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VA DRUG FORMULARY

Drug Review Process
Is Standardized at the
National Level, but
Actions Are Needed to
Ensure Timely
Adjudication of
Nonformulary Drug
Requests



GAO

Accountability * Integrity * Reliability

Why GAO Did This Study

In 2009, the Department of Veterans Affairs (VA) spent nearly \$4 billion on prescriptions for veterans. In general, VA provides drugs on its national formulary. However, all VA medical centers must have a nonformulary drug request process that is overseen by their regional Veterans Integrated Service Network (VISN). This report responds to a House Committee on Appropriations report directing GAO to review VA's formulary process and to an additional congressional request. Specifically, GAO reviewed (1) the process VA uses to review drugs for its national formulary, (2) the approaches VISNs and medical centers take to implementing the nonformulary drug request process, (3) the extent to which VA ensures the timely adjudication of nonformulary drug requests, and (4) the mechanisms VA has in place to obtain beneficiary input on the national formulary and make the drug review process transparent. GAO reviewed VA policy guidance and VA's pharmacy-related information technology (IT) initiatives, analyzed 2008 and 2009 drug review data and 2009 nonformulary drug request data, and interviewed VA officials from the national level, each VISN, and a judgmental sample of four medical centers.

What GAO Recommends

GAO recommends that VA establish additional mechanisms to ensure nonformulary drug requests are adjudicated in a timely fashion. VA concurred with this recommendation.

[View GAO-10-776](#) or [key components](#).

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VA DRUG FORMULARY

Drug Review Process Is Standardized at the National Level, but Actions Are Needed to Ensure Timely Adjudication of Nonformulary Drug Requests

What GAO Found

VA uses a standardized process to review drugs for its national formulary that is coordinated at the national level by its Pharmacy Benefits Management Services (PBM). The Chief Consultant from VA's PBM told us that most drug reviews are initiated in response to FDA's approval of drugs for use on the market. To begin the process of deciding whether to include a drug on the national formulary, PBM develops evidence-based drug monographs that include information on safety, efficacy, and cost. PBM seeks comments on these monographs from VISN and medical center staff and, when appropriate, subject-matter experts. Once a monograph is complete, PBM sends it to its Medical Advisory Panel and the VISN Pharmacist Executive Committee, which review the monograph and vote on whether to add the drug to the national formulary. According to information provided by PBM, reviews for a majority of the drugs VA considered for addition to the national formulary in 2008 and 2009 were completed within a year of FDA approval, but there were a number of factors, such as safety concerns, that caused some to take longer.

VISNs and medical centers vary in how they implement the nonformulary drug request process, including how they adjudicate nonformulary drug requests, collect and report required data to VA's PBM, and address appeals of denied requests. GAO found that IT enhancements could help facilitate more consistent implementation of the process. Although VA is working on replacing its pharmacy IT system, officials could not tell GAO whether components that would support the nonformulary drug request process will be implemented.

VA requires that nonformulary drug requests be adjudicated within 96 hours, but it is unable to determine the total number of adjudications that exceed this standard due to limitations in the way data are collected, reported, and analyzed. While the total number of nonformulary drug request adjudications that exceed 96 hours is unknown, GAO found that data reported to VA's PBM on quarterly average adjudication times for medical centers are sufficient to demonstrate that not all requests are adjudicated within this time frame. Additionally, PBM does not have the framework in place to ensure that appeals of denied nonformulary drug requests are resolved in a timely fashion.

VA obtains input from beneficiaries on the national formulary mainly through Veterans Service Organization meetings and complaints, though some VISNs have taken additional steps to seek this input. Officials from VA's PBM told GAO that they make the drug review process transparent to veterans through national formulary information available on PBM's Web site, and some VISN and medical center officials described undertaking other activities to educate beneficiaries. At the national level, VA officials are considering options for increasing beneficiary input on the national formulary and improving the transparency of the drug review process, and most VISN and medical center officials told us there could be benefit to doing so.

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Abbreviations

CPRS	Computerized Patient Record System
DOD	Department of Defense
FDA	Food and Drug Administration
IT	information technology
MAP	Medical Advisory Panel
OI&T	Office of Information and Technology
PBM	Pharmacy Benefits Management Services
PRE	Pharmacy Reengineering
P&T	pharmacy and therapeutics
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture
VPE	VISN Pharmacist Executive
VSO	Veterans Service Organization

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Congressional Addressees

In 2009, the Department of Veterans Affairs (VA) spent nearly \$4 billion on the 249 million prescriptions it dispensed to veterans, representing about 9 percent of VA's total health care budget. In general, medications provided through the VA pharmacy benefit must be prescribed by a VA provider, filled through a VA pharmacy, and listed on the Veterans Affairs National Formulary.¹ The national formulary is a list of drugs, grouped by class, that VA providers are expected to use when prescribing drugs for veterans.² Providers can request access to medications not listed on the national formulary when it is clinically necessary to do so, and all VA medical centers are required to have a nonformulary drug request process.³ Most drugs, whether on the national formulary or nonformulary, are ordered electronically through the Veterans Health Information Systems and Technology Architecture (VistA)—VA's health information technology (IT) system.⁴ In 2009, 94 percent of drugs dispensed by VA were national formulary drugs.

Until recently, drugs not listed on the national formulary might have been available through formularies established at each of VA's 21 regional Veterans Integrated Service Networks (VISN); however, effective January 2009, VA eliminated the use of VISN formularies, making the national formulary the only drug formulary used by VA.⁵ VA's Pharmacy Benefits Management Services (PBM) is the office within the Veterans Health

¹For purposes of this report, we use "providers" to refer to health care professionals with prescriptive authority within VA.

²Drug classes are groups of drugs similar in chemical structure, pharmacological effect, or clinical use.

³For purposes of this report, we use "medical centers" to refer to VA medical care facilities that provide drug prescriptions.

⁴VistA, which began operation in 1983 as the Decentralized Hospital Computer Program, is the primary repository of clinical, administrative, and infrastructure data in VA. VistA is not standardized at the national level; rather, each medical center is responsible for maintaining its own VistA system.

⁵VA established VISNs in 1995 to decentralize general decision-making and budgetary duties from its headquarters. Each VISN oversees health care delivery for the VA medical centers in its designated area.

Administration (VHA) responsible for administering VA's pharmacy benefit on a nationwide basis. VA's PBM works in conjunction with the Medical Advisory Panel (MAP) and the VISN Pharmacist Executive (VPE) Committee to manage the national formulary, and also provides guidance for VISNs and medical centers which are responsible for implementing the nonformulary drug request process.⁶

Members of Congress and interested stakeholders had questions about whether VA's policies and practices for managing the national formulary and processing nonformulary drug requests provide veterans with timely access to needed medications. Additionally, they had questions about the extent to which beneficiaries can provide input on the national formulary and if VA's process for reviewing drugs for its national formulary is sufficiently transparent. We conducted this work in response to a House Committee on Appropriations report associated with H.R. 3082, the 2010 Military Construction, Veterans Affairs, and Related Agencies Appropriations Bill, which directed us to review and report on VA's formulary process, and in response to a similar request from the Chairman, Subcommittee on Health, House Committee on Veterans Affairs.⁷ In this report, we (1) describe the process VA uses to review drugs for its national formulary, (2) describe the approaches VISNs and medical centers take to implementing the nonformulary drug request process, (3) examine the extent to which VA ensures the timely adjudication of nonformulary drug requests, and (4) describe the mechanisms VA has in place to obtain beneficiary input on the national formulary and make its drug review process transparent to them.

To describe the process VA uses to review drugs for its national formulary, we reviewed VA policy guidance, such as VA's formulary management handbook.⁸ We obtained and summarized information provided by VA's

⁶MAP is comprised of practicing VA physicians and clinicians from VA's PBM. The VPE Committee is comprised of pharmacists representing each VISN who generally serve both as the VISN representative on the VPE Committee and the manager of the VISN-Pharmacy Benefits Management Office. According to PBM officials, a MAP representative sits on the VPE Committee and a VPE Committee representative sits on MAP. Additionally, a clinical representative from the Department of Defense (DOD) sits on both committees.

⁷H.R. Rep. No. 111-188, at 41 (2009). Although H.R. 3082 did not become law, the conference report for the Consolidated Appropriations Act for 2010, which included appropriations for VA, noted that the language of House Report 111-188 should be complied with unless specifically addressed to the contrary. See H.R. Conf. Rep. No. 111-366, at 1334 (2009).

⁸VHA Handbook 1108.08, *VHA Formulary Management Process*, February 2009.

PBM on drug reviews VA conducted in 2008 and 2009 and identified (1) the number of reviews conducted, (2) the outcomes of these reviews, and (3) drug review completion times. We determined drug review completion times by calculating the amount of time elapsed from the date PBM reported a drug as approved by the Food and Drug Administration (FDA) to the date it reported VA completing its review of the drug.⁹ We also obtained information from PBM on the number of new drugs approved by FDA in 2008 and 2009 and whether VA had completed reviews of these drugs as of March 2010.¹⁰ Additionally, we interviewed officials from VA at the national, regional, and local levels. Specifically, we interviewed national-level officials from PBM, including the Chief Consultant, and VPEs from the 21 regional VISNs.¹¹ To interview officials at the local level, we identified a judgmental sample of four medical centers. We selected the four medical centers to achieve variation in the percentage of nonformulary drug prescriptions dispensed between 2006 and 2009 and variation in the total number of prescriptions dispensed—both national formulary and nonformulary—during 2009.¹² We also considered geographic location. From each medical center, we interviewed the chief of pharmacy and the physician pharmacy and therapeutics (P&T) committee chair. Finally, we observed a MAP meeting and interviewed some of the members.

