

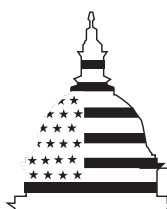
GAO

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

January 2001

VA DRUG FORMULARY

Better Oversight Is Required, but Veterans Are Getting Needed Drugs



G A O

Accountability * Integrity * Reliability

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Abbreviations

FDA	Food and Drug Administration
IOM	Institute of Medicine
PBM	Pharmacy Benefits Management Strategic Healthcare Group
P&T	pharmacy and therapeutics
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



United States General Accounting Office
Washington, D.C. 20548

January 29, 2001

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

Dear Senator Rockefeller:

The large number of drugs manufactured to treat various medical conditions has led health care organizations to develop lists of medications that they encourage their health care providers to use when they write prescriptions for patients. These lists of medications, grouped by therapeutic class, are known as drug formularies. Organizations prefer, and sometimes require, that these drugs be used as the provider's first choice because organizations believe these drugs represent the best value among therapeutic choices and because by concentrating their purchases organizations can secure better prices.

As early as 1955, the Department of Veterans Affairs' (VA) medical centers began using formularies to manage their pharmacy inventories, and until recently each of VA's 173 medical centers maintained its own formulary. In June 1997, VA established its national formulary by consolidating locally developed and managed formularies into a core list of drugs. The national formulary was intended to give health care providers who have outpatient prescription privileges the same list of formulary drugs no matter where in the VA system they practice medicine, and to assure veterans that they will have access to the same group of formulary drugs for their treatment at all VA medical centers no matter where they seek care. VA medical centers were directed to make all national formulary drugs available to prescribers. To provide flexibility in meeting local patient needs, VA allows its 22 regional Veterans Integrated Service Networks (VISN) to add drugs locally to supplement the national formulary and requires them to establish approval processes for prescribers to obtain drugs not listed on their formularies.

Over the past few years, you and others in the Congress have raised questions about VA's national formulary. In December 1999, we issued a

report addressing your interest in how VA manages its national formulary.¹ In June 2000, the Institute of Medicine (IOM), as mandated by the Congress in House Report 105-610, issued its report on the effect VA's national formulary has had on the cost and quality of VA health care, the restrictiveness of VA's national formulary, and how the national formulary compares with private and other government formularies.²

To supplement the findings of our December 1999 report, you asked us to review (1) the impact of national formulary implementation by VISNs and medical centers on VA's goal of standardizing its formulary and (2) VISN and medical center processes for obtaining nonformulary outpatient prescriptions. You also asked that we examine whether VA's national formulary allows health care providers to prescribe the medications they believe their patients need.

To address these VA formulary issues, we reviewed the formulary policies and activities of VA's central office and its VISNs and compiled and analyzed nationwide VA prescription data. To assess implementation at the local level, we also discussed formulary issues with VA officials at three medical centers we visited in three different VISNs. We selected these medical centers on the basis of their percentage of prescriptions filled for formulary drugs. At your request, we also conducted a survey of 2,000 health care providers who have VA prescription writing privileges (prescribers) to determine whether they believe implementation of the national formulary has adversely affected their ability to prescribe needed medications for the veterans they treat. In addition, we reviewed the congressionally mandated IOM assessment of VA's national formulary issued in June 2000, and we incorporated its pertinent results in our report.

Appendix I contains further details of our scope and methodology. We performed our work between January 2000 and January 2001 in accordance with generally accepted government auditing standards.

¹*VA Health Care: VA's Management of Drugs on Its National Formulary* (GAO/HEHS-00-34, Dec. 14, 1999).

²IOM, *Description and Analysis of the VA National Formulary* (Washington, D.C.: IOM, June 2000).

Results in Brief

While VA has made significant progress in establishing a national formulary, it has not provided sufficient oversight to ensure that it is fully achieving its national formulary goal of standardization. For example, not all VISNs' medical centers are in compliance with the national formulary. Specifically, two of the three facilities we visited, each in a separate VISN, omitted more than 140 required national formulary drugs, and all three facilities inappropriately modified the national formulary list of required drugs for certain drug classes by adding or omitting some drugs. As VA policy allows, VISNs have added drugs to supplement the national formulary, ranging from 5 drugs at one VISN to 63 drugs at another. However, the wide variation in the number of drugs added by the VISNs raises concern that this practice, if not appropriately monitored, may result in unacceptable decreases in formulary standardization. To address this issue, VA plans to begin reviewing new drugs approved by the Food and Drug Administration (FDA) to determine if they will be added to the national formulary or if VISNs may continue to add them to their formularies to supplement the national formulary.

The approval process for the use of nonformulary drugs across VA's health care system does not ensure that all facilities have an efficient and timely process. We found wide variability in how requests are made, who approves such requests, and how much time it takes. Similarly, IOM determined that many variants of the nonformulary approval process were being used. In addition, VA does not have systematic data to determine the extent to which nonformulary drugs are being requested, approved, or denied. Although VISNs are required to establish systems to analyze such requests, 12 of the 22 VISNs have not done so. As a result, VA does not know whether approved requests met established criteria or whether denied requests were appropriate.

VA health care providers who prescribe drugs generally reported that veterans get the drugs they need. These prescribers reported that the national formulary generally contains the drugs their patients need or, when necessary, prescribers can usually get nonformulary drugs. Despite their overall satisfaction, we believe the weaknesses we identified merit correction. Consequently, we are recommending that VA (1) ensure compliance with national formulary policy, (2) ensure that drugs added to supplement the national formulary do not inappropriately decrease formulary standardization, and (3) improve the nonformulary process. In responding to a draft of this report, VA agreed with our findings and concurred with our recommendations.

Background

In fiscal year 2000, VA's Veterans Health Administration (VHA) provided primary and specialty medical care to approximately 3.2 million veterans at a cost of about \$18 billion. VA's pharmacy benefit cost approximately \$2 billion—about 12 percent of the total VHA budget—and provided approximately 86 million prescriptions. In contrast, 10 years ago VA's pharmacy benefit represented about 6 percent of VA's total health care budget.

Health care organizations' efforts to control pharmacy costs and improve quality of care include (1) implementing formularies that limit the number of drug choices available; (2) establishing 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.

VA does not have authority to use financial incentives to encourage compliance with its formulary. VA provides outpatient pharmacy services free to veterans receiving medications for treatment of service-connected conditions and to low-income veterans whose incomes do not exceed a threshold amount. Other veterans who have prescriptions filled by VA may be charged \$2 for each 30-day supply of medication.³

In 1995, VA began transforming its delivery and management of health care to expand access to care and increase efficiency. As part of this transformation, VA decentralized decision-making and budgeting authority to 22 VISNs, which became responsible for managing all VA health care. VISNs were given substantial operational autonomy. Although VISN and medical center directors are held accountable in annual performance agreements for meeting certain national and local goals, attaining formulary goals has not been part of their performance standards.

VA medical centers began using formularies as early as 1955 to manage their pharmacy inventories. Because of the geographic mobility of VA patients, VA officials believed that a national formulary would improve

³The Veterans Millennium Health Care and Benefits Act (P.L. 106-117, Nov. 30, 1999) authorized the Secretary of the Department of Veterans Affairs to increase the current \$2 copayment for each 30-day supply of medication and to establish maximum monthly and maximum annual pharmaceutical copayments for veterans who have multiple outpatient prescriptions. To date, VA has not implemented a change in the copayment amount.

veterans' continuity of care. In September 1995, VA established a centralized group to manage its pharmacy benefit on a nationwide basis. In November 1995, VISNs were established, and the Under Secretary for Health directed each VISN to develop and implement a VISN-wide formulary. To develop their formularies, the VISNs generally combined existing medical center formularies and eliminated rarely prescribed drugs. VISN formularies became effective on April 30, 1996. Also in 1996, the Congress required VA to improve veterans' access to care regardless of the region of the United States in which they live. As part of its response, VA implemented a national drug formulary on June 1, 1997, by combining the core set of drugs common to the newly developed VISN formularies. In addition to the national and VISN formularies, a few medical centers retained their own formularies.

VA's Pharmacy Benefits Management Strategic Healthcare Group (PBM) is responsible for managing the national formulary list, maintaining databases that reflect drug use, and monitoring the use of certain drugs. VISN directors are responsible for implementing and monitoring compliance with the national formulary, ensuring that VISN restrictions placed on national formulary products are appropriate, and ensuring that a nonformulary drug approval process is functioning in all of their medical centers.

As all formularies do, VA's national formulary limits the number of drug choices available to health care providers. VA's formulary lists more than 1,100 unique drugs that are assigned to 1 of 254 drug classes—groups of drugs similar in chemistry, method of action, or purpose of use. After performing reviews of drug classes representing the highest costs and volume of prescriptions, VA decided that some drugs in 4 of its 254 drug classes were therapeutically interchangeable—that is, essentially equivalent in terms of efficacy, safety, and outcomes—and therefore had the same therapeutic effect. This determination allowed VA to select one or more of these drugs for its formulary to seek better prices through competitively bid committed-use contracts.⁴ Other therapeutically equivalent drugs in these classes were then excluded from the formulary. These four classes are known as “closed” classes. VA has not made clinical decisions regarding therapeutic interchange in the remaining 250 drug

⁴Under committed-use contracts, VA commits to use primarily the contract drug, instead of other therapeutically interchangeable drugs, to guarantee drug companies a high volume of use in exchange for lower prices.

classes, and it does not limit the number of drugs that can be added to these classes. These are known as “open” classes.

In some cases, drugs listed on the national formulary may be restricted. Restrictions are generally placed on the use of drugs if they have the potential to be used inappropriately. For example, restrictions are placed on drugs with potentially serious side effects, such as interferon, which is used to treat such conditions as hepatitis C. VA has also adopted guidelines to assist practitioners in making decisions about the diagnosis, treatment, and management of specific clinical conditions, such as congestive heart failure. In addition, VA has adopted criteria to help standardize treatment, improve the quality of patient care, and promote cost-effective drug prescriptions. Finally, VA limits prescribing privileges for some drugs to specially trained physicians and requires consultation with a specialist before certain drugs can be prescribed.

National Formulary Standardization Not Yet Achieved

VA has made significant progress in establishing a national formulary, with most drugs being prescribed from the formulary list. Nevertheless, VA’s oversight has not been sufficient to ensure that it is fully achieving its national formulary goal of standardizing its drug benefit nationwide. We found that some facilities have omitted required national formulary drugs. In addition, the extent to which VISNs add drugs to supplement the national formulary has the potential for conflicting with VA’s ability to achieve standardization if not closely managed. Also, we found that some facilities, contrary to policy, have modified the list of drugs available in closed classes.

National Formulary Drugs Were Omitted From Formularies in Medical Centers We Visited

Almost 3 years after VA facilities were directed to make available locally all national formulary drugs, two of the three medical centers we visited did not list all national formulary drugs in the formularies used by their prescribers. VHA’s national formulary policy directive states that items listed on the national formulary shall be made available throughout the VA health care system and must be available in all VA facilities.⁵ While a physical supply of all national formulary drugs is not required to be maintained at all facilities, if a clinical need for a particular formulary drug

⁵Items on the national formulary include both drugs and medical and surgical supply items, such as diabetic supplies and bandages. Our study focused exclusively on drugs.

arises in the course of treating a patient, it must be made available to the patient.

Many drugs listed on the national formulary were not available as formulary choices in two of the three medical centers we visited. In the first, about 25 percent (286 drugs) of the national formulary drugs were not available as formulary choices. These included drugs used to treat high blood pressure and mental disorders, as well as drugs used to treat the unique medical needs of women. At the second medical center, about 13 percent (147 drugs) of the national formulary drugs were omitted, including drugs used to treat certain types of cancer and others used to treat stomach conditions.

Health care providers at these two medical centers were required to seek nonformulary drug approvals for over 22,000 prescriptions of national formulary drugs from October 1999 through March 2000. If the national formulary had been properly implemented at these medical centers, prescribers would not have had to use extra time to request and obtain nonformulary drug approvals for these drugs, and patients could have started treatment earlier. Our analysis showed that over 14,000 prescriptions were filled as nonformulary drugs for 91 of the 286 drugs at the first center.⁶ No prescriptions were filled for the remaining 195 drugs. At the other medical center, over 8,000 prescriptions for 23 of the 147 drugs were filled as nonformulary drugs. No prescriptions were filled for the remaining 124 drugs.

