or a patient previously responded to a nonformulary drug, and risk is associated with a change to a formulary drug. The process for approving waivers varies among medical facilities and VISNs in terms of the review steps required, who approves the waiver, and the time needed to obtain approval. In a report to the Congress in February 1999,[9] VA stated that VISNs received an average of 109 requests to use nonformulary drugs each month in 1998 and that 88 percent of these requests were approved. Nationally, nonformulary drugs account for approximately 3 percent of all VA prescriptions.

[9]VA, VHA, Non-Formulary Drug Use Process (Washington, D.C.: VA, Feb. 1999).

Newly Approved Drugs Are Treated Differently in National and VISN Formularies

VA's national formulary policy states that it will consider a new drug for addition to the national formulary only after it has been on the U.S. market for 1 year, unless the FDA designates the product as a unique therapeutic entity. PBM officials told us that a 1-year delay in adding these drugs to the national formulary was imposed because of concerns about potential complications that may accompany the use of some newly approved drugs. They noted that because clinical trials are conducted with relatively small numbers of people and in controlled environments, they might not accurately reflect drug usage and side-effect rates found in VA's population. In addition, side effects and interactions for newly approved drugs might be identified only after the drugs come into wider use. For example, several new products were removed from the market after they received FDA approval because of concerns about serious side effects. These products included Redux® (a drug used to treat obesity) and Posicor® (a calcium channel blocker used to treat heart disease). In addition, several new drugs had to be relabeled to highlight their potential for serious adverse effects, including Rezulin® (for diabetes) and Viagra® (for erectile dysfunction). As a result, PBM officials believe that the delay in adding newly approved drugs to the national formulary gives veterans an additional margin of safety.

VISNs, however, are not restricted in their ability to add newly approved drugs and may add them to their formularies immediately upon FDA approval. PBM officials stated that VISNs are allowed to add these new drugs to provide flexibility in cases in which VISN leaders believe they need to provide quick access to an important new drug. Of the drugs added to VISN formulary lists between June 1997 and June 1999, nearly a quarter were added within 1 year of FDA's approval.

Because VHA's policy uses different criteria for adding newly approved drugs to the national and VISN formularies, discrepancies exist across the VA health care system in veterans' access and in their possible exposure to side effects. Veterans seeking health care in VISNs that have added new drugs to their formularies soon after FDA approval have access to, and may obtain benefit from, those drugs before veterans seeking care in other VISNs. On the other hand, some VA officials are concerned that veterans treated with newly approved drugs in such VISNs may be exposed to potential side effects that are identified within the first year of their general use.

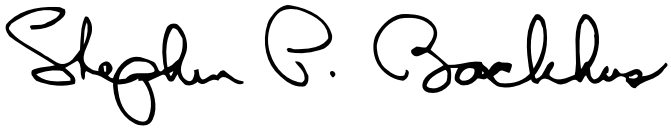
Agency Comments

In commenting on a draft of this report, PBM officials in VA generally concurred with the factual content. They also provided technical comments, which we incorporated where appropriate.

We are sending copies of this report to the Honorable Togo West, Secretary of Veterans Affairs, and other congressional committees having interest in this issue. We will make copies available to others on request.

Major contributors to this report were George Poindexter, Stuart Fleishman, Mike O'Dell, and Kathie Kendrick. Please call me at (202) 512-7101 if you have any questions or need additional assistance.

Sincerely yours,



Stephen P. Backhus
Director, Veterans' Affairs
and Military Health Care Issues

Contents

Abbreviations

FDA	Food and Drug Administration
NAC	National Acquisition Center
PBM	Pharmacy Benefits Management Strategic Healthcare Group
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Glossary

Clinical Guidelines	Treatment procedures arrived at and agreed upon by a medical committee or group for certain common medical conditions; a guideline provides the clinician with specific treatment options or steps when faced with a particular set of clinical symptoms, signs, or laboratory data.
Closed Class	A drug class for which VA has made a clinical decision to limit the number of drugs listed and subsequently has awarded a national committed-use contract. VISNs may not place additional drugs on their formularies in these classes; however, nonformulary drugs may be obtained by using a waiver process.
Drug Class	A group of drugs that are similar in chemistry, method of action, or purpose.
Formulary	A list of drugs or classes of drugs a health care system or other organization has identified as appropriate for treating patients.
Medical Advisory Panel	VHA's Medical Advisory Panel is a working group of 11 practicing physicians who are currently on staff at VA medical centers and 1 physician practicing in the Department of Defense. Members are appointed to serve for a 2-year term. The Panel's mission is to help manage VA's national formulary and to assist in developing evidence-based clinical guidelines. The Panel is organizationally part of the PBM.
Medical Center Formulary	A list of drugs and medical and surgical supplies that includes all items listed on the VA national formulary, the VISN formulary, and any other items that the medical center requires to meet the special needs of its patient population. Not all VISNs allow medical centers to maintain their own formularies.
National Acquisition Center (NAC)	The Office of Acquisition and Materiel Management's National Acquisition Center is the largest combined contracting activity within VA. NAC is responsible for purchasing drugs and medical supplies for VA as well as other government agencies. It administers VA's Federal Supply Schedule and National Contract Programs, including the acquisition and direct delivery of pharmaceuticals; purchases of medical, surgical, and dental

	supplies and high technology medical equipment; and just-in-time distribution programs (also known as Prime Vendor Distribution Programs).
Nonformulary Medications	Medications not listed on a particular formulary.
Nonformulary Waiver Process	A process that VA requires at each VISN or medical center allowing a physician to request a nonformulary medication to meet patient care needs. Nonformulary drugs may be approved under the following circumstances: (1) when there are contraindication(s) to formulary drugs, (2) if a patient experiences adverse reactions to formulary drugs, (3) when all formulary drugs are therapeutic failures, or (4) when no formulary alternative exists.
Open Class	A drug class for which VA has not made a clinical decision to limit the number of drugs listed on the VA national formulary. VISNs may place additional drugs on their formularies in these classes.
Pharmacy and Therapeutics Committee	A committee of physicians, pharmacists, and other health care professionals that addresses formulary issues and establishes drug treatment policies.
Pharmacy Benefits Management	Pharmacy benefits management is the design, implementation, and administration of outpatient drug benefit programs for employers and managed care organizations.
Pharmacy Benefits Management Strategic Healthcare Group (PBM)	Established in September 1995, VA's PBM is modeled after a strategy commonly used in the private sector, to manage the cost, use, outcomes, and distribution of pharmaceuticals.
Prior Authorization	The approval a provider must obtain prior to using certain medical products or drugs so that services will be covered by the health plan.
Restricted Medications	Medications that require close monitoring to ensure appropriate use. Restrictions may include implementing evidence-based guidelines and

	giving prescribing privileges to providers with certain expertise. In the absence of national guidelines, reasonable restrictions may be imposed at the VISN level and, in some instances, by medical centers.
Strategic Healthcare Group (SHG)	A multidisciplinary group of personnel and programs within VA organized to support the provision of a continuum of care to a specific population of patients or the provision of care in a particular setting. The SHG functions by integrating data, skills, and best practices into systemwide policy, planning, and service delivery through the development of clinical care strategies (for example, practice guidelines or critical pathways) and decision support mechanisms.
Therapeutic Effect	The way a drug works to cure or heal the condition for which it is prescribed.
Therapeutic Interchange	The authorized substitution of one drug for another that is essentially equivalent in terms of efficacy, safety, and outcomes. Therapeutic interchange interventions follow established guidelines or protocols and may involve switching nonformulary medications to formulary drugs.
Therapeutic Substitution	The substitution of a prescribed drug for a different drug in the same class without the prior authorization of the individual prescriber.
VA National Formulary	A list of drugs and medical and surgical supplies that VA has determined are appropriate for use in treating veterans. Although a physical inventory of these items is not required, they must be available at all VA facilities. If a clinical need for a formulary product arises in the course of treating a patient, then the formulary product must be made available to the patient.
VISN Formulary	A list of drugs and medical and surgical supplies that includes all items listed on the VA national formulary and any other items that the VISN has determined are required to meet the special needs of the patient population treated in the VISN.

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