To describe the approaches VISNs and medical centers take to implementing the nonformulary drug request process, we reviewed VA's formulary management handbook and interviewed officials from VA's PBM, the 21 VPEs, and officials from our sample of four medical centers. Additionally, we obtained documentation from VA on its pharmacy-related

⁹FDA is the agency within the Department of Health and Human Services responsible for ensuring the safety and effectiveness of medical products. Before a drug can be marketed in the United States, it must be approved by the FDA.

¹⁰For purposes of this report, a "new drug" is an FDA-approved new molecular entity, which is a drug that includes an active ingredient that has not previously been approved for marketing in the United States in any form.

¹¹The Chief Consultant heads VA's PBM and is responsible for planning and directing a variety of VA pharmacy issues including formulary management.

¹²To achieve variation in the percentage of nonformulary drug prescriptions dispensed between 2006 and 2009, we selected medical centers that (1) consistently prescribed a higher level of nonformulary drugs compared to the average level, (2) consistently prescribed a lower level of nonformulary drugs compared to the average level, and (3) prescribed a higher level of nonformulary drugs in 2006 and a markedly lower level in 2009.

health IT initiatives and interviewed officials from PBM and VA's Office of Information and Technology (OI&T) who are responsible for designing and implementing these initiatives. We also reviewed our past and ongoing work on VA health IT initiatives.¹³

To examine the extent to which VA ensures the timely adjudication of nonformulary drug requests, we reviewed VA's formulary management handbook for policies to use as criteria, and determined that VA requires nonformulary drug requests to be adjudicated within 96 hours. We interviewed officials from VA's PBM, the 21 VPEs, and officials from our sample of four medical centers. We also obtained and analyzed quarterly nonformulary drug request data on the average time taken to adjudicate requests reported to PBM for calendar year 2009 at the VISN and medical center levels. We reviewed related documentation, interviewed knowledgeable VA officials, conducted tests for missing data, outliers, and obvious errors, and determined that data reported for 13 of the 21 VISNs and their medical centers were reliable for our purposes.¹⁴

To describe the mechanisms VA has in place to obtain beneficiary input on the national formulary and make its drug review process transparent to them, we reviewed VA's formulary management handbook as well as reviewed the Web site for VA's PBM for the type of information available to beneficiaries. In addition, we interviewed officials from PBM, the 21 VPEs, and officials from our sample of four medical centers as well as observed discussions at the MAP meeting we attended. We also interviewed officials from the Department of Defense (DOD) regarding its

¹³GAO, *Veterans Affairs: Health Information System Modernization Far from Complete; Improved Project Planning and Oversight Needed*, [GAO-08-805](#) (Washington, D.C.: June 30, 2008).

¹⁴We determined that data for the remaining eight VISNs and their medical centers were not reliable for our purposes, because VPEs for these VISNs told us that medical centers in their regions may include data on national formulary drugs in the nonformulary drug request data that they report to VA's PBM.

Uniform Formulary Beneficiary Advisory Panel and attended a meeting of this group.¹⁵

We conducted this performance audit from November 2009 through August 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Formularies are used to help control pharmacy costs, enhance patient safety, and improve quality of care by, among other things, limiting drug choices to those a health care organization has determined are the most medically appropriate and cost-effective for a given patient population. As early as 1955, VA medical centers began using formularies, and at the time, each medical center maintained its own formulary at the local level. In September 1995, VA created a centralized group to manage its pharmacy benefit nationwide, now called PBM, and soon began the process of moving to a single, national formulary. As an interim step, VA established regional formularies operated by each VISN. On June 1, 1997, VA implemented the national formulary to help standardize veterans' access to care across the country, though the medical centers and VISNs continued to maintain their own local and regional formularies. In 2001, VA abolished medical center formularies and in 2009, VA eliminated VISN formularies.

Discussion of the elimination of the regional VISN formularies began in 2005. In 2006, VA reviewed all drugs on VISN formularies that were not on the national formulary to determine if these drugs should be considered for inclusion on the national formulary. According to officials from VA's PBM, in cases where VA decided not to add a drug from a VISN formulary to the national formulary, VISN and medical center staff were given

¹⁵The National Defense Authorization Act for Fiscal Year 2000 directed the Secretary of Defense to establish a pharmacy benefits program. See Pub. L. No. 106-65, § 701, 113 Stat. 512, 677-80 (1999) (codified as amended at 10 U.S.C. § 1074g). As part of this program, the law directed the Secretary of Defense to establish the P&T Committee to develop the uniform formulary, and the Uniform Formulary Beneficiary Advisory Panel to review and comment on the development of the uniform formulary. The panel was required to include members that represent the views and interests of beneficiaries.

6 months to appeal the decision. In the end, 91 drugs from VISN formularies were added to the national formulary. Around the same time that this review was taking place, VISNs were asked to stop adding new drugs to their formularies, unless the drugs were also being added at the national level.

While VISNs and medical centers no longer maintain their own formularies, VA's decentralized approach to developing VistA means that each medical center is still responsible for maintaining a local drug file that matches VA's national drug file.¹⁶ In addition to maintaining a local drug file, each medical center decides whether and how it will customize other VistA applications onsite. VistA contains over a hundred separate computer applications, including the Computerized Patient Record System (CPRS). VA providers can use CPRS to review and update patient medical records and to place electronic orders for medications, procedures, and tests.

As part of its responsibilities for managing VA's pharmacy benefit at the national level, VA's PBM updates the national formulary listing, maintains databases that track drug use, and reviews data on nonformulary drug requests that it requires each VISN to report quarterly. PBM clinicians are responsible for maintaining a clinical portfolio on drugs for certain diseases, and are expected to continuously review information on new drugs that are relevant to their portfolio, as well as stay current on information on existing drugs. When appropriate, these clinicians will initiate a drug review. PBM works with MAP and the VPE Committee to conduct reviews of drugs for its national formulary, including the review of drugs approved by FDA for use on the market.

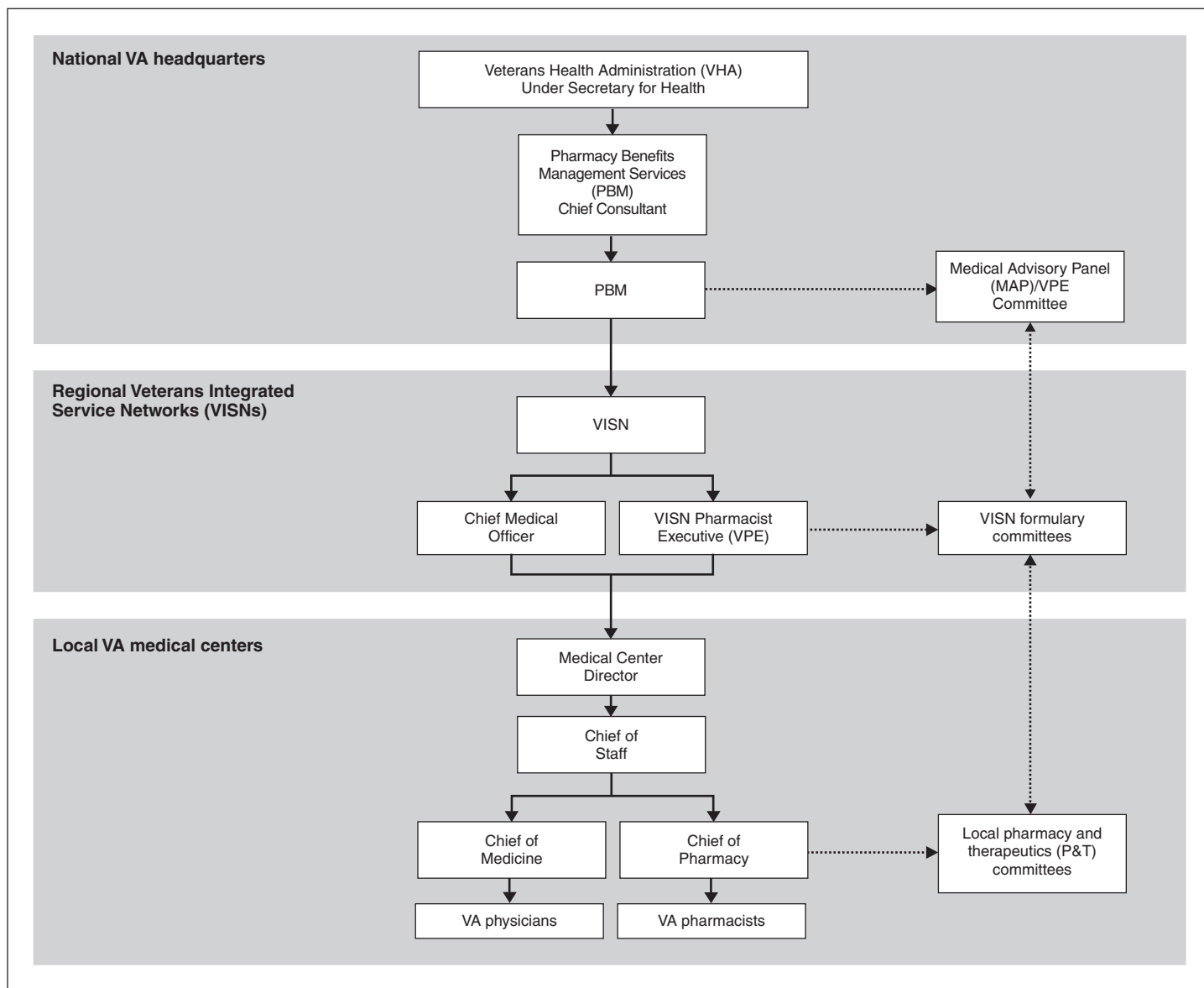
In addition to working with VA's PBM on the national-level VPE Committee, each VPE works in conjunction with its VISN formulary committee at the regional level to provide oversight and guidance for national formulary management activities for the medical centers within the network.¹⁷ In turn, at the medical center level, each chief of pharmacy