Drugs Added to Supplement the National Formulary Decrease Standardization

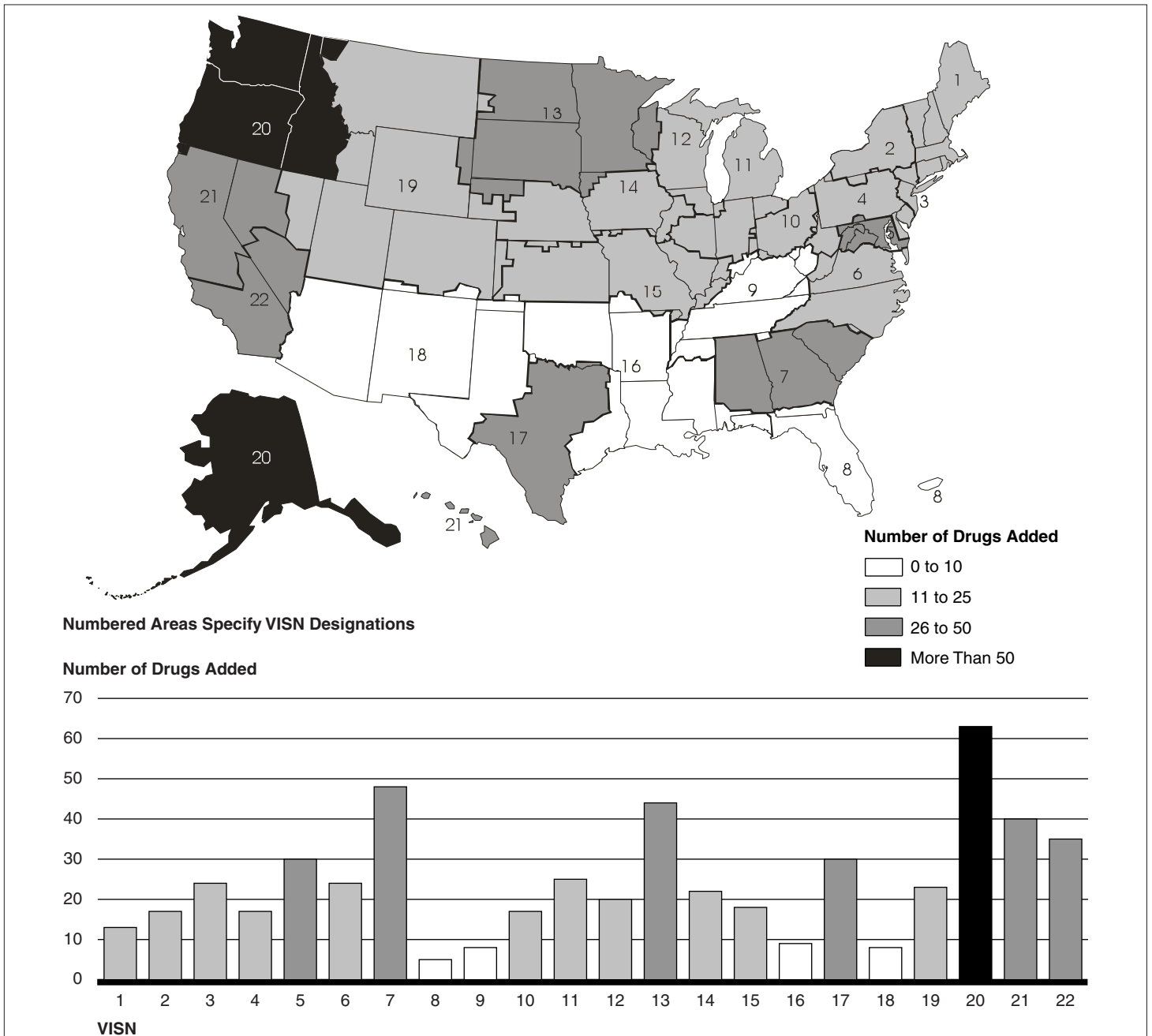
VA's policy allowing VISNs to supplement the national formulary locally has the potential for conflicting with VA's ability to achieve standardization if not closely managed. From June 1997 through March 2000, VISNs added 244 unique drugs to supplement the list of drugs on the national formulary. The number of drugs added by each VISN varies widely, ranging from as many as 63 by VISN 20 (Portland) to as few as 5 by VISN 8 (Bay Pines). (Fig. 1 shows the number of drugs added by each VISN.) Adding drugs to supplement the national formulary is intended to allow VISNs to be responsive to the unique needs of their patients and to allow quicker

⁶After our visit, we were informed by a pharmacy official that the medical center adopted the national formulary as its own on June 30, 2000.

formulary designation of new FDA-approved drugs.⁷ However, the wide variation in the number of drugs added by the VISNs to supplement the national formulary raises concern that this practice, if not appropriately monitored, could result in unacceptable decreases in formulary standardization. VA officials have acknowledged that this variation affects standardization and told us they plan to address it. For example, the PBM plans to review new drugs when approved by the FDA to determine if they will be added to the national formulary or if VISNs may continue to add them to their formularies to supplement the national formulary.

⁷VA formulary policy provides that a new drug must be on the market for a minimum of 1 year before it can be added to the national formulary.

Figure 1: Variation in Number of Unique Drugs VISNs Added to Supplement National Formulary, June 1997—March 2000



Source: GAO analysis of data from VA's PBM.

Medical Centers Inappropriately Modified the List of Drugs in Closed Classes

The medical centers we visited also inappropriately modified the national formulary list of drugs in the closed classes. Contrary to VA formulary policy, two of three medical centers added two different drugs to two of the four closed classes, and one facility did not make a drug available (see fig. 2).

Figure 2: Medical Center Modifications to Formulary Closed Classes

VA National Formulary Closed Classes/Drugs	Medical Center		
	1	2	3
AN500-Antineoplastic Hormones for Treating Prostate Cancer			
Goserelin Acetate Implant ^a	●	●	●
Leuprolide Acetate		▲	▲
CV350-Antilipemic Agents for Treating High Cholesterol			
Gemfibrozil ^a	●	●	●
Lovastatin ^a	●	●	●
Simvastatin ^a	●	●	●
Atorvastatin		▲	
CV800-ACE Inhibitors for Treating High Blood Pressure			
Captopril ^a	●	●	●
Fosinopril ^a	●	●	●
Lisinopril ^a	○	●	●
GA900-Gastric Medications for Treating Stomach Ulcers			
Lansoprazole ^a	●	●	●

- Required National Formulary Drug Contained on Medical Center Formulary
- Required National Formulary Drug Omitted From Medical Center's Formulary
- ▲ Drug Not on VA's National Formulary and Inappropriately Added to the Closed Classes

^aDrug purchased under national committed-use contract.

Source: VA medical centers.

While our analysis was performed at the medical center level, the IOM found similar nonconformity at the VISN level. Specifically, IOM reported

that 16 of the 22 VISNs modified the list of national formulary drugs for the closed classes.⁸

Most Prescribed Drugs Are on the National Formulary

From October 1999 through March 2000, 90 percent of VA outpatient prescriptions were written for national formulary drugs. The percentage of national formulary drug prescriptions filled by individual VISNs varied slightly, from 89 percent to 92 percent. We found wider variation among medical centers within VISNs—84 percent to 96 percent (see table 1).

Table 1: Percentage of Total Outpatient Prescriptions Filled for National Formulary Drugs by VISN and Medical Centers Within Each VISN, October 1999 Through March 2000

VISN (office location)	Percentages of prescriptions filled using national formulary drugs	Range of percentages of prescriptions filled using national formulary drugs, by medical centers within VISNs
1 (Boston)	91	89—93
2 (Albany)	89	88—91
3 (Bronx)	89	87—94
4 (Pittsburgh)	91	87—94
5 (Baltimore)	90	87—94
6 (Durham)	90	88—92
7 (Atlanta)	90	88—92
8 (Bay Pines)	90	87—93
9 (Nashville)	92	89—95
10 (Cincinnati)	92	90—94
11 (Ann Arbor)	91	87—94
12 (Chicago)	92	89—94
13 (Minneapolis)	91	90—93
14 (Omaha)	89	84—92
15 (Kansas City)	92	89—96
16 (Jackson)	90	87—94
17 (Dallas)	90	88—91
18 (Phoenix)	92	85—95

⁸IOM, *Description and Analysis of the VA National Formulary*, pp. 32-3.

