



# Department of Veterans Affairs Office of Inspector General

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## Audit of VA Consolidated Mail Outpatient Pharmacy Inventory Accountability

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## Executive Summary

### Results in Brief

The VA Office of Inspector General (OIG) conducted an audit to determine whether VA's Consolidated Mail Outpatient Pharmacies (CMOP) effectively and efficiently accounted for non-controlled pharmaceutical inventories and to determine whether the CMOPs managed and safeguarded non-controlled pharmaceutical inventories at risk for diversion. CMOPs determine which pharmaceuticals are at risk for diversion by using professional judgment, past experience, and information from outside sources. The audit examined CMOP operations and controls at two of the seven VA CMOPs that provide pharmaceuticals to veterans nationwide. Work was conducted at the Charleston and Dallas CMOPs—both represented well-established CMOPs and Charleston's operations received the second highest dollar value of CMOP pharmaceuticