United States General Accounting Office

GAO

Testimony

Before the Committee on Veterans' Affairs, U.S. Senate

For Release on Delivery
Expected at 2:30 p.m.
Tuesday, July 24, 2001

VA HEALTH CARE

Continuing Oversight Needed to Achieve Formulary Goals

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Mr. Chairman and Members of the Committee:

I am pleased to be here today to discuss the Department of Veterans Affairs (VA) management and oversight of its national drug formulary. VA's national formulary is intended, in part, to control costs and better ensure that veterans have access to the same drugs regardless of which VA medical center they visit. VA medical centers were directed to make all national formulary drugs available to prescribers—health care providers who have VA prescription-writing privileges.[1] To meet local patient needs, VA allows its 22 networks to add drugs to supplement the national formulary.[2] VA also requires each network to establish an approval process for obtaining drugs not listed in its formulary.

My testimony addresses problems we identified in two recent reports regarding implementation and standardization of the formulary and the approval process for nonformulary drugs at each network.[3] In conducting our work, we reviewed the formulary policies and activities of VA's headquarters and its 22 networks, analyzed nationwide VA prescription data, conducted site visits and interviewed VA officials at three medical centers located in three different networks, and surveyed 2,000 prescribers. We also updated this statement to reflect VA's most recent actions to implement our recommendations for improving its management and oversight.

In summary, while VA has made significant progress establishing a national formulary that has generally met with prescribers' and patients' acceptance, VA's oversight has not been sufficient to fully ensure standardization of its drug benefit nationwide. In our January 2001 report, we found that the three medical centers we visited were not in compliance with the national formulary. Specifically, two of three medical centers omitted more than 140 required national formulary drugs, and all three facilities inappropriately modified the national formulary list of required

[1]Veterans Health Administration's Directive 97-047, *VA National Formulary Directive,* Oct. 16, 1997.

[2]In 1995, VA began transforming its delivery and management of health care to expand access to care and increase efficiency. VA decentralize decisionmaking and budgeting authority to 22 regional Veterans Integrated Service Networks (VISN), which became responsible for managing all VA health care.

[3]*VA Health Care: VA's Management of Drugs on Its National Formulary* (GAO/HEHS-00-34, Dec. 14, 1999) and *VA Drug Formulary: Better Oversight Is Required, but Veterans Are Getting Needed Drugs* (GAO-01-183, Jan. 29, 2001).

drugs for certain drug classes by adding or omitting some drugs. In addition, as VA policy allows, VISNs added drugs to supplement the national formulary ranging from 5 drugs at one VISN to 63 drugs at another. However, VA lacked criteria for determining the appropriateness of the actions networks took to add these drugs.

In addition to problems standardizing the national formulary, we identified weaknesses in the nonformulary approval process. While the national formulary directive requires certain criteria for approving nonformulary drugs, it does not prescribe 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 to obtain approval. We found that the length of time to approve nonformulary drugs averages 9 days, but can be as short as a few minutes in some 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 meet its established criteria or if denied requests are appropriate.

In our January 2001 report, we made several recommendations to VA to improve its management and oversight of its national formulary. VA concurred with all of our recommendations and has taken, or plans to take, steps to implement them. Although these are clearly steps in the right direction, it is too early to tell how successful VA will be in establishing the continuous oversight needed to improve formulary management.

Background

In fiscal year 2000, VA's pharmacy benefit provided approximately 86 million prescriptions at a cost of approximately $2 billion—or about 12 percent of VA's total health care budget, compared to 6 percent of VA's total health care budget a decade ago. VA provides outpatient pharmacy services free to veterans receiving medications for treatment of service-connected conditions and to low-income veterans. Other veterans who

have prescriptions filled by VA may be charged a copayment for each 30-day supply of medication.[4]

Like many health care organizations, VA uses several measures in an effort to improve quality of care and control pharmacy costs. These include (1) implementing a national formulary, which standardizes the list of drugs available; (2) developing clinical guidelines for prescribing drugs; and (3) using compliance programs, such as prior authorization, to encourage or require physicians to prescribe formulary drugs.

VA medical centers individually began using formularies as early as 1955 to manage their pharmacy inventories. However, it was not until 40 years later in September 1995, that VA established a centralized group to manage its pharmacy benefit nationwide. In November 1995, when VISNs were established, VA's 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. In 1996, VA was required 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. VA's formulary meets the Joint Commission for the Accreditation of Health Care Organizations' requirements for developing and maintaining an appropriate selection of medications for prescribers to use in treating their patient populations.