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VISN (office location)	Percentages of prescriptions filled using national formulary drugs	Range of percentages of prescriptions filled using national formulary drugs, by medical centers within VISNs
19 (Denver)	92	90—94
20 (Portland)	91	84—94
21 (San Francisco)	92	90—93
22 (Long Beach)	92	90—94
VA systemwide	90	84—96

Source: VA's PBM outpatient prescription database.

The remaining 10 percent of prescriptions filled systemwide were for drugs VISNs and medical centers added to supplement the national formulary or for nonformulary drugs. VA's PBM and IOM estimate that drugs added to supplement the national formulary probably account for about 7 percent of all prescriptions filled and nonformulary drugs account for approximately 3 percent of all prescriptions filled. However, at the time of our review, VA's nationwide data could identify a filled prescription only as either a national formulary drug or not. Without specific information, VA does not know if the additions are resulting in an appropriate balance between local needs and national formulary standardization. VA officials told us that they are modifying the database to enable it to identify which drugs are added to supplement the national formulary and which are nonformulary.

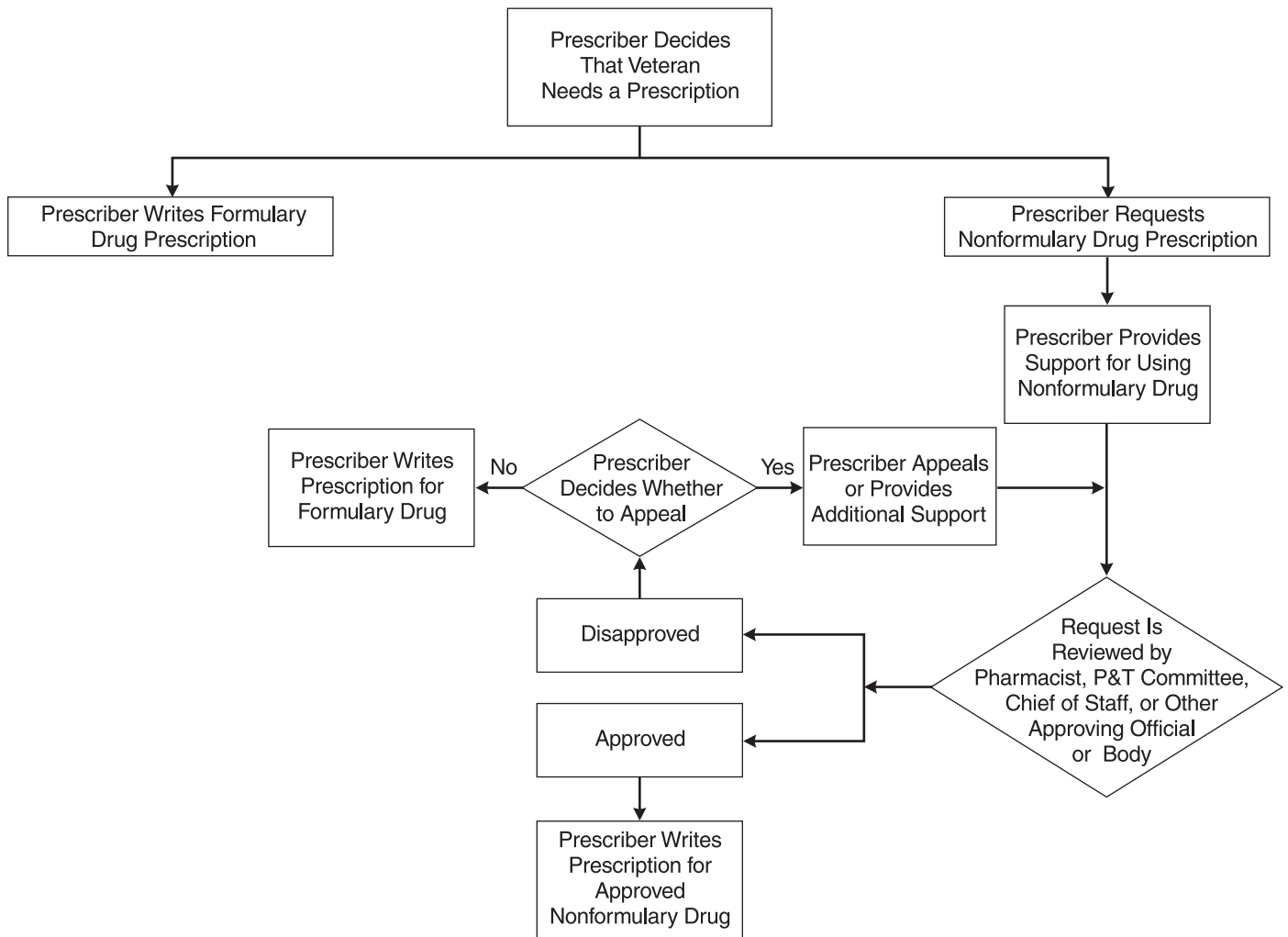
Approval Processes for Nonformulary Drugs Have Weaknesses

Medical center approval processes for nonformulary drugs are not always timely, and the amount of time needed to obtain such approvals varied widely across medical centers. In addition, some VISNs have not established processes to collect and analyze data on nonformulary requests. As a result, VA does not know if approved requests met its established criteria or if denied requests were appropriate.

Time to Process Nonformulary Drug Approvals Varies Among Facilities

Although the national formulary directive requires certain criteria for approval of nonformulary drugs, it does not dictate a specific nonformulary approval process. As a result, the processes health care providers must follow to obtain nonformulary drugs differ among VA facilities regarding how requests are made, who receives them, who approves them, and how long it takes. In addition, IOM documented wide variations in the nonformulary drug approval process. Figure 3 shows the steps prescribers must generally follow to obtain nonformulary and formulary drugs.

Figure 3: Steps Generally Followed to Obtain Nonformulary and Formulary Drugs



Source: GAO survey and interviews with VA officials.

The person who first receives a nonformulary drug approval request may not be the person who approves it. For example, 61 percent of prescribers reported that nonformulary drug requests must first be submitted to a facility pharmacist, 14 percent said they must first be submitted to facility pharmacy and therapeutics (P&T) committees, and 8 percent said they must first be sent to service chiefs. In contrast, 31 percent of prescribers reported that it is a facility pharmacist who approves nonformulary drug requests, 26 percent said that the facility P&T committee approves them,

and 15 percent told us that the facility chief of staff approves them. The remaining 28 percent reported that various other facility officials or members of the medical staff approve nonformulary drug requests.

