

**STATEMENT OF
BELINDA J. FINN
ASSISTANT INSPECTOR GENERAL FOR AUDITS AND EVALUATIONS
OFFICE OF INSPECTOR GENERAL
DEPARTMENT OF VETERANS AFFAIRS
BEFORE
THE SUBCOMMITTEE ON HEALTH
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
HEARING ON
"IS THE VA MEETING THE PHARMACEUTICAL NEEDS OF VETERANS?
AN EXAMINATION OF THE VA NATIONAL FORMULARY, ISSUES OF PATIENT
SAFETY, AND MANAGEMENT OF THE PHARMACY BENEFITS PROGRAM"
ON
SEPTEMBER 22, 2009**

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to discuss systemic weaknesses impacting the Veterans Health Administration's (VHA) ability to accurately account for its inventories of non-controlled drugs in VHA medical facilities and consolidated mail outpatient pharmacies (CMOPs). We issued two recent Office of Inspector General (OIG) reports, *Audit of VA Consolidated Mail Outpatient Pharmacy Inventory Accountability* and *Audit of Veterans Health Administration's Management of Non-Controlled Drugs*, related to this issue. I am accompanied by Irene Barnett, Ph.D., Audit Manager, Bedford Office for Audits and Evaluations, OIG.

BACKGROUND

VHA medical facilities and CMOPs dispensed about 126 million prescriptions for VA patients and spent \$3.7 billion on pharmaceuticals in fiscal year (FY) 2008. Prescription drugs are generally categorized as controlled or non-controlled. Non-controlled drugs are not regulated under the Controlled Substances Act of 1970 due to the reduced risk for abuse and addiction. Approximately 95 percent of the pharmaceutical spending was on non-controlled drugs. Also, non-controlled drugs are not subject to the same stringent inventory and oversight controls that controlled drugs are subject to, yet some non-controlled drugs are expensive, others contain active ingredients that can be used to manufacture illicit drugs, and some are considered to be at high risk of diversion given the high street value of the specific drug. Within VHA, prescription medications are generally dispensed directly to veterans by facility inpatient or outpatient pharmacies or by mail from a medical facility's pharmacy or a CMOP. The CMOPs spend about twice as much money on pharmaceuticals than VHA medical facilities. As part of our recent oversight of pharmaceutical inventories, we visited two of VHA's seven CMOP operations in Charleston, SC, and Dallas, TX, and six of VHA's medical facilities in Fayetteville, NC, New York, NY, Long Beach, CA, Wichita, KS, Seattle, WA,

and Spokane, WA. In addition, we also analyzed the inventory records of over 30 VA medical centers.

We reported VHA medical facilities and CMOPs could not accurately account for non-controlled drug inventories because of inadequate inventory management practices, record keeping, and inaccurate pharmacy data. VHA needs to improve its ability to account for non-controlled drugs to reduce the risk of diversion and standardize its pharmacy inventory practices among its medical facilities and CMOPs. Without improved controls, VHA cannot ensure its non-controlled drug inventories are appropriately safeguarded, nor can VHA accurately account for these expensive inventories.

FINDINGS

VHA cannot accurately account for its non-controlled drug inventories because it has neither implemented nor enforced sufficient controls to ensure pharmacy inventory practices are standardized and pharmacy data is accurate. Furthermore, VHA does not currently require its facilities to monitor any non-controlled drugs on an ongoing basis.

We found that both CMOPs and VHA medical facilities maintain inventory management controls and use systems of inventory control that rely upon annual physical counts of drugs. However, we identified significant weaknesses in how well the facilities perform physical counts and adjust inventory records.

Inadequate Inventory Controls Led to Significant Inventory Variances

VHA Handbook 1761.2, *VHA Inventory Management*, requires that an annual wall-to-wall physical inventory be performed for all items. In addition, VHA's *Pharmacy Inventory Guidelines* state that inventory quantities of an open product should be estimated to the nearest tenth of a bottle. The CMOPs did not perform complete annual physical counts for all items, as required and inconsistently estimated their inventory quantities of open products. Additionally, the inventory management system used by most CMOPs does not always track drug dispensing. CMOP personnel physically count all drugs that are manually dispensed, but they do not count all drugs dispensed from individual pill dispensers because they considered the physical count of open products to be too labor intensive.