VA's formulary lists more than 1,100 unique drugs in 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. This determination allowed VA to select one or more of these drugs for its formulary so that it

[4]Section 201 of the Veterans Millennium Health Care and Benefits Act (P.L. 106-117) authorized the Secretary of the Department of Veterans Affairs to prescribe regulations to increase the copayment for each 30-day supply of medication for outpatient treatment of non-service-connected disabilities or conditions and to establish maximum monthly and maximum annual pharmaceutical copayments for veterans who have multiple outpatient prescriptions. In response, the Secretary has proposed regulations that, among other things, increases the copayment from $2 to $7. (Fed. Reg., Vol. 66, No. 136, July 16, 2001, pp. 36960-63.)

could seek better prices through competitively bid committed-use contracts.[5] 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 classes, and it does not limit the number of drugs that can be added to these classes. These are known as "open" classes.

To manage its pharmacy benefit nationwide, VA established the Pharmacy Benefits Management Strategic Healthcare Group (PBM). PBM is responsible for managing the national formulary list, maintaining databases that reflect drug use, and monitoring the use of certain drugs. PBM also facilitates the addition and deletion of drugs on the national formulary on the basis of safety and efficacy data, determines which drugs are therapeutically interchangeable in order to purchase drugs through competitive bidding, and develops safeguards to protect veterans from the inappropriate use of certain drugs. VISN directors are responsible for implementing and monitoring compliance with the national formulary and ensuring that a nonformulary drug approval process is functioning at each of their medical centers. 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.

National Formulary Standardization Not Yet Achieved

While VA has made significant progress in establishing a national formulary, its oversight has not been sufficient to ensure that it is fully achieving its national formulary goal of standardizing its drug benefit nationwide. In our January 2001 report, we found three factors that have impeded formulary standardization: (1) medical centers we visited omitted some national formulary drugs from their local formularies, (2) VISNs varied in the number of drugs they added to local formularies to supplement the national formulary without appropriate oversight, and (3) medical centers inappropriately added or deleted drugs in closed classes. Nevertheless, most prescribed drugs were on the national formulary, and prescribers and patients were generally satisfied with the national formulary.

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

The first factor impeding standardization is that medical centers omitted some national formulary drugs from their local formularies. Almost 3 years after VA facilities were directed to make all national formulary drugs available locally, two of the three medical centers we visited in spring of 2000 omitted required drugs from the formularies used by their prescribers. At one medical center, 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, mental disorders, and women's medical needs. 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.

From October 1999 through March 2000, health care providers at these two medical centers had to obtain nonformulary drug approvals for over 22,000 prescriptions for drugs that should have been available without question because they are on the national formulary. Our analysis showed that at the first center, over 14,000 prescriptions were filled as nonformulary drugs for 91 drugs that should have been on the formulary.[6] At the other medical center, over 8,000 prescriptions for 23 national formulary drugs were filled as nonformulary drugs. 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.