¹⁶Local drug files categorize drugs used within VA by a number of indicators, including whether a drug is on the national formulary or whether it is a nonformulary drug. The national drug file provides for standardization of the local drug files in all VA medical centers. VISNs 2 and 15 have combined local drug files at the regional level.

¹⁷A VISN formulary committee is a group within each VISN comprised of clinical personnel such as physicians and pharmacists.

works with the local P&T committee to implement national formulary decisions and ensure compliance with these decisions. (See fig. 1.)

Figure 1: Key VA Officials and Entities for National Formulary Management at the National, Regional, and Local Levels



Source: GAO analysis of VA documents and interviews with VA officials.

Although nearly all drugs that VA providers prescribe are on the national formulary, in some cases, providers determine that it is clinically necessary to prescribe nonformulary drugs.¹⁸ VA monitors the prescription of nonformulary drugs to ensure appropriate use and accordingly, each VA medical center must have a nonformulary drug request process. While VISNs and medical centers are responsible for implementing the nonformulary drug request process, VA has outlined certain requirements within its formulary management handbook. The handbook states that, at the local level, each VA medical center is responsible for establishing a process to adjudicate nonformulary drug requests that ensures decisions are evidence-based in accordance with certain prescribing criteria.¹⁹ VA also requires that medical centers adjudicate nonformulary drug requests within 96 hours.²⁰ Each medical center chief of staff is responsible for establishing a system to address any provider-initiated appeals of denied nonformulary drug requests.

At the regional level, VISNs are responsible for ensuring that medical centers have a nonformulary drug request process in place. Each VISN is also responsible for establishing a process to analyze nonformulary drug request data at the VISN and medical center levels to determine if the process is implemented appropriately and effectively in medical centers, and report these data to VA's PBM on a quarterly basis. Reported information must include the numbers of nonformulary drug requests received, approved, and denied as well as the average time taken to adjudicate completed requests.

¹⁸Although providers must receive authorization to prescribe nonformulary drugs, veterans pay the same copayment for national formulary and nonformulary drugs. There is no copayment for veterans receiving medications for treatment of service-connected conditions, veterans whose incomes fall below the maximum VA pension, and veterans who are exempt by other special authority. Other veterans are generally charged \$8 for each 30-day prescription, though certain eligibility groups are charged \$9.

¹⁹According to VA's formulary management handbook, nonformulary drug requests are only to be approved when: (1) a documented contraindication exists to national formulary drug(s); (2) a documented adverse reaction occurred to national formulary drugs(s); (3) a documented therapeutic failure to national formulary alternatives exists; (4) no national formulary alternative exists; (5) the patient has previously responded to a nonformulary drug and serious risk is associated with a change to a national formulary drug; or (6) other circumstances having compelling evidence-based clinical reasons.

²⁰VA's formulary management handbook states that emergency requests for nonformulary drugs are to be addressed immediately.

In addition to requirements for the nonformulary drug request process, the handbook requires that VISNs ensure that local forums exist where formulary issues can be discussed with veterans service organizations (VSOs) on an ongoing basis.²¹ While VSO meetings may also be held at the regional and national level, there is no requirement that these meetings organize specifically for the purposes of discussing formulary issues.

We previously reported on the national formulary in December 1999 and in January 2001.²² We found that veterans had access to needed medications, but VA needed to improve its oversight activities. In our 2001 report, we recommended that VA take steps to better ensure that VISNs and medical centers comply with the national formulary and nonformulary drug request policies and procedures. VA responded to these recommendations by, among other things, having its PBM check drug utilization data—which tracks drugs dispensed across VA—for outliers and requiring that nonformulary drug requests be adjudicated within 96 hours.

VA's Process for Reviewing Drugs for Its National Formulary Is Standardized

VA uses a standardized process to review drugs for its national formulary that is coordinated at the national level by its PBM. PBM's Chief Consultant told us that most reviews are initiated in response to FDA's approval of drugs for use on the market. To begin reviewing a drug for inclusion on the national formulary, clinicians from PBM develop evidence-based drug monographs that include information on safety, efficacy, and cost, and seek comments on these monographs from VISN and medical center staff. Completed monographs are then reviewed by MAP and the VPE Committee, who vote on whether to add the drug to the national formulary. A majority of the drugs VA considered for addition to the national formulary in 2008 and 2009 were reviewed within one year of FDA approval, but there were various factors that caused some reviews to take longer.

²¹VSOs are organizations that represent the interests of veterans. In addition to VSO representatives, veterans can be invited to attend VSO meetings.

²²GAO, *VA Health Care: VA's Management of Drugs on Its National Formulary*, [GAO/HEHS-00-34](#) (Washington, D.C.: Dec. 14, 1999); and GAO, *VA Drug Formulary: Better Oversight Is Required, but Veterans Are Getting Needed Drugs*, [GAO-01-183](#) (Washington, D.C.: Jan. 29, 2001).

VA's PBM Initiates Most Drug Reviews in Response to FDA Approval of Drugs

VA's drug review process is coordinated at the national level by its PBM, whose Chief Consultant told us that most reviews are initiated following FDA's approval of a drug for use on the market to determine whether to add the drug to the national formulary.²³ While there are different types of FDA approvals, PBM's Chief Consultant said that most drug reviews are triggered by FDA approval of a new drug.²⁴ PBM also initiates drug reviews to consider whether to remove a drug from the national formulary, such as in response to the emergence of new safety issues. Additionally, PBM officials said that they may decide to conduct a drug class review to determine whether there is superiority of one or more drugs in a class, or if the drugs are equivalent in terms of safety and efficacy. Such reviews are undertaken when VA is considering negotiating a drug contract or to determine a drug's place in therapy relative to other drugs in its class.²⁵

According to VA officials, medical center staff can submit requests to their local P&T committees to review a drug for addition to or removal from the national formulary.²⁶ P&T committees review and forward approved requests to their regional VISN formulary committees. If VISN formulary committees review and approve requests, they forward them to VA's PBM for consideration at the national level.²⁷ In 2009, VISNs submitted 13 requests for drug reviews, and while 2 of the requests were later withdrawn, PBM approved all of the requests for national review.

²³VA does not review FDA-approved drugs that are not appropriate for use in the VA population, such as pediatric drugs.

²⁴As previously noted, for purposes of this report, a "new drug" is an FDA-approved new molecular entity, which is a drug that includes an active ingredient that has not previously been approved for marketing in the United States in any form. FDA also approves drugs for other reasons, such as when a prescription drug changes to over-the-counter status or a drug is approved for a new indication.

²⁵If VA determines that drugs within a class are therapeutically interchangeable, a decision may be made to have drug companies competitively bid for a committed-use contract. In these contracts, VA commits to using a drug throughout its health care system, thereby assuring the company a high volume of use. In turn, the drug company is more likely to offer a lower price. These contracts do allow for use of alternative drugs if it is determined that the committed-use contract drug is not clinically appropriate for a patient.

²⁶Other individuals or groups can submit drug review requests directly to VA's PBM, including the VHA Chief Medical Consultant, the VHA Chief Medical Officer, the VPE Committee, and MAP.

²⁷VISN formulary committees must submit a standardized drug review request form. Officials from VA's PBM said that they will deny drug review requests that are not routed through or reviewed by a VISN formulary committee, or if the request form is incomplete.

VA Uses Evidence-Based Drug Reviews and Relies on Internal Stakeholders to Select Drugs for Its National Formulary

VA uses a standardized process to review drugs for inclusion on its national formulary, which begins with a clinician from its PBM researching relevant literature to develop an evidence-based drug monograph. Each drug monograph includes the clinician's research methodology, safety and efficacy tables, and data on cost.²⁸ Further, the clinician may consult with VA subject matter experts to assist with the development of monographs when necessary. Once a draft of a monograph is ready, the clinician forwards it to the VPEs and requests that the document be disseminated to VISN and medical center staff, including physicians and pharmacists, for comment. Generally, within a period of 2 to 4 weeks, comments about the monograph are returned to the PBM clinician. The clinician compiles and reviews these comments, and incorporates any changes deemed appropriate to the monograph.²⁹

Once VA's PBM has completed a drug monograph, MAP and the VPE Committee review PBM's findings and vote whether to add the drug to the national formulary based on an assessment of the drug's safety, efficacy, and cost as well as its relevance to the veteran population.³⁰ While most members of MAP and the VPE Committee are VA staff, a clinical representative from DOD participates in the MAP and VPE Committee meetings and votes on MAP decisions.³¹ A number of MAP and VPE Committee members we interviewed told us that they consider a drug's

²⁸Clinicians from VA's PBM develop safety tables to examine reported adverse drug events within the patient population. The efficacy tables compare the effectiveness of the drug with others already on the national formulary and are based on the results of clinical trials. VA defines an adverse drug event as an injury resulting from the use of a drug, including adverse drug reactions and overdoses.