The time required to obtain approval for use of a nonformulary drug varied greatly depending on the local approval processes. The majority of prescribers (60 percent) we surveyed reported that it took an average of 9 days to obtain approval for use of nonformulary drugs.⁹ But many prescribers also reported that it took only a few hours (18 percent) or minutes (22 percent) to obtain such approvals.

During our medical center visits, we observed that some medical center approval processes are less convenient than others. For example, to obtain approval to use a nonformulary drug in one facility we visited, prescribers were required to submit a request in writing to the P&T committee for its review and approval. Because the P&T committee met only once a month, the final approval to use the requested drug was sometimes delayed as long as 30 days. The requesting prescriber, however, could write a prescription for an immediate 30-day supply if the medication need was urgent.

In contrast, in another medical center we visited, a clinical pharmacist was assigned to work directly with health care providers to help with drug selection, establish dose levels, and facilitate the approval of nonformulary drugs. In that facility, clinical pharmacists were allowed to approve the use of nonformulary drugs. If a health care provider believed that a patient should be prescribed a nonformulary drug, the physician and pharmacist could consult at the point of care and make a final decision with virtually no delay.

Prescribers in our survey were almost equally divided on the ease or difficulty of getting nonformulary drug requests approved (see table 2).

⁹In emergencies, exceptions are made to allow the patient to obtain the drug more quickly.

Table 2: Ease of Obtaining Nonformulary Drug Approvals Reported by Prescribers

Response categories	Percentage reporting
“Easy” or “very easy”	29
“About as easy as difficult”	40
“Difficult” or “very difficult”	32

Note: Percentages do not total 100 because of rounding.

Source: GAO survey.

Regardless of whether the nonformulary drug approval process was perceived as easy or difficult, the vast majority of prescribers told us such requests were generally approved. According to our survey results, 65 percent of prescribers sought approval for a nonformulary drug in 1999. These prescribers reported that they made, on average, 25 such requests (the median was 10 requests). We estimated that 84 percent of all prescribers’ nonformulary requests were approved.

When a nonformulary drug request was disapproved, 60 percent of prescribers reported that they switched to a formulary drug. However, more than one-quarter of the prescribers who had nonformulary drug requests disapproved resubmitted their requests with additional information.

The majority of prescribers we surveyed told us they were more likely to convert VA patients who were on nonformulary drugs obtained at another VA facility to formulary drugs than to request a nonformulary drug (see table 3).

Table 3: Likelihood of Prescribers’ Converting Patients From Nonformulary Drug Prescriptions to Formulary Drug Prescriptions

Response categories	Percentage reporting
“Likely to convert” or “very likely to convert”	64
“As likely to convert as to seek approval for the nonformulary drug”	18
“Likely to seek approval for the nonformulary drug” or “very likely to seek approval of nonformulary drug”	18

Source: GAO survey.

Consequently, patients who move from one area of the country to another or temporarily seek care in a different VA facility are likely to be switched from a nonformulary drug to a formulary drug.

Some VISNs Are Not Collecting and Analyzing Nonformulary Drug Data as Required

VA's national formulary policy requires that a request to use a nonformulary drug be based on at least one of six criteria: (1) the formulary agent is contraindicated, (2) the patient has had an adverse reaction to the formulary agent, (3) all formulary alternatives have failed therapeutically, (4) no formulary alternative exists, (5) the patient has previously responded to the nonformulary agent and risk is associated with changing to the formulary agent, and (6) other circumstances involving compelling evidence-based reasons exist. Each VISN is responsible for establishing a process to collect and analyze data concerning nonformulary drug requests.

Contrary to the national formulary policy, not all VISNs have established a process to collect and analyze nonformulary request data at the VISN and local levels. Twelve of VA's 22 VISNs reported that they do not collect information on approved and denied nonformulary drug requests. Three VISNs reported that they collect information only on approved nonformulary drug requests, and seven reported that they collect information for both approved and denied requests. Consequently, data that could help VISNs, medical centers, and the PBM offices are not always collected and analyzed for trends in a systematic manner. Such information could help VA at all levels to determine the extent to which nonformulary drugs are being requested and whether medical center processes for approving these requests meet established criteria. In its report, IOM noted that inadequate documentation could diminish confidence in the nonformulary process.

Prescribers Report Having Access to the Drugs Veterans Need

Seventy percent of VA prescribers in our survey reported that the formulary they use contains the drugs their patients need either to a "great extent" or to a "very great extent." Twenty-seven percent reported that the formulary meets their patients' needs to a "moderate extent," with 4 percent reporting that it meets their patients' needs to "some extent." No VA prescribers reported that the formulary meets their patients' needs to a "very little or no extent." This is consistent with IOM's conclusion that the VA formulary "is not overly restrictive."

Overall, two and one-half times as many prescribers indicated that the formulary they currently use “helps” or “greatly helps” their ability to prescribe drugs as those who said it “hinders” or “greatly hinders” them (see table 4).

Table 4: Prescribers Reported Current Formulary Helps More Than Hinders Their Ability to Prescribe Drugs

Response categories	Percentage responding
“Helps” or “greatly helps”	48
“Helps as much as hinders”	34
“Hinders” or “greatly hinders”	18

Source: GAO survey.

Some prescribers reported that the formulary they use helps them keep current with new drugs and helps remove some of the pressures created by direct-to-consumer advertising. Other prescribers reported that newly approved drugs are not made available on the national formulary as soon as they would like, and some reported their frustration with delays experienced when certain formulary drugs must be approved by specially trained physicians before they can be prescribed.

Prescribers we surveyed reported they were generally satisfied with the national formulary. We asked prescribers who said that they had worked for VA before the national formulary was established whether the current formulary does a better job of keeping the list of drugs in the drug classes from which they most frequently prescribe up to date, as compared with the formulary they used to use. Three-quarters told us that they had worked for VA before the national formulary was implemented in June 1997. Thirty-eight percent of these prescribers reported that the national formulary was “better” or “considerably better” than previous formularies. About half (48 percent) indicated that the current formulary was “about the same” as the one it replaced. Seven percent reported that it was “worse” or “considerably worse” than previous formularies.

Few veterans have complained about not being able to obtain the drugs they believe they need. At the VA medical centers we visited, patient

advocates¹⁰ told us that veterans made very few complaints concerning their prescriptions. In its analysis of the patient advocates' complaint databases, IOM found that less than one-half of one percent of veterans' complaints were related to drug access.¹¹ IOM further reported that complaints involving specific identifiable drugs often involved drugs that are marketed directly to consumers, such as sildenafil (Viagra), which is used to treat erectile dysfunction.¹² Fifty-one percent of the prescribers in our survey reported that over the past 3 years, an increasing number of their patients have requested a drug they have seen or heard advertised in the media. Our review also indicated that the few prescription complaints made were often related to veterans' trying to obtain "lifestyle" drugs or refusals by VA physicians and pharmacists to fill prescriptions written by non-VA health care providers.¹³ VA officials told us that VA does not fill prescriptions written by non-VA-authorized prescribers, in part to ensure that one practitioner manages a patient's care.