We performed inventory analyses at two of VA's seven CMOPs supporting operations nationwide and identified pill variances ranging from a negative variance of 3,092 pills to a positive variance of 192,498 pills. The existence of these variances demonstrated the unreliability and inaccuracy of the CMOPs' inventory records. Further, 14 of 18 pharmaceutical items that we reviewed had positive variances. These variances can enable and mask a deliberate diversion and loss of drugs. CMOP personnel were unable to explain the positive or negative pill variances between the actual pill counts and the amounts we computed as the ending inventory. However, they indicated the variances might be the result of the inventory management system inaccurately tracking dispensed pills and because annual wall-to-wall physical inventories were not completed for all drugs.

Physical inventories performed within VA medical facilities did not provide adequate accountability for non-controlled drugs. VHA requires pharmacy managers to verify that physical inventories are conducted completely and accurately by conducting random checks of at least 25 items. None of the pharmacy managers at the six VHA medical facilities we visited were able to demonstrate compliance with this requirement. In fact, we also found that three VHA facilities had not conducted annual physical inventories in 2007 and one did not complete the annual physical inventory in 2008 by the deadline.

VHA pharmacy managers at 9 of the 31 facilities reported that pharmacy personnel are not consistently entering information on quantities of drugs transferred to secondary locations, such as an emergency room or inpatient ward, into the Veterans Health Information System and Technology Architecture (VistA). This results in incomplete information and may explain the negative inventory discrepancies we calculated for selected drug items at many facilities. Dispensing data on non-controlled drug inventories will be understated at facilities where pharmacy personnel are not consistently and accurately entering information on drug transfers in VistA.

We were particularly concerned about negative inventory discrepancies we identified for at least one drug of the five selected for testing at all 31 VHA medical facilities. Negative inventory discrepancies reflect an ending inventory that was lower than it should have been given the quantities of drugs purchased and dispensed by the facility. We estimated that the 31 medical facilities were unable to account for about 380,000 pills, or eight percent of their total available inventory. We considered the inventory variances to be significant.

Physical inventories act as a check on the effectiveness of other inventory controls. While VHA requires its facilities to conduct annual physical inventories of non-controlled drugs, it does not ensure inventory data is accurate or use the data as a tool to identify drug loss or possible drug diversion. We identified multiple weaknesses in VHA's annual physical inventories of non-controlled drugs. For example, VHA does not require facilities to maintain their annual physical inventory reports for a certain time or record inventory results in a standardized electronic format that could enable a centralized analysis of inventory information. According to VHA officials, the current VistA system cannot provide information to account for a facility's inventory accurately because it lacks the capability to maintain a perpetual inventory.

Other inventory management practices were also reducing the integrity of available inventory management information. For example, CMOPs did not have a policy for controlling and monitoring adjustments to drug inventory records. When CMOPs conduct a physical count for a particular drug and a variance exists between the physical count and the system balance, CMOP personnel simply adjust the inventory system balance so that the inventory balances correspond to actual physical counts. Individuals can make an unlimited number of adjustments in any quantities. Further, CMOP management was not verifying adjustments made to drug inventory balances.

CMOPs did not adequately secure, track, and monitor non-controlled drugs being held for return credit or consistently comply with existing VHA policies. We identified instances where CMOP staff did not maintain a record of non-controlled drugs held for return, or reconcile credits received to the list of non-controlled drugs returned. VHA Directive 2008-021, *Monitoring of Non-Controlled Substance Medication Returns*, requires non-controlled drugs held for return credit to be secured, tracked, and monitored to reduce the possibility of fraud and maximize revenues received through drug returns.

We found that physical security controls were in place to prevent the unauthorized physical removal of pharmaceuticals at the two CMOPs we visited. However, we identified security weaknesses in CMOP inventory information systems. For example, we identified 61 users at the two CMOPs we visited whose inventory management system access allowed them to order, receive, and adjust non-controlled drug inventories. Inventory management system controls were not effectively tracking system user activity to determine if an employee had used all three permissions that allowed users to order, receive, and adjust against the same drug.

Further, CMOP inventory information systems were also at increased risk of inappropriate alterations because generic user accounts enabled employees to order a drug through the ordering system without being identified as a specific user. The same employee could then use their unique ID and password to reduce the inventory balance and divert the drug.

Drug Transactions Not Accurately and Consistently Recorded

VHA has established some procedures regarding the use of VistA to record drug transactions; however, controls are not in place to ensure that accurate and complete information on drug transactions is captured. For example, we found that local pharmacy personnel are not consistently recording information in VistA on transactions such as pharmacy stock transfers and drug returns. Prescription labels can be reprinted when an original label is damaged although the reprint function in VistA should not generally be used to dispense drugs. Some dispensing data may be incomplete because pharmacy personnel are inappropriately using the label reprint function in VistA to dispense drugs. These practices negatively impacted the reliability of inventory information.