²⁹Officials from VA's PBM said that reviews of drugs for removal from the national formulary are generally completed in a shorter timeframe than reviews for drug additions and do not involve a formal process for soliciting comments from VISN and medical center staff. Officials said that drug class reviews also go through a process similar to drug additions, but MAP and the VPE Committee must review class reviews before they go to VA physicians and providers for comment. Additionally, PBM requires conflict of interest statements from staff submitting comments on drug class reviews, while for all other drug reviews, conflict of interest statements are voluntary.

³⁰Officials from VA's PBM told us that MAP and the VPE Committee hold quarterly in-person meetings, three of which are joint meetings of both groups. They said that the months when the committees do not meet in-person, they hold separate monthly teleconferences. In-between meetings, the committees communicate as needed.

³¹Officials from VA's PBM told us that a representative from VA also sits on DOD's P&T Committee and votes on uniform formulary decisions; however, VA does not often collaborate with DOD when developing drug monographs or other documents related to the drug review process.

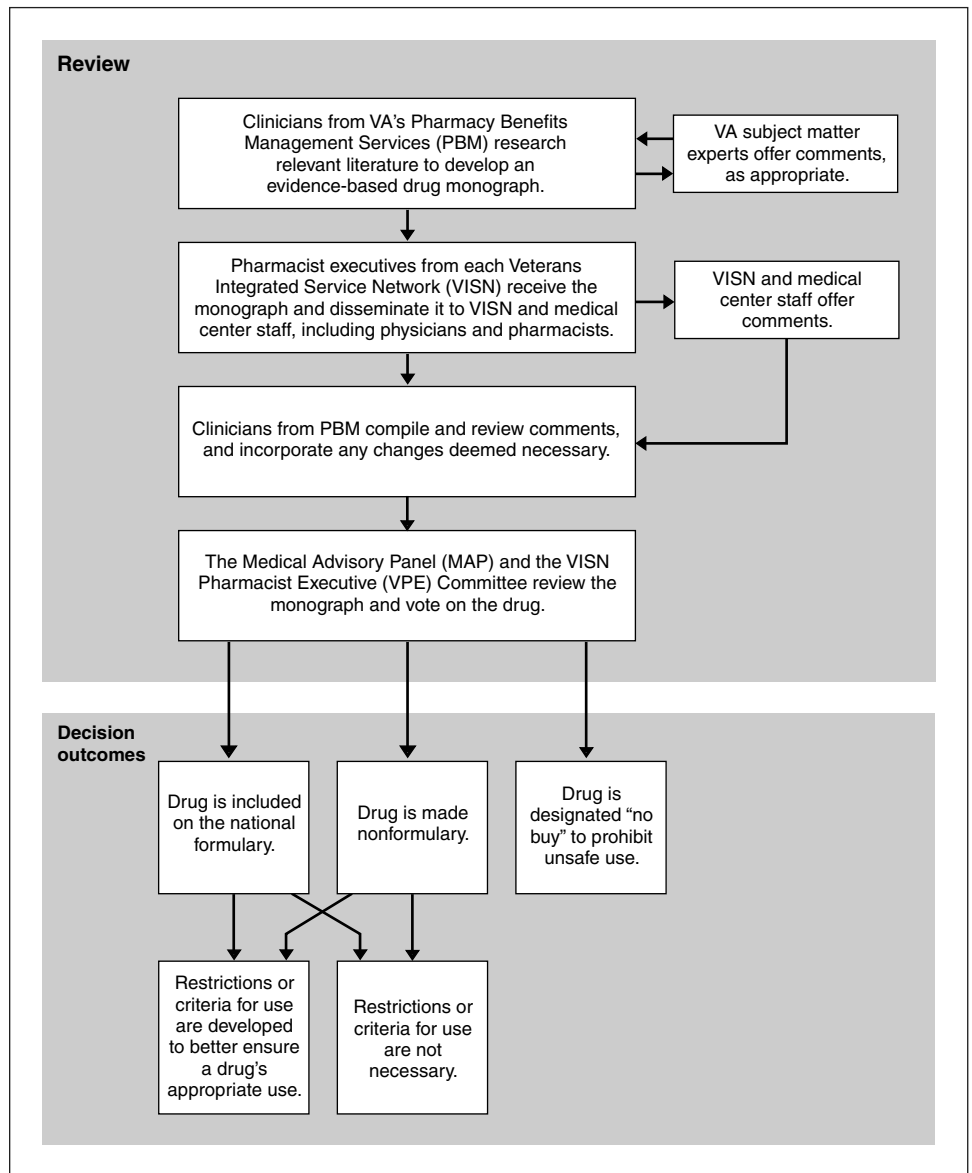
safety and efficacy before they consider cost when reviewing a monograph. Most members also said that the two groups typically agree on national formulary decisions, but that when disagreements occur, they usually stem from operational issues, such as establishing process guidelines for ordering a drug within VA. In the event of a disagreement, VA's policy is that final decisions rest with MAP.

MAP and the VPE Committee may also recommend that restrictions or criteria for use be developed to better ensure a drug's appropriate use.³² Criteria for use are reviewed by MAP and the VPE Committee and then sent to VISN and medical center staff for comment. Once comments are received, members vote to approve the final document. Officials from VA's PBM told us that MAP and the VPE Committee are also authorized to classify a drug as "no buy" for purposes of prohibiting its use in cases where there are serious safety concerns in a population similar to the VA population. However, as of April 2010, there were no drugs on the national "no-buy" list. In addition, PBM has developed national guidance to improve the safety of "off-label" prescribing, which occurs when providers prescribe drugs for indications other than those FDA has approved. While PBM authorizes its providers to prescribe drugs "off-label," it recommends that providers use an evidence-based approach and follow protocols established by their local P&T committee.³³ Figure 2 illustrates VA's drug review process.

³²According to the Chief Consultant from VA's PBM, restrictions are generally used to limit prescribing privileges to specially trained providers or place a quantity limit on a drug. Criteria for use are clinical guidance that provide instructions on how to appropriately use a drug.

³³If a drug does not have established protocols for "off-label" use, VA's PBM recommends that providers consult with their P&T committee to determine appropriate use.

Figure 2: VA's Drug Review Process



Source: GAO analysis of VA documents and interviews with VA officials.

After MAP and the VPE Committee make national formulary decisions, VA's PBM updates the national drug file. VISN formulary committees communicate national formulary decisions to medical center P&T committees. P&T committees subsequently inform medical center staff of these decisions. Pharmacy IT staff at each medical center update the local

drug file by matching the local drug file to the drug's code at the national level. PBM officials we interviewed stated that it is more difficult for some medical centers to update local drug files than others, generally due to IT staffing resources.³⁴

In 2008 and 2009, VA considered 61 drugs for inclusion on the national formulary. Of those, MAP and the VPE Committee voted to add 11 drugs to the national formulary and to approve 50 drugs for nonformulary use. In addition, MAP and the VPE Committee voted to add either restrictions or criteria for use to 25 of these drugs to ensure they were used appropriately. According to officials from VA's PBM, MAP and the VPE Committee made the 50 drugs nonformulary for reasons including (1) they determined the drug under review offered no significant benefit over national formulary alternatives already available, (2) they determined that the drug would have limited use for the veteran population, or (3) they had concerns about ensuring the drug's safe and appropriate use, and therefore required prospective review.

Drug Review Times Vary

The time it takes VA to review a drug varies and is primarily determined by whether there are factors that complicate the drug review process, such as safety concerns, and the drug's priority status. Of the 61 drugs that VA considered for addition to the national formulary during 2008 and 2009, information provided by VA's PBM indicates that 35 reviews were concluded within one year of the time FDA approved the drug and an additional 17 reviews were completed within 2 years of FDA approval. The remaining 9 reviews were completed more than 2 years after the FDA approval, with 4 of these reviews taking 3 to 5 years to complete. PBM officials reported a number of reasons why some of these reviews took longer than others. In some cases, safety concerns necessitated the development of criteria for use, which delayed the drug review process. For example, one drug, approved by FDA for the treatment of a rare blood disease, was determined to potentially increase a patient's risk of infection and took VA 18 months to review. Officials said that developing criteria for use increased review time because the criteria were complicated and required consultation with a hematologist. In other cases, reviews were delayed because there was a lack of reputable information, such as studies

³⁴The Chief Consultant from VA's PBM told us that PBM monitors data transmitted from local drug files to ensure that drugs are appropriately marked as national formulary or nonformulary. If any are not appropriately marked, PBM asks medical centers to fix this.

published in peer-reviewed journals. Additionally, drug reviews took longer when alternative drugs were already available on the national formulary and PBM decided to conduct a drug class review. PBM officials told us that drug class reviews can take twice as long as the review of an individual drug because they involve compiling information on multiple drugs.