Conclusions

Over the past 3½ years, VA has made significant progress in establishing its national formulary, which has generally met with prescriber acceptance. Prescribers reported that veterans are generally receiving the drugs they need and that veterans rarely register complaints concerning prescription drugs.

VA has not provided sufficient oversight, however, to ensure that VISNs and medical centers comply with formulary policies and that the flexibility given to them does not unduly compromise VA's goal of formulary standardization. Contrary to VA formulary policy, some facilities omitted national formulary drugs or modified the closed drug classes. While adding

¹⁰Patient advocates are VA employees who are responsible for receiving and acting on complaints from veterans.

¹¹IOM obtained formulary-related complaints from a nationwide database of veteran complaints for over 90 percent of all VA facilities representing all 22 VISNs. IOM determined that only 2,385 of 570,937 veteran complaints were attributed to the national formulary. No VISN had significantly more complaints than any other. (IOM, *Description and Analysis of the VA National Formulary*, p. 145).

¹²Sildenafil is available within VA only through the nonformulary drug approval process.

¹³We asked prescribers in our survey how often in 1999 their patients asked them to rewrite a prescription from a non-VA prescriber so that it could be filled by VA. Thirty-one percent said "often" or "very often," 34 percent reported that it occurred "occasionally," and 21 percent said "seldom." Fourteen percent said that they never received such requests.

a limited number of drugs to supplement the national formulary is permitted, as more drugs are added by VISNs, formulary differences among facilities are likely to become more pronounced, decreasing formulary standardization. While VA recognizes the trade-off between local flexibility and standardization, it lacks criteria for determining the appropriateness of adding drugs to supplement the national formulary. Consequently, VA cannot determine whether the resulting decrease in standardization is acceptable. Not all VISN directors have met their responsibilities for implementing national formulary policy.

Inefficiencies that exist in the nonformulary drug approval processes across the system can cause delays in making final treatment decisions. In addition, the processes require health care provider time and energy that might be better used for direct patient care. We believe a more efficient nonformulary drug approval process could enable facilities to benefit from lessons learned in other locations. Finally, VISNs lack the data needed to analyze nonformulary drug requests to determine whether all approved requests met approval criteria and all denied requests were appropriate.

Recommendations for Executive Action

In order to ensure more effective management of the national formulary, we recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to take the following actions:

- Establish a mechanism to ensure that VISN directors comply with national formulary policy.
- Establish criteria that VISNs should use to determine the appropriateness of adding drugs to supplement the national formulary and monitor the VISNs' application of these criteria.
- Establish a nonformulary drug approval process for medical centers that ensures appropriate and timely decisions and provides that veterans for whom a nonformulary drug has been approved will have continued access to that drug, when appropriate, across VA's health care system.
- Enforce existing requirements that VISNs collect and analyze the data needed to determine that nonformulary drug approval processes are implemented appropriately and effectively in their medical centers, including tracking both approved and denied requests.

Agency Comments and Our Evaluation

In commenting on a draft of this report, VA agreed with our findings and concurred with our recommendations. VA highlighted key improvements planned or already in progress that should further enhance the process. VA's actions to address our recommendations are summarized below.

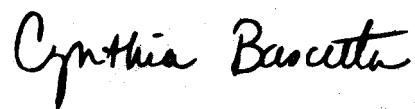
- VA plans to improve oversight at all organizational levels to help facilitate consistent compliance with national formulary policy. In its comments, VA discussed important components of improving compliance with the national formulary, including examining data to identify outliers. However, VA did not articulate a mechanism for ensuring that its oversight results in consistent compliance, which may reduce the effectiveness of its planned actions.
- VA plans to establish criteria for VISNs to use to determine the appropriateness of adding drugs to supplement the national formulary.
- VA plans to establish steps for its nonformulary drug approval process that all medical centers and VISNs must follow. However, in its comments, VA did not specifically address how veterans would have continued access to previously approved nonformulary drugs across VA's health care system. We believe such access is important.
- VA plans to establish steps for reporting its nonformulary approval activities. In its comments, VA did not explicitly include tracking of denied requests as part of the nonformulary approval activities. We expect that its nonformulary approval activities will include tracking denied requests, as well as approved nonformulary drug requests, to determine the appropriateness of all medical center prescribing decisions.

VA plans to implement these corrective actions by June 2001. Its comments are included in appendix II.

We are sending copies of this report to the Honorable Anthony J. Principi, Secretary of Veterans Affairs; appropriate congressional committees; and other interested parties. We will also make copies available to others upon request.

Please call me at (202) 512-7101 if you or your staff have questions about this report or need additional assistance. Another contact and staff acknowledgments are listed in appendix III.

Sincerely yours,

A handwritten signature in black ink that reads "Cynthia Bascetta". The signature is written in a cursive style with a large initial "C".

Cynthia A. Bascetta, Director
Health Care—Veterans' Health
and Benefits Issues

Scope and Methodology

To obtain policies and procedures from the 22 Veterans Integrated Service Networks (VISN), we mailed a questionnaire to each of the 22 VISN formulary leaders—pharmacists or physicians who serve on the Department of Veterans Affairs’ (VA) Pharmacy Benefits Management advisory board. To determine the extent to which VA health care providers write prescriptions for national formulary drugs, we analyzed data from VA’s national outpatient prescription database. To assess the implementation of the national formulary and obtain firsthand opinions about it, we interviewed medical and administrative staff at three VA medical centers located in three different VISNs. To obtain VA health care providers’ views on VA’s formulary, including whether or not it is restrictive, we mailed a questionnaire to a nationally representative sample of 2,000 VA health care prescribers. We also used information contained in the Institute of Medicine’s *Description and Analysis of the VA National Formulary*, issued in June 2000.

VISN Survey

To obtain policies and procedures from the 22 VISNs, we mailed a questionnaire to VISN formulary leaders.¹ We asked if there were VISN-wide policies for several areas, including adding drugs to the VISN formulary, requesting nonformulary drugs, converting patients from one drug to another, and tracking requests for nonformulary drugs. In addition, we sought information on the number of drugs added to and dropped from the VISN formulary, the number of requests for nonformulary drugs, and the number of requests that were approved and denied. All 22 VISN formulary leaders completed and returned questionnaires.

¹Each VISN has a formulary leader—typically a senior pharmacy manager or physician. Collectively, the 22 leaders compose a national advisory board that assists VA’s Pharmacy Benefits Management Strategic Healthcare Group (PBM) and its medical advisory panel. Formulary leaders are knowledgeable in pharmacological matters, including drugs and treatment practices, and in national and local formulary policies and procedures. The role of a formulary leader includes helping PBM decide what drugs will be added to or deleted from the national formulary, developing and adopting national policies affecting the use of drugs on the national formulary, and assisting with other matters the leaders or PBM officials raise during their periodic meetings.