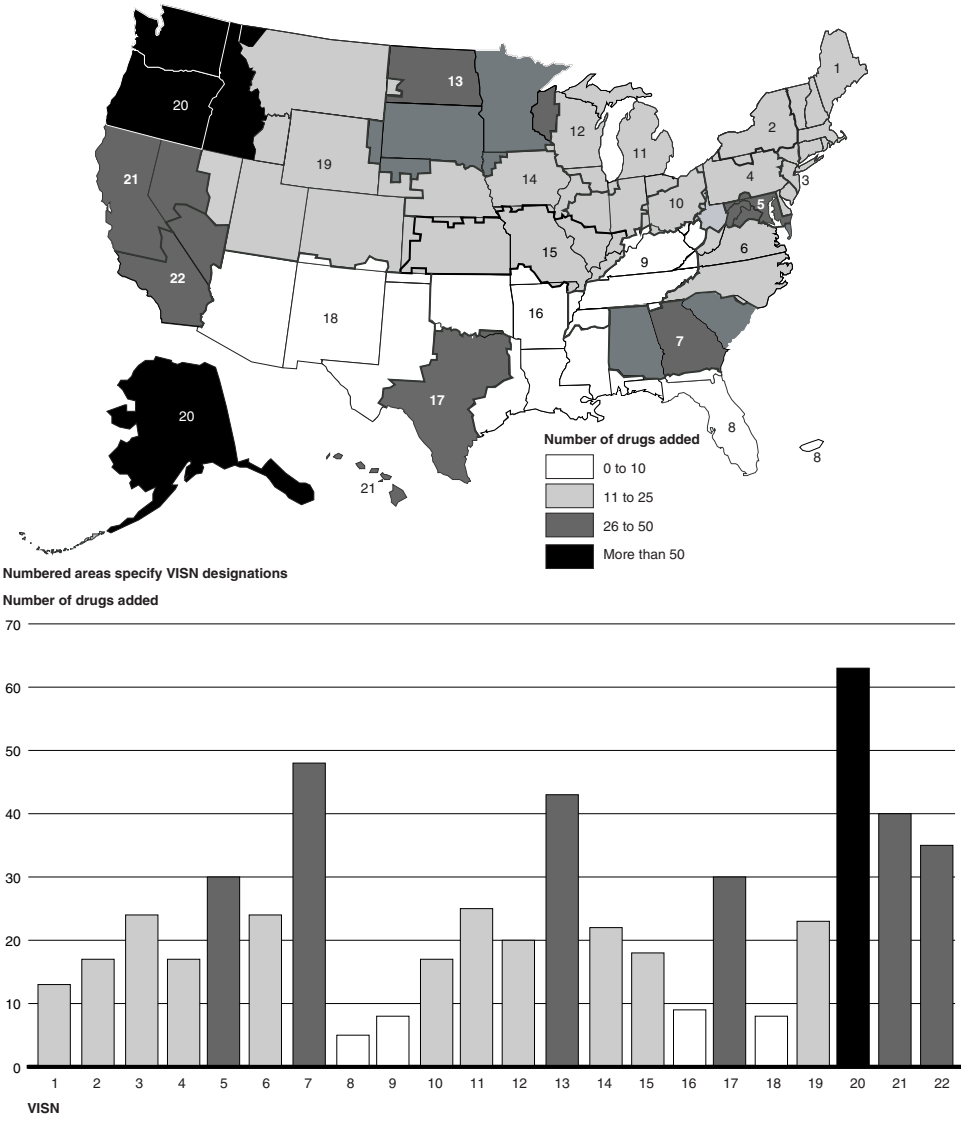
The second factor impeding standardization is the wide variation in the number of drugs added by VISNs to their local formularies. VA's policy allowing VISNs to supplement the national formulary locally has the potential for conflicting with VA's goal of achieving standardization if it is not closely managed. From June 1997 through March 2000, the 22 VISNs added a total of 244 unique drugs to supplement the list of drugs on the national formulary. As figure 1 shows, the number of drugs added by each VISN varies widely, ranging from as many as 63 to as few as 5. 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 formulary designation of new drugs approved by the Food and Drug

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

Administration (FDA).[7] VA officials have acknowledged that this variation affects standardization and told us they plan to address it. For example, PBM plans to more quickly review new drugs when approved by FDA to determine if they should be added to the national formulary.

[7]VA national 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 VA's National Formulary, June 1997—March 2000



Source: GAO analysis of PBM data.

The third factor is that medical centers we visited 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 in a closed class available. Moreover, the Institute of

Medicine (IOM) found broad nonconformity at the VISN level.[8] Specifically, IOM reported that 16 of the 22 VISNs modified the list of national formulary drugs for the closed classes.[9] This also undermines VA's ability to achieve cost savings through its committed-use contracts.

While VA has not yet fully achieved national formulary standardization, most prescribed drugs were 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.

Of the remaining 10 percent of prescriptions filled systemwide, VA's national database could not distinguish between nonformulary drugs and drugs added to local formularies by VISNs and medical centers to supplement the national formulary. VA's PBM and the 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. VA officials told us that they are modifying the database to enable them to identify which drugs are added to supplement the national formulary and which are nonformulary. This will allow them to better oversee the balance between local needs and national standardization.

Prescribers we surveyed reported they were generally satisfied with the national formulary. Seventy percent of VA prescribers in our survey reported that the formulary includes the drugs their patients need either to a "great extent" or to a "very great extent." Approximately 27 percent reported that the formulary meets their patients' needs to a "moderate extent," with 4 percent reporting that it meets their patients' needs to a lesser extent. No VA prescribers reported that the formulary meets their patients' needs to "very little or no extent." This is consistent with IOM's conclusion that the VA formulary "is not overly restrictive."