Officials from VA's PBM told us they experience a backlog of drugs to review because there are always more potential reviews than they can accommodate, and thus, they review high-priority drugs first.³⁵ Additionally, the officials said they have implemented strategies to alleviate the drug review workload, such as soliciting assistance from VISN and medical center staff to prepare and present drug monographs, and conducting abbreviated drug reviews when appropriate.³⁶ Some VPEs we spoke with said that they can talk to PBM clinicians about moving a drug up on the priority list if necessary.

In addition to the 61 drugs VA considered for addition to the national formulary in 2008 and 2009, we examined new drugs approved by FDA in 2008 and 2009, and the progress VA made in reviewing them. (See table 1.) According to information provided by VA's PBM, of the 52 new drugs FDA approved for use on the market in 2008 and 2009, VA either reviewed, or was in the process of reviewing, 38 of them as of March 2010.³⁷ Reviews of the remaining 14 drugs were pending, since VA categorized these drugs as a lower priority for reasons such as there being a viable alternative drug

³⁵ Officials from VA's PBM stated that high priority is given to new drugs and drugs with emerging safety issues. VA's formulary management handbook states that the review of new drugs is prioritized based on their relevance to the veteran population and the availability of comprehensive, clinically relevant information, and that when these criteria are met reviews of new drugs ordinarily do not exceed one year. PBM officials also said that a drug may be given higher priority if there is an increase in demand, the drug has a potential efficacy benefit over existing drugs, or if there is a drug shortage for existing alternatives.

³⁶ Officials from VA's PBM told us that abbreviated reviews are shorter than standard reviews and are not sent to VISN and medical center staff for comment. Abbreviated reviews are generally conducted for new formulations of existing drugs, drugs for which little available data exist, or drugs that will have little or no use in the veteran population. Of the 61 drugs VA considered for inclusion on the national formulary in 2008 and 2009, 24 of the reviews were abbreviated.

³⁷ FDA's Web site lists 49 new drugs as being approved in 2008 and 2009. Officials from VA's PBM told us that VA includes all new biologics in this category. In 2008 and 2009, some new biologics were not included on FDA's list, which is why VA's number of new drugs approved is slightly higher than FDA's number.

on the national formulary or the drug having limited use for the veteran population.

Table 1: Status of VA's Review of New Drugs Approved by FDA in 2008 and 2009, as of March 2010

	Approved in 2008	Approved in 2009	Total
Review complete	9	7	16
Review in progress	8	14	22
Review pending	7	7	14
Total	24	28	52

Source: GAO summary of information provided by VA's PBM.

Although drug review times vary, if providers determine that it is clinically necessary, veterans may be able to access a drug before a national review is complete. Officials from VA's PBM told us that, due to the length of time it takes for PBM to conduct a drug review, VISNs and medical centers may develop interim guidance for reviewing and approving nonformulary requests for a drug not yet reviewed at the national level. The officials said that the VISN or medical center creating interim guidance could develop drug monographs and criteria for use for the purpose of evaluating nonformulary drug requests. PBM officials also said that they neither encouraged nor discouraged this practice, and think it is common among VISNs and medical centers. Officials from one medical center we interviewed told us that they conduct reviews of drugs that have not yet been reviewed at the national level, and that if they approve a drug for nonformulary use, they typically develop local restrictions or criteria for use until national guidance is issued. Officials from another medical center stated that they would not decide whether to permit nonformulary use of drugs that have not been reviewed by MAP and the VPE Committee, but noted that if a veteran urgently needed one of these medications, they would forward the request to the VISN.

VISNS and Medical Centers Vary in Approaches to Implementing the Nonformulary Drug Request Process; Technology Enhancements Could Further Standardize the Process

VISNs and medical centers vary in approaches to implementing the nonformulary drug request process, including how they adjudicate nonformulary drug requests, collect and report required data to VA's PBM, and address appeals of denied requests. We found that IT enhancements could help facilitate more consistent implementation of the process. Although VA intends to replace its pharmacy IT system, it is uncertain whether changes that would support the nonformulary drug request process will be implemented.

Processes for Adjudicating Nonformulary Drug Requests, Collecting and Reporting Required Data, and Addressing Appeals Vary

The process for adjudicating nonformulary drug requests varies among medical centers, in part due to differences in local IT resources. Most medical centers use CPRS to electronically process nonformulary drug requests, though providers can also make requests outside of the system either through submitting paper-based requests or contacting adjudicating officials directly to verbally request nonformulary drugs.³⁸ Further, the extent to which medical centers can automate CPRS depends on the availability of onsite IT expertise. Some medical centers, for example, are able to create drug-specific order templates in CPRS for nonformulary drugs. Officials from VA's PBM told us that these templates are interactive and prompt providers through criteria checks to ensure appropriate use. If criteria are met, the drug is automatically submitted for ordering. Although this method further automates the nonformulary drug request process and better ensures that information about the drug is easily accessible to providers, some VPEs told us that it can be challenging from an IT perspective and that not all medical centers have the IT resources needed to create order templates. One VPE told us that the VISN has created order templates so that medical centers with more limited IT resources can use them, and another VPE said that the VISN would like to do this.

³⁸At the end of 2009, 95 percent of medical centers reported using CPRS to electronically process nonformulary drug requests.

While some medical centers are able to create drug-specific order templates, most VPEs and medical center officials whom we interviewed told us that CPRS is used to create electronic nonformulary drug request forms, which providers submit to a pharmacist for adjudication.³⁹ The format of these request forms can vary. For example, some may be used just for nonformulary drug requests, while others may be used more broadly to request both national formulary drugs that have restrictions and nonformulary drugs. Additionally, some nonformulary drug request forms may be populated with drug-specific information, while others require providers to fill-in information for requested drugs. Officials from two of the four medical centers whom we interviewed cited challenges with using nonformulary drug request forms. For example, officials from one medical center told us that due to the way the nonformulary drug request form is designed, providers may not realize how to access information needed to justify their requests and subsequently have them denied.

VISNs vary in the processes they use to collect required nonformulary drug request data and report these data at the VISN and medical center levels to VA's PBM on a quarterly basis. VPEs from 18 of the 21 VISNs told us they collect required data—which include the numbers of nonformulary drug requests received, approved, and denied, as well as the average time taken to adjudicate completed requests— from their medical centers and report them to PBM, while 3 VPEs said that they instruct medical centers to report nonformulary drug request data directly to PBM. VPEs from the 18 VISNs obtain nonformulary drug request data in a variety of ways, such as extracting data from shared databases, or requiring medical center staff to complete spreadsheets or input data into an internal VISN Web site.

Medical centers have established different processes for addressing provider-initiated appeals of denied nonformulary drug requests, and one VISN has centralized the appeals process.⁴⁰ The VPEs we interviewed stated that medical centers rely on different personnel to adjudicate appeals of denied nonformulary drug requests, such as the chief of staff, the chief of pharmacy, the P&T committee chair, or the entire P&T

³⁹According to interviews with VPEs and medical center staff, nonformulary drug requests are typically adjudicated by medical center pharmacists. However, one VISN has centralized adjudications of nonformulary drug requests and VISN-level pharmacists adjudicate most requests.

⁴⁰The VISN that centralized the appeals process is the same VISN that centralized adjudications of nonformulary drug requests.

committee. Furthermore, the appeals process may involve several layers of review. For example, officials from one medical center explained that appeals are first routed to a pharmacy supervisor. If the pharmacy supervisor also denies the nonformulary drug request, it is forwarded to the chief of medicine for review. If the chief of medicine denies the request, the provider can make a final appeal to the chief of staff. Some VPEs also said that VISN chief medical officers and formulary committees may become involved in adjudicating appeals at the regional level.

Technology Enhancements That Could Further Standardize the Nonformulary Drug Request Process Have Been Considered, but Implementation Is Not Planned

Based on interviews with VA officials, we found that IT improvements could facilitate more consistent implementation of the nonformulary drug request process among VISNs and medical centers, and some of these capabilities were included in the original scope of VA's Pharmacy Reengineering (PRE) project.⁴¹ Since 2001, VA has been working on PRE with the intention of improving pharmacy operations, customer service, and patient safety by replacing current pharmacy software with new technology.⁴² At the national level, VA's Office of Information and Technology is responsible for planning, executing, and providing oversight for PRE—which includes allocating resources to the project—while its PBM is responsible for developing and prioritizing PRE requirements.⁴³ PBM officials told us that PRE was expected to make adjudicating nonformulary drug requests and to make collecting and reporting related data easier and more standard systemwide. For example, PBM's Chief Consultant said that with enhanced software, providers at all VA medical centers would be prompted to complete a series of criteria checks when requesting a nonformulary drug, and if met, the request would be automatically approved.⁴⁴ PBM officials also stated that PRE would help improve data collection and reporting related to nonformulary drug

⁴¹In 2001, VHA undertook an initiative—called HealthVet—to standardize its health information technology system and eliminate the approximately 128 different systems used by VISNs and medical centers. PRE is one of the HealthVet components.