Outpatient Prescription Database Analysis

VA's national database on outpatient prescriptions contains information for each outpatient prescription filled at each VA medical center, including the drug prescribed, date of the prescription, patient and prescriber identifiers, medical center responsible for filling the prescription, and whether the prescribed drug is a national formulary drug. We used this database to

- develop a sample of VA health care providers who wrote prescriptions,
- determine the total number of outpatient prescriptions filled at VISNs and VA medical centers,
- determine the number of filled outpatient prescriptions written for national formulary drugs within a certain time frame,² and
- determine how many VISN formulary drug prescriptions were filled in the three VISNs where we performed site visits.

We interviewed PBM headquarters officials who had either oversight or maintenance responsibility for the database to help assess the validity and reliability of the outpatient prescription data. We also performed our own analytic checks of the data. We found that data critical to our analysis—the data field indicating whether a prescription had been written for a national formulary drug—contained errors. We worked with PBM officials to correct the data, and they implemented a monthly routine to detect and correct these errors in the future. We reran our data checks, verified that the database had been corrected, and concluded that the data were acceptable for the purposes of our work.

Site Visits

To assess formulary implementation at the local level, we interviewed medical and administrative staff at three different VA medical centers—one located in Biloxi, Mississippi (VISN 16); one in Gainesville, Florida (VISN 8); and one in Omaha, Nebraska (VISN 14). We selected these VISNs and medical centers on the basis of formulary drug use from October through December 1999, the period for which the most recent and complete data were available at the time we did our work. For example, VISN 8 had the highest percentage of prescriptions for national formulary drugs (93 percent), VISN 16's percentage of national formulary drug prescriptions was at the national average (90 percent), and VISN 14 had the lowest

²October 1, 1999, to March 31, 2000, was the time frame for which the most recent and complete data were available at the time of our work.

percentage of prescriptions filled using national formulary drugs (88 percent).

Questionnaire to Prescribers

We mailed questionnaires to a representative sample of 2,000 VA health care prescribers whose prescriptions had been dispensed from October 1 through December 31, 1999, to obtain their opinions and experiential data on various aspects of VA's national formulary. We drew this random sample from VA's most recent national outpatient prescription database—a data file that contains information, including a prescriber identifier, on all outpatient prescriptions filled in the VA health care system.

We mailed questionnaires to the entire sample of prescribers on April 17, 2000, with follow-up mailings on May 17 and June 21 to those who had not responded by those dates. We accepted returned questionnaires through September 1, 2000. Some prescribers' responses indicated that they did not write prescriptions for drugs; their prescription privileges were limited to medical and surgical supplies, such as diabetic strips and food supplements. Other returned questionnaires indicated that the addressee had either left or retired from VA. These providers were thus considered ineligible for our purposes and were removed from the sample. Approximately 11 percent of the questionnaires were returned as undeliverable, and we received no response from approximately 16 percent of those to whom we mailed questionnaires. After adjusting the sample accordingly, we determined the number of useable returned questionnaires to be 1,217—a response rate of about 69 percent. (See table 5.)

Table 5: Questionnaire Sample and Response Size

	Number
Total questionnaires mailed	2,000
Returned by nonprescribers ^a	225
Adjusted sample size	1,775
Not deliverable by Postal Service	226
Delivered but not returned	328
Received after closing date	4
Useable questionnaires returned	1,217
Final response rate	69%

^aThese are uncompleted, but returned, questionnaires. They represent individuals who indicated that they either did not have drug prescribing privileges (50 people, or 2.6 percent of the sample) or had left or had retired from VA (175 people, or 8.7 percent of the sample.) These individuals would have been excluded from the original sample if that information had been known in advance.

Because this was a simple random sample, we believe that our results are projectable to all of VA's health care providers who have outpatient drug prescribing privileges.

Sampling Errors

Surveys based on a sample are subject to sampling errors. Sampling error represents the extent to which a survey's results differ from what would have been obtained had everyone in the universe of interest received and returned the same questionnaire—in this case, all VA health care providers who have outpatient drug prescribing privileges. Sampling errors have two elements: the width of the confidence interval around the estimate (sometimes referred to as the precision of the estimate) and the confidence level at which the confidence interval is computed.

The confidence interval reflects the fact that estimates actually encompass a range of possible values, not just a single value, or a “point estimate.” The interval is expressed as a point, plus or minus some value. For example, in our questionnaire, we asked prescribers, “To what extent does your VA formulary contain the drugs you believe your patients need?” The percentage of respondents who reported a “great extent” or “very great extent” was 69.1. This particular question had a confidence interval of plus or minus 2.6 percentage points. Thus, the “true” answer for this question may or may not be 69.1 percent, but it has a high probability of falling between 66.5 and 71.7 percent (69.1-percent point estimate, plus or minus 2.6 percentage points). Confidence intervals vary for individual questions (depending upon how many of the individuals who could have answered a question actually did so), but, unless otherwise noted, all percentages presented in this report are within a range of plus or minus 3.5 percentage points.

The confidence level is a measure of how certain we are that the “true” answer lies within a confidence interval. We used a 95-percent confidence level, which means that if we repeatedly took new samples of prescribers from the October through December prescription database and performed the same analysis of their responses each time, 95 percent of these samples would yield estimates that would fall within the confidence interval stated. In the previous example, this means that we are 95-percent certain that between 66.5 and 71.7 percent of prescribers believe that the VA formulary

contains to a “great extent” or “very great extent” the drugs they believe their patients need.

Nonsampling Errors

Surveys can also be subject to other types of systematic error or bias that can affect results, known as nonsampling errors. One potential source of nonsampling error can be the questionnaire itself. To ensure that questions were clear and unbiased, we consulted with subject matter and questionnaire experts within GAO and obtained comments from individuals representing VA’s PBM and medical advisory panel, a working group of 11 practicing VA physicians and 1 practicing Department of Defense physician who help manage VA’s national formulary, as well as individuals representing the Institute of Medicine. Finally, the questionnaire was tested with 14 VA prescribers in VA medical centers in four locations: Phoenix, Arizona; Washington, D.C.; Hampton, Virginia; and Cincinnati, Ohio.

Prescribers’ Demographics

Prescribers were asked to provide demographic and VA employment information as well as opinions about the relevance and usefulness of VA’s formulary. On average, VA prescribers in our sample have worked for VA for 11 years, with most of those years at their current medical facility. Physicians and nurses constitute the largest groups of prescribers (65 and 15 percent, respectively), followed by physician assistants (7 percent) and other allied health professionals, such as dentists (14 percent). Most of the prescribers’ time working in VA is spent treating patients—on average, 26 hours each week. According to the national prescription file from which we drew our sample, VA prescribers who completed our questionnaire averaged 849 prescription fills from October through December 1999, the 3-month period we chose as the basis of our survey. The median number of filled prescriptions was relatively low—252—because a few prescribers had a large number of prescriptions filled during the period, while many prescribers had only a few prescriptions filled.