Pharmacy personnel from six medical facilities we visited are using the reprint function to dispense drugs to patients, which can affect the accuracy of drug dispensing captured in VistA. The VistA application lacks adequate controls to track why a reprint label is being generated or to ensure that the function is being appropriately used. Further, VistA captures the quantity of drugs dispensed using the reprint function only if the original prescription was not released to the patient. Without procedures to standardize the use of the reprint function and to capture data on drug transfers, accountability of drug inventories is compromised.

VHA facilities are not consistently capturing information on the quantities of drugs originally dispensed and then returned to inventory for reuse. Pharmacy managers at VHA facilities told us some personnel are returning drugs to inventory without adjusting inventory records in VistA, which inflates a facility's dispensing data. We calculated a positive inventory discrepancy for at least one drug at 24 of 31 VHA medical facilities where we specifically analyzed inventory information. We estimated that these facilities had an excess of about 87,000 pills—or ten percent—available to dispense. These pills are available to dispense or divert since they do not exist according to the inventory records.

The VHA Directive 98-020, *Drug Accountability Software*, which required facilities to monitor at least 20 non-controlled drugs for possible diversion, expired in 2003. At the time of our audits, VHA had not provided facilities with technical guidance on how to monitor non-controlled drugs on an ongoing basis to detect diversion, or taken steps to improve the usefulness of its annual physical inventory information.

Most pharmacy managers in VHA medical facilities reported that they monitor at least one non-controlled drug for diversion on an ongoing basis, with most monitoring one to five drugs. Typical action includes comparing data on drug purchasing and dispensing to identify unaccounted for drugs. The willingness to monitor certain non-controlled drugs in the absence of VHA policy is a positive action. However, over one-third of pharmacy managers reported that they lack adequate information to monitor non-controlled drugs for diversion. Given the number of high-risk non-controlled drugs medical facilities maintain in stock, VHA needs to identify certain high-risk drugs that should be monitored and provide facilities with guidance on how to monitor and safeguard these drugs on an ongoing basis.

Overall, both VHA's VistA and CMOP inventory management software require improvements to allow medical facilities and CMOPs to better account for pharmacy inventory. In 2003, VHA initiated the Pharmacy Re-engineering project to make improvements to VistA. The project was slated for completion in 2005, but this project has experienced significant delays. Current schedule projections are that the project may not be completed until 2014. Since needed upgrades may take years to be fully implemented, it is vital that VHA take more immediate action to improve accountability over non-controlled drug inventories.

CONCLUSION

With pharmaceutical expenditures exceeding \$3.7 billion in FY 2008 and future costs expected to increase, VHA needs accurate inventories and strong record keeping to account for non-controlled drug inventories. OIG audits reported large variances in the amount of non-controlled drugs at VHA medical facilities and CMOPs and concluded that VHA does not have reliable inventory information that could detect the loss or unauthorized diversion of drugs. The implementation and enforcement of inventory controls to provide accurate and complete information is imperative to VHA's ability to account for, manage, and safeguard non-controlled drugs.

We recommended the Under Secretary for Health take actions to improve accountability over non-controlled drugs, including:

- Enforcing requirements for conducting annual wall-to wall inventories.
- Ensuring annual physical inventory reports are reasonably accurate and pharmacy managers are held accountable for the accuracy of annual inventories.
- Developing policy and establishing controls to monitor and control adjustments to drug inventory records.
- Enforcing compliance with the policy for returned drugs.
- Establishing procedures that restrict a single user from ordering, receiving, and adjusting against the same drug and removing generic user IDs and passwords.
- Developing procedures to identify high-risk non-controlled drugs and requiring pharmacy managers to monitor those drugs.
- Developing appropriate internal controls to ensure information on drug dispensing, drug transfers, and drug returns is accurately and consistently recorded in VistA.
- Limiting access to the VistA label reprint function to appropriate pharmacy personnel.

The Under Secretary for Health agreed with our findings and recommendations to improve accountability over non-controlled drug inventories. VHA provided acceptable implementation plans to address the recommendations. We will follow up on the implementation of actions to address the report recommendations.

Mr. Chairman, thank you for the opportunity to discuss these important issues. We would be pleased to answer any questions that you or other members of the Subcommittee may have.