⁴²Among other things, PRE is expected to include new drug file and pharmacy data management systems, as well as new functions related to drug ordering, medication dispensing, and clinical monitoring.

⁴³Officials from VA's PBM told us that they are prioritizing PRE requirements based on patient safety.

⁴⁴According to some VPEs whom we interviewed, not all medical centers have the onsite IT expertise to customize CPRS to perform these types of functions.

requests if it is implemented as intended.⁴⁵ VPEs from 15 of the 21 VISNs we spoke with stated that improvements could be made to VA's pharmacy IT system, and most cited various benefits that improvements could provide, such as better ensuring that prescribing criteria are adhered to and enhancing the ability to collect and report nonformulary drug request data.

However, VA has recently restructured the PRE project and has not established plans for delivering all originally proposed capabilities. In July 2009, the department suspended IT projects—including PRE—that had either fallen behind schedule or gone over budget.⁴⁶ Subsequently, the department instituted a new IT project management approach that, among other things, requires projects to plan and deliver releases of new IT functions in increments of up to 6 months.⁴⁷ In October 2009, VA restarted PRE with plans for an initial set of four increments and has since identified two additional increments, for a total of six increments. According to officials from VA's OI&T and PBM, the six increments reflect an effort to meet the department's highest priority pharmacy reengineering needs while delivering new IT functions more frequently.⁴⁸ However, capabilities that directly support the nonformulary drug request process and related data collection and reporting are not included in these increments, and as of May 2010, future increments had not been planned. Furthermore, VA's development and implementation of future increments could be impacted by delays the project is experiencing with the first six increments. Specifically, while increment four was scheduled to be

⁴⁵VA officials told us that while OI&T has developed general requirements for capabilities related to collecting and reporting nonformulary drug request data, detailed specifications for these capabilities have not been clearly defined.

⁴⁶In 2008, we reported that VA had experienced significant delays and challenges with the development and implementation of HealtheVet, including PRE, and that VA had extended PRE's implementation date from 2008 into 2011. We recommended that VA take several steps to better ensure the success of HealtheVet including that it develop a project management plan and a schedule for performing milestone reviews of HealtheVet projects. [GAO-08-805](#).

⁴⁷In June 2009, VA implemented the Program Management Accountability System in an effort to increase efficiency and accountability for IT projects, and allow the department to take corrective actions sooner.

⁴⁸Enhanced drug order checks are one of the capabilities the first six PRE increments are intended to support. Of the over 40,000 adverse drug events reported during fiscal year 2008, VA estimated that 526 events were related to dosage order checks and projected that enhanced drug order checks could have prevented many of these. As a result, VA has prioritized their development in PRE to better ensure patient safety.

implemented by June 2010, in August 2010 officials said that they intended to implement this increment by the end of the month. Officials also told us that increments five and six may not meet their estimated implementation date of December 2010.⁴⁹ As a result, the extent to which PRE will help standardize the nonformulary drug request process, as the project was originally envisioned, is uncertain.

VA's Efforts to Ensure the Timely Adjudication of Nonformulary Drug Requests Have Limitations

Per VA policy, nonformulary drug requests must be adjudicated within 96 hours; however, VA is unable to determine the total number of adjudications that exceed this standard due to limitations in the way data are collected, reported, and analyzed. While the total number of nonformulary drug request adjudications that exceed 96 hours is unknown, we found that data reported to VA's PBM on quarterly average adjudication times for medical centers are sufficient to demonstrate that not all requests are adjudicated within this time frame. Additionally, PBM has limited oversight of the timeliness of appeals of denied nonformulary drug requests.

VA Is Unable to Determine the Total Number of Nonformulary Drug Request Adjudications That Exceed Its 96-Hour Standard, but Reported Data Are Sufficient to Demonstrate That Not All Are Completed within This Time Frame

VA policy requires that nonformulary drug requests be adjudicated within 96 hours, but it is unable to determine the total number of adjudications that exceed this standard due to limitations in the way data are collected, reported, and analyzed. As previously noted, VISNs are required to report nonformulary drug request average adjudication times at the VISN and medical center levels to VA's PBM on a quarterly basis. VA's decision to limit data collection and analysis of the timeliness of nonformulary drug request adjudications to average adjudication times has oversight implications compared to collecting and analyzing data on individual requests. First, without collecting and analyzing request-level data, the total number of adjudications that exceed 96 hours is unknown systemwide. Second, averages can be strongly influenced by the presence

⁴⁹OI&T officials told us that a number of factors have delayed implementation of these increments, but that contracting difficulties were the primary factor. Officials from VA's PBM noted that the way VA awards contracts for PRE has caused problems. They explained that contracts for IT staff are awarded for a specified time period rather than the completion of a deliverable. For example, contractors have been changed during the middle of major testing activities and halted progress. OI&T officials said that new contracting guidance under the Program Management Accountability System should help address this issue.

of a few extreme values, or outliers, and may not give an accurate view of the typical adjudication times at medical centers.⁵⁰

Additionally, inconsistencies in the way nonformulary drug request data are collected and reported across VA means that data reported for some VISNs and their medical centers may not be entirely accurate or complete. VPEs for 8 of the 21 VISNs told us that medical centers in their regions may include requests for restricted national formulary drugs in the nonformulary drug request data that they report to VA's PBM.⁵¹ If quarterly average adjudication times were to exceed 96 hours at medical centers within these VISNs, it would not be possible to determine whether this was the result of requests for restricted national formulary drugs or requests for nonformulary drugs. PBM officials said that they were not aware of this practice and would remind VPEs that only requests for nonformulary drugs are to be reported. Also, VISNs and medical centers determine how they will collect and report data on nonformulary drug requests made through paper-based forms and direct verbal communications with adjudicators, and some medical centers may not include these types of requests in reported data. Specifically, officials whom we interviewed from one medical center told us that only requests for 26 nonformulary drugs are made through CPRS and reported to PBM, while other nonformulary drug requests are made through direct communications with adjudicators to manage workloads. The VPE for this medical center said that steps are being taken to ensure that it includes all nonformulary drug requests in the data it reports. Finally, six medical centers did not report nonformulary drug request data for every quarter in 2009. PBM officials told us they were not aware of this issue and would ensure that VPEs check that all medical centers report data.

While VA is unable to determine the total number of nonformulary drug request adjudications that exceed 96 hours, we found that data reported to VA's PBM on quarterly average adjudication times for medical centers are sufficient to demonstrate that not all requests are adjudicated within this

⁵⁰When outliers are present, it can be useful to calculate the median which is the midpoint of the data that separates the lower half of the distribution from the upper half.

⁵¹Medical centers that use CPRS to process nonformulary drug requests electronically may also use it to process requests for restricted national formulary drugs; however, not all medical centers have customized CPRS so that it distinguishes the two types of requests. As a result, CPRS-generated nonformulary drug request reports may also include data on requests for restricted formulary drugs.

time frame.⁵² To conduct our review of the data reported to PBM, we limited our analysis to the 13 VISNs and their medical centers where VPEs told us that requests for restricted national formulary drugs are not included in reported nonformulary drug request data. Therefore, even though reported data for these VISNs and medical centers may be incomplete due to, for example, missing paper-based and verbal requests, the data are sufficiently reliable to show that at least some nonformulary drug requests are not being adjudicated within VA's 96-hour standard. Specifically, we found that during 2009, 7 of these VISNs each had one or more medical centers that took longer than 96 hours—on average—to adjudicate nonformulary drug requests in a given quarter.⁵³ Quarterly average adjudication times that exceeded 96 hours within the 7 VISNs ranged from just over 97 hours at one medical center to 240 hours at another medical center.⁵⁴

Officials from VA's PBM told us that they analyze nonformulary drug request data aggregated at the VISN level to monitor the timeliness of adjudications; however, this approach may not alert them to adjudication problems occurring at medical centers. PBM officials stated that VISNs and medical centers are primarily responsible for ensuring compliance with nonformulary drug request policies; thus, while medical center-level nonformulary drug request data are collected and reported to PBM, it analyzes data aggregated at the VISN level to ensure timely adjudications and expects VISNs and medical centers to monitor medical center-level data. PBM officials told us that they would follow-up with VISNs if aggregated data showed an average adjudication time that was greater than 96 hours. However, while at least 7 VISNs had medical centers with reported quarterly average adjudication over 96 hours in 2009, none of the VISN-level averages exceeded VA's standard.

⁵²VPEs and medical center officials provided examples of why nonformulary drug request adjudications could exceed 96 hours, including medical center workload and staffing constraints, complex patient cases, and the need for information from private providers outside of VA.

⁵³In addition to the 7 VISNs, several other VISNs each had at least one medical center with a reported nonformulary drug request average adjudication time over 96 hours in 2009. However, VPEs from these VISNs told us that requests for restricted national formulary drugs may be included in reported nonformulary drug request data, and as a result, we did not include them in our total count.

⁵⁴Overall, quarterly nonformulary drug request average adjudication times for medical centers across the 13 VISNs ranged from 1 hour to 240 hours.