Comments From the Department of Veterans Affairs



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

JAN 17 2001

Ms. Cynthia A. Bascetta
Director, Health Care
Veterans Health and Benefits Issues
U. S. General Accounting Office
441 G Street, NW
Washington, DC 20548

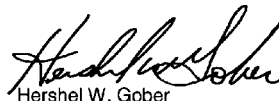
Dear Ms. Bascetta:

This is in response to your draft report, ***VA DRUG FORMULARY: Better Oversight Is Required, but Veterans Are Getting Needed Drugs*** (GAO-01-183). I agree with your findings and concur in your recommendations. I appreciate that GAO has recognized the Veterans Health Administration's (VHA) significant progress in assuring that all of our patients have needed access to medications throughout the Department's national health care delivery system.

Nevertheless, I also agree with GAO that ongoing oversight improvements at all organizational levels will enhance the process even more. The Department is actively addressing issues that the GAO raises in its recommendations. I am pleased to report that VA is committed to the ongoing evolution of the national formulary and the processes associated with its effective management. Included in that commitment is an emphasis on increased standardization and a fair and equitable process to assess and approve non-formulary requests.

I appreciate the opportunity to comment on your draft report.

Sincerely,


Hershel W. Gober
Acting

Enclosure

Appendix II
Comments From the Department of Veterans
Affairs

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
VA DRUG FORMULARY: Better Oversight Is
Required, but Veterans Are Getting Needed Drugs
(GAO-01-183)

VHA's full implementation of its national formulary has resulted in key improvements over the past 3 years. As GAO's report cites, 90% of all dispensed VA outpatient prescriptions represent items on our national formulary, with another 7% included in the Veterans Integrated Service Network (VISN) formularies. Only 3% of the total outpatient medication workload consists of non-formulary items. These data validate that VA's formulary utilization strategies are effective and that our statistics compare favorably with the 12% non-formulary benchmark for other managed care organizations that the Institute of Medicine identified in its June 2000 review of the VA National Formulary (*Description and Analysis of the VA National Formulary*, available at <http://www.nap.edu>). This is also cited in managed care literature.

GAO recommends that I direct the Under Secretary for Health to:

- **Establish a mechanism to ensure that VISN Directors comply with national formulary policy.**

Concur - Inherent in many of GAO's observations is concern about the variance among the VISNs and individual medical centers in implementing national formulary policy and the lack of adequate oversight in assuring such compliance. Recently, VHA's Pharmacy Benefits Management Strategic Health Group (PBM) developed changes to the pharmacy data extract. These changes will have the capability to provide national data on VISN, non-formulary and national formulary utilization. VHA pilot tested this system augmentation in selected facilities in December 2000 and is refining it for systemwide implementation anticipated in March 2001. PBM administrators will then have access to comparative VISN formulary usage data that it will examine for outliers and then share with all of the VISNs. PBM staff continues to coordinate closely with the VISN formulary leaders to facilitate consistent compliance with national formulary policy. All VISN formulary leaders are reviewing GAO's report. VHA also included GAO's report as a discussion topic during the January 8, 2001, formulary leader teleconference call.

Appendix II
Comments From the Department of Veterans
Affairs

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
***VA DRUG FORMULARY: Better Oversight Is
Required, but Veterans Are Getting Needed Drugs***
(GAO-01-183)
(Continued)

- **Establish criteria that VISNs should use to determine the appropriateness of adding drugs to supplement the national formulary and monitor the VISNs' application of these criteria.**

Concur - In further supporting more uniform policy implementation, the PBM Medical Advisory Panel has drafted criteria for VISNs to determine the appropriateness of adding supplemental drugs to the national formulary. We anticipate that these guidelines, which have already gone through an initial administrative review, will be posted on the PBM Web Site and widely communicated throughout the system via established channels by the end of March 2001. In addition, VHA is developing a template for VISNs to document all VISN formulary additions. These data will then be centrally reported to PBM staff on a quarterly basis. Additionally, PBM will review all new FDA-approved molecular entities but will not add them to the VISN formularies until the national review is completed.

- **Establish a nonformulary drug approval process for medical centers that ensures appropriate and timely decisions and provides that veterans, for whom a nonformulary drug has been approved, will have continued access to that drug where appropriate, across VA's health care system.**

Concur - PBM will incorporate the above and other new molecular entity approval processes into proposed revisions to the official VHA National Formulary Directive. This directive will also outline fundamental steps that all medical centers and VISNs must take in establishing and reporting their non-formulary approval activities. Approval processes will necessarily vary somewhat among facilities to reflect variations in the delivery setting, staffing, availability of clinical pharmacists, etc. Also included in the directive will be a requirement that the VISN directors review all individual medical facility and VISN non-formulary policies for compliance with established VHA policy. VHA expects to issue the revised directive no later than June 2001.

Appendix II
Comments From the Department of Veterans
Affairs

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
***VA DRUG FORMULARY: Better Oversight Is
Required, but Veterans Are Getting Needed Drugs***
(GAO-01-183)
(Continued)

- **Enforce existing requirements that VISNs collect and analyze the data needed to determine that nonformulary drug approval processes are implemented appropriately and effectively in their medical centers, including tracking both approved and denied requests.**

Concur - Basic software changes are needed in VHA's national VISTA (Veterans Health Information Systems and Technology Architecture) data system to strengthen formulary management. Currently, VISTA has no mechanism to identify drugs as "restricted." Therefore, restricted national formulary items are sometimes marked as non-formulary in the local drug file in order to trigger a review of the order for appropriateness. Obviously, this situation can impact the accuracy of reported formulary status. Proposed software changes will provide needed formulary status identification options and will eliminate the need for locally developed "work-arounds." Planned software updates will involve coordination among various program offices. PBM has begun initial discussion with VHA's Information Management Office about planning for the changes. VHA plans to convene a work group by April/May of this year to plan for specific modification actions.

GAO Contact and Staff Acknowledgments

GAO Contact

Walter Gembacz, (202) 512-6982

**Staff
Acknowledgments**

George Poindexter, Stuart Fleishman, Mike O'Dell, and Kathie Kendrick made key contributions to this report.

Related GAO Products

State Pharmacy Programs: Assistance Designed to Target Coverage and Stretch Budgets (GAO/HEHS-00-162, Sept. 6, 2000).

Prescription Drug Benefits: Applying Private Sector Management Methods to Medicare (GAO/T-HEHS-00-84, Mar. 22, 2000).

VA Health Care: VA's Management of Drugs on Its National Formulary (GAO/HEHS-00-34, Dec. 14, 1999).

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

Defense Health Care: Fully Integrated Pharmacy System Would Improve Service and Cost-Effectiveness (GAO/HEHS-98-176, June 12, 1998).

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