[8]In June 2000, IOM issued a 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. (IOM, *Description and Analysis of the VA National Formulary* [Washington, D.C.: IOM, June 2000].)

[9]IOM, *Description and Analysis of the VA National Formulary*, pp. 32-33.

Veterans also appear satisfied with their ability to obtain the drugs they believe they need. At the VA medical centers we visited, patient advocates[10] told us that veterans made very few complaints concerning their prescriptions. In its analysis of patient complaints, IOM found that less than one-half of 1 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 Viagra.[12] 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 may fill prescriptions written by non-VA health care providers only under limited circumstances, for example, when the veteran is housebound and receives additional compensation because of a service-connected disability.[14]

Approval Processes for Nonformulary Drugs Have Weaknesses

While the national formulary directive requires certain criteria for approval of nonformulary drugs, it does not prescribe 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 to obtain approval. 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 meet its established criteria or if denied requests are appropriate.

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

[11]IOM 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.)

[12]Viagra (sildenafil), which is used to treat erectile dysfunction, is available within VA only through the nonformulary drug approval process.

[13]We asked prescribers in our survey how often in 1999 their patients asked them to rewrite prescriptions from non-VA prescribers so that they 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.

[14]*See* 38 U.S.C. §1712(d); 38 C.F.R. §17.96, and Op. VA Gen. Coun. 41-91 (1991).

Both the people involved and the length of time to approve nonformulary drugs varied. 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 facility pharmacists, 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 facility pharmacists approve nonformulary drug requests, 26 percent said that facility P&T committees approve them, and 15 percent told us that facility chiefs of staff approve 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 also varied depending on the local approval processes. The majority of prescribers we surveyed (60 percent) reported that it took an average of 9 days to obtain approval for use of nonformulary drugs.[15] 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 expeditious 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, another medical center we visited assigned a clinical pharmacist 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.

[15]In emergencies, exceptions are made to allow the patient to obtain the drug more quickly.

Prescribers we surveyed were almost equally divided on the ease or difficulty of getting nonformulary drug requests approved. (See table 1.)

Table 1: 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 majority of prescribers told us that their requests were generally approved. According to our survey results, 65 percent of prescribers sought approval for nonformulary drugs 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.

For patients moving from one location to another, the majority of prescribers we surveyed told us that they were more likely to convert VA patients who were on a nonformulary drug obtained at another VA facility to a formulary drug than to request approval for the nonformulary drug. (See table 2.)

Table 2: 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.

Contrary to the national formulary policy, not all VISNs have established a process for collecting and analyzing data on nonformulary requests 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. Such information could help VA officials 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 on such matters could diminish confidence in the nonformulary process.

Plans for Improving Oversight Are Progressing

We are encouraged by VA's actions, but it is too early to tell how successful it will be in addressing our recommendations for improving its management and oversight of the national formulary. To improve standardization of its formulary, we recommended that VA establish (1) a mechanism to ensure that VISN directors comply with VA's national formulary policy and (2) 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. VA's PBM has developed changes to its database that will provide comparative national data on VISN, nonformulary, and national formulary drug use. PBM also plans to share these data, including identification of outliers, with all 22 VISNs and coordinate with VISN formulary leaders to facilitate consistent compliance with national formulary policy. In addition, VA (1) drafted criteria for VISNs to use to determine the appropriateness of adding drugs to supplement the national formulary list, which it intends to include in a directive; (2) is developing a template for VISNs to document all VISN formulary additions; and (3) intends to review more quickly all new FDA-approved drugs for inclusion in the national formulary.

To improve its nonformulary drug approval process, we recommended that (1) VA establish a process to ensure timely and appropriate decisions by medical centers and (2) veterans be allowed continued access to previously approved nonformulary drugs, regardless of where they seek care in VA's health care system. In addressing these recommendations, VA plans to incorporate into its revised formulary directive the fundamental steps that all medical centers must take in establishing and reporting their nonformulary activities. VA also plans to include in its revised formulary directive a specific requirement that approved nonformulary medications will continue if a veteran changes his or her care to a different VA facility.

We also recommended that VA 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. VA plans to establish steps for reporting its nonformulary approval activities. PBM has begun initial discussions with VA's Information Management Office about planning for the changes.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions you or other members of the Committee may have.

GAO Contacts and Acknowledgments

For more information about this statement, please call me at (202) 512-7101, or Walter Gembacz, Assistant Director, at (202) 512-6982. A key contributor to this statement was Mike O'Dell.

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