VA's PBM Has Limited Oversight of the Timeliness of Appeals of Denied Nonformulary Drug Requests

At the national level, VA's PBM does not have the framework in place to ensure that appeals of denied nonformulary drug requests are resolved in a timely fashion. While PBM officials told us that they expect nonformulary drug request appeals to be adjudicated in a timely manner, they have not established a time frame in policy. Most VPEs also told us that they expect appeals to be adjudicated in a timely manner, and some stated that the 96-hour nonformulary drug request adjudication threshold also applies to appeals. However, we found that not all appeals processes may be structured to produce timely results. For example, officials from one medical center told us that the local P&T committee adjudicates appeals for nonformulary drugs that are not urgently needed. However, one official noted that appeals that go to the P&T committee can take a month or more to resolve as they are dependent on the P&T committee's meeting schedule. Other VPEs also stated that the medical centers in their regions may require P&T committees to adjudicate appeals.

Furthermore, VA's PBM does not require VISNs and medical centers to collect and analyze data on the nonformulary drug request appeals process; therefore, the number of appeals, outcomes, and adjudication times are unknown systemwide. Of the 21 VISNs, only one VPE reported that the VISN collects and analyzes data on nonformulary drug request appeals.⁵⁵ Some VPEs told us that medical centers may track nonformulary drug request appeals data. However, officials from three of the medical centers whom we interviewed told us that their sites do not collect such data, with an official from one noting that this is because the medical center has yet to receive any appeals. An official from the fourth medical center whom we interviewed said that appeals are published in P&T committee meeting notes, but that the medical center does not aggregate these data.

⁵⁵This VPE was from the one VISN that has centralized adjudications of nonformulary drug requests and appeals and told us that the VISN reviews the percentage of appeals upheld and overturned by drug, adjudicating VISN pharmacist, and medical center provider.

VA Has Some Mechanisms to Obtain Beneficiary Input on the National Formulary and Make Its Drug Review Process Transparent and Is Considering Additional Steps

VA obtains beneficiary input on the national formulary mainly through VSO meetings and complaints, though some VISNs have taken additional steps to seek this input. Officials from VA's PBM told us that they make the drug review process transparent to veterans through online information about the national formulary, and some VPEs and medical center officials described undertaking other activities to educate beneficiaries. At the national level, VA officials are considering options for increasing beneficiary input on the national formulary and improving the transparency of the drug review process, and most VPEs and medical center officials told us there could be benefit to doing so.

VA Obtains Beneficiary Input on the National Formulary Mainly through VSO Meetings and Complaints

VA officials told us that they may obtain beneficiary input on the national formulary through VSO meetings; although the extent to which pharmacy staff attend these meetings varies among VISNs and medical centers, and officials said that national formulary issues are not frequently discussed. All VPEs told us that medical centers in their regions hold local VSO meetings, and many said that there are VSO meetings held at the regional level as well. However, 3 of the 21 VPEs said that they or a VISN-level pharmacy representative regularly attend VSO meetings either at the regional or local level. Eleven VPEs said that they sometimes attend these meetings, and 7 said that they do not attend, but noted that pharmacy staff at medical centers may attend the meetings.⁵⁶ Of the medical center chiefs of pharmacy we interviewed, one attends VSO meetings at the medical center regularly, two attend if invited, and one does not currently attend these meetings.

While officials from most VISNs and medical centers whom we interviewed told us that pharmacy benefits are discussed during VSO meetings, many also said that issues related to the national formulary are not often raised. Rather, they stated that pharmacy benefit concerns tend to focus on operational issues, such as copayments and ordering medication refills. A few VPEs noted that when questions about the national formulary are raised during VSO meetings, they are usually patient-specific and addressed outside of the meetings.

⁵⁶A majority of the VPEs who said they sometimes attend VSO meetings indicated that they do so to discuss pharmacy-related topics.

At the national level, the Chief Consultant from VA's PBM said that, as necessary, he discusses national formulary issues at VSO meetings held by VA's Under Secretary for Health on a quarterly basis; however, the Chief Consultant has only attended one of these meetings in the past 6 years. He said that he also receives occasional questions from VSO representatives about the national formulary.

Outside of VSO meetings, most VPEs and medical center officials said that VA obtains beneficiary input on the national formulary through complaints by veterans or those acting on their behalf, such as providers, patient advocates, or members of Congress.⁵⁷ Almost all VPEs noted that, at the regional level, they do not receive many complaints related to the national formulary and that most complaints are handled locally. Officials from three of the four medical centers we spoke with discussed receiving complaints on the national formulary. For example, an official from one medical center said that the medical center receives complaints from patients who transferred to VA from the private sector and want to stay on a medication that is not on VA's national formulary.

Officials from VA's PBM told us that, at the national level, they occasionally receive complaints about the national formulary, but they do not routinely monitor beneficiary input in a centralized way. For example, while patient advocates are required to collect data on veteran complaints at medical centers, PBM officials reported that they do not have information on these or other local complaints. PBM officials also told us that while VA's Office of Quality and Performance administers the Survey of Healthcare Experiences of Patients, this survey is limited in scope and they do not use it to obtain beneficiary input on the national formulary. PBM officials reported that they are not aware of other surveys conducted for this purpose.

Some VISNs have taken additional steps to seek beneficiary input on the national formulary. For example, one VPE whom we interviewed conducts site visits at medical centers in the region and talks to beneficiaries about national formulary issues during these visits. Another VPE said that the VISN recently added a 2-hour session at the end of its Executive

⁵⁷Patient advocates are VA employees who are responsible for receiving and acting on complaints from veterans at medical centers. A report issued by the Institute of Medicine in 2000 found that national formulary concerns constituted less than 1 percent of all complaints reported to patient advocates, see Institute of Medicine, *Description and Analysis of the VA National Formulary* (Washington, D.C.: 2000).

Leadership Council meetings for beneficiaries to attend and discuss concerns. The VPE said that so far pharmacy benefit concerns have been raised at every meeting, including concerns about access to national formulary and nonformulary drugs. A VPE from a third VISN said that the region tried adding comment cards for pharmacy suggestions, but that they did not receive many suggestions.

VA's PBM Provides National Formulary Information on Its Web Site, and Some VISNs and Medical Centers Engage in Other Activities to Educate Beneficiaries about the Drug Review Process

Officials from VA's PBM told us that they make the drug review process transparent to beneficiaries through national formulary information that is available online. Our review of PBM's Web site found that PBM posts the national formulary listing via an Excel spreadsheet, with a separate spreadsheet that highlights formulary changes. In addition, PBM provides a link to its *Ez-Minutes* newsletter, which is accessible online or through an e-mail subscription. *Ez-Minutes* provides a listing of national formulary decisions, but does not provide context for these decisions, such as when a drug is made nonformulary due to safety concerns.⁵⁸ PBM also posts documents related to the drug review process on its Web site, such as drug monographs and criteria for use documents. Finally, the Web site provides answers to frequently asked questions about the national formulary.

In addition to the information provided by VA's PBM, some VPEs and medical center officials described undertaking other activities to educate beneficiaries on VA's drug review process at the regional and local levels. For example, one VPE whom we interviewed said that the VISN had begun a new program called, "Formulary Awareness: Veterans Helping Veterans." The VPE told us that this program has a number of components including recruiting individuals to be in waiting rooms and wear buttons that say "Ask! Is your medication on formulary?" and providing brochures, pens, and tent cards at medical centers with information that includes a national formulary fact of the month. Another VPE said that the VISN sends a newsletter to veterans in its region that includes a section on how the national formulary works, points veterans to PBM's Web site, and provides pharmacist contact information if veterans have any questions. Likewise, one medical center official whom we interviewed posts explanations

⁵⁸Another approach, currently employed by DOD, is to make national P&T committee meeting minutes available online. DOD's minutes include a more comprehensive discussion of national formulary decisions than VA's *Ez-Minutes*. In addition to listing decisions, DOD's minutes include the clinical evidence used to make decisions, justification for recommendations, and a breakdown of voting results. The minutes do not include proprietary drug cost information.

about why VA has a national formulary on the bulletin boards in pharmacy waiting room areas. Also, officials from three of the medical centers whom we interviewed noted that they send letters to beneficiaries when national formulary changes impact them, and officials from the fourth medical center said that they ask providers to inform veterans of these changes.

VA Officials Are Considering Options for Increasing Beneficiary Input and Improving the Transparency of the Drug Review Process

At the national level, VA officials are considering options for increasing beneficiary input on the national formulary and improving the transparency of the drug review process. Options were discussed during a MAP meeting in January 2010, and while no formal decision was made, the overall consensus was to try to work within existing lines of communication. Following this meeting, officials from VA's PBM told us that MAP and the VPE Committee were in discussions to develop a process whereby veteran input at local VSO meetings could be reported and addressed nationally. The officials said that they would like to use local VSO meetings as a mechanism for obtaining input, because it would be easier for veterans to travel to meetings in their local area and these meetings may allow for input on not only national formulary issues, but also other pharmacy benefit issues that may be local in scope. In June 2010, options were again discussed during a meeting of MAP and the VPE Committee. PBM's chief consultant told us that a final decision was not made during this meeting, but that the next step is to discuss the issue with VHA management.

Officials from most VISNs and medical centers we interviewed told us that there could be benefit to increasing beneficiary input on the national formulary or improving the transparency of VA's drug review process, and a number gave suggestions for doing so. For example, one medical center official said that the *Ez-Minutes* newsletter contains technical language and that it would be beneficial for VA's PBM to create something that was easier for beneficiaries and their representatives to understand. Likewise, a VPE suggested that national formulary changes be sent to local VSOs along with non-technical explanations of the reasons for the changes. Another VPE said that one way to better obtain beneficiary input on the national formulary would be to survey patients through an independent organization.

While VA officials are considering options for increasing beneficiary input on the national formulary and improving the transparency of the drug review process, they have concerns about formally involving beneficiaries or their representatives in national formulary decisions. Specifically, this matter was raised during the January MAP meeting around a discussion

about DOD's Uniform Formulary Beneficiary Advisory Panel.⁵⁹ During our interviews, VPEs and medical center officials also raised concerns about this issue. Their concerns included that lay people may not have the technical knowledge to make evidence-based decisions, and that they could be unduly influenced by direct to consumer advertising from pharmaceutical companies. Officials were also concerned that another layer of review would slow down the drug review process. We spoke with DOD officials about the Uniform Formulary Beneficiary Advisory Panel, and they said that although the panel's input on DOD's formulary decisions is limited, it has provided useful feedback on how to operationalize formulary decisions, and resulted in DOD communicating formulary decisions in less technical terms to beneficiaries.

Conclusions

In 2009, VA provided millions of prescriptions to veterans through its pharmacy benefit. While VA's process for reviewing drugs to decide whether they should be included on its national formulary is overseen by its PBM, VISNs and medical centers are responsible for implementing the nonformulary drug request process, and there is variation in the approaches that VISNs and medical centers take. For example, some VISNs and medical centers have more automated approaches to adjudicating nonformulary drug requests and collecting and reporting required data than others. In response to recommendations we made in our 2001 report, VA established a requirement for routine nonformulary drug requests to be adjudicated within 96 hours. However, some adjudications continue to surpass this threshold, and data reported to monitor timeliness are not always accurate or complete for all VISNs and their medical centers. Additionally, reported data are only required to include average adjudication times for nonformulary drug requests, which do not capture the total number of adjudications that fall outside VA's 96-hour standard. Finally, VA does not require that appeals of denied nonformulary drug requests are resolved within a certain time frame or that the outcomes of appeals are tracked. Given these limitations, additional steps are needed to ensure that veterans receive clinically necessary nonformulary drugs in a timely manner.

⁵⁹The Uniform Formulary Beneficiary Advisory Panel reviews and comments on the recommendations of DOD's P&T Committee in order to provide a beneficiary perspective on formulary decisions. Final formulary decisions are based on both the P&T Committee's recommendations and the Uniform Formulary Beneficiary Advisory Panel's comments.

VA is in the process of making changes to its pharmacy IT system through its PRE project, which could help facilitate more consistent implementation of the nonformulary drug request process among VISNs and medical centers. We previously reported on delays and challenges VA has faced implementing PRE, and it remains unclear when PRE will be complete. If PRE does not move forward, VA will continue to rely on its current IT system to manage its pharmacy benefit and depend on locally developed IT solutions to adjudicate nonformulary drug requests and collect data on outcomes.

Recommendations for Executive Action

To provide assurance that requests for nonformulary drugs are adjudicated in a timely fashion, we recommend that the Secretary of Veterans Affairs take three actions. Specifically, the Secretary should direct the Under Secretary for Health to establish mechanisms to ensure that:

- reported nonformulary drug request data are accurate and complete;
- reported nonformulary drug request data are collected at the request-level and analyzed by VA's PBM, VISNs, and medical centers at this level; and
- appeals of denied nonformulary drug requests are tracked.

Additionally, we recommend that the Secretary of Veterans Affairs direct the Chief Information Officer to clarify plans regarding when functionality related to the nonformulary drug request process will be implemented under PRE.

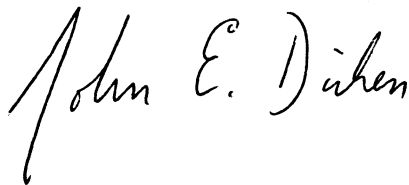
Agency Comments and Our Evaluation

In commenting on a draft of this report, VA stated that it generally agreed with our conclusions and concurred with our recommendations. VA's comments are reprinted in appendix I. Specifically, with regard to our first recommendation to establish mechanisms to ensure that requests for nonformulary drugs are adjudicated in a timely fashion, VA set a target date of October 30, 2010 for developing these mechanisms and plans to implement them during the first quarter of fiscal year 2011. With regard to our recommendation to clarify plans for when functionality related to the nonformulary drug request process will be implemented under PRE, VA acknowledged the importance of improving the nonformulary drug request process through PRE, but stated that addressing patient safety issues in VA's current pharmacy software takes precedence. VA reported that the department intends to complete field testing of currently approved PRE

increments related to patient safety by November 1, 2010. VA further stated that it can then begin an analysis, which could be completed within 90 days, to determine how improvements to the nonformulary drug request process will be addressed in future PRE increments. We appreciate VA's focus on patient safety within PRE, but reiterate the importance of VA clarifying its plans for the remainder of the project. VA also provided technical comments, which we incorporated where appropriate.

We are sending copies of this report to the Secretary of Veterans Affairs and appropriate congressional committees. In addition, the report is available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staffs have questions about this report, please contact me at (202) 512-7114 or at dickenj@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in appendix II.



John E. Dicken
Director, Health Care

List of Congressional Addressees

The Honorable Tim Johnson
Chairman
The Honorable Kay Bailey Hutchison
Ranking Member
Subcommittee on Military Construction, Veterans' Affairs,
and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Chet Edwards
Chairman
The Honorable Zach Wamp
Ranking Member
Subcommittee on Military Construction, Veterans' Affairs,
and Related Agencies
Committee on Appropriations
House of Representatives

The Honorable Michael H. Michaud
Chairman
Subcommittee on Health
Committee on Veterans' Affairs
House of Representatives

Appendix I: Comments from the Department of Veterans Affairs



Department of Veterans Affairs
Office of the Secretary

August 13, 2010

Mr. John E. Dicken
Director
Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dicken:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, ***VA DRUG FORMULARY: Drug Review Process Is Standardized at the National Level, but Actions Are Needed to Ensure Timely Adjudication of Non-formulary Drug Requests*** (GAO-10-776) and generally agrees with GAO's conclusions and concurs with GAO's recommendations to the Department.

The enclosure specifically addresses GAO's recommendations and provides technical comments to the draft report. VA appreciates the opportunity to comment on your draft report.

Sincerely,


John R. Gingrich
Chief of Staff

Enclosure

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***VA DRUG FORMULARY: Drug Review Process Is Standardized at
the National Level, but Actions Are Needed to Ensure Timely
Adjudication of Non-formulary Drug Requests***
(GAO-10-776)

GAO Recommendation 1: To provide assurance that requests for nonformulary drugs are adjudicated in a timely fashion, we recommend that the Secretary of Veterans Affairs take three actions. Specifically, the Secretary should direct the Under Secretary for Health to establish mechanisms that:

- Reported nonformulary drug request data are accurate and complete;
- Reported nonformulary drug request data are collected at the request-level and analyzed by VA's PBM, VISNs, and medical centers at this level; and
- Appeals of denied nonformulary drug requests are tracked.

VA Comment: Concur. The Veterans Health Administration's Pharmacy Benefits Management Office will develop mechanisms to improve the collection, reporting and analysis of nonformulary request data and will assist staff from the Office of the Deputy Under Secretary for Health for Operations and Management to implement the new mechanisms. The target completion date to develop the mechanisms is October 30, 2010, with implementation beginning in the first quarter of fiscal year 2011.

GAO Recommendation 2: We recommend that the Secretary of Veterans Affairs direct the Chief Information Officer to clarify plans regarding when functionality related to the nonformulary drug request process will be implemented under PRE.

VA Comment: Concur. Many of the requirements describing the non-formulary request process are defined, but spread among the requirements documents describing the Ordering, Clinical Monitoring, Reporting and Drug file domains defined under the "original" Pharmacy Reengineering program. Not all parts of these domains have to be completed to implement the non-formulary request process, but parts of each would be required. Significant effort will be required to extract the requirements specific to these functions from those domains, and to identify any new ones necessary to implement the non-formulary request functions separate from the other features included in these domains.

The PRE team and the Pharmacy Benefits Management resources supporting Pharmacy reengineering are fully engaged to support the current approved PRE increments for development under the Project Management Accountability System (PMAS). These increments provide functionality to address a number of

Enclosure

Department of Veterans Affairs (VA) Comments to
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(GAO-10-776)

patient safety issues existing in the legacy pharmacy applications, and are currently planned to complete field testing by November 1, 2010. While VA recognizes the importance of improving the non-formulary request process, current safety related pharmacy re-engineering projects take precedence, and improvements to the non-formulary request process will be handled in future PMAS increments. An analysis to determine the schedule and scope for this work can begin immediately after completion of field testing of current increments and could be completed within 90 days of initiation.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

John E. Dicken, (202) 512-7114 or dickenj@gao.gov

Staff Acknowledgments

In addition to the contact named above, Jennifer Grover, Assistant Director; Mark Bird; Leonard Brown; Martha Kelly; Drew Long; Denise McCabe; Lisa Motley; Jessica Smith; Rachel Svoboda; Eric Trout; and Merry Woo made key contributions to this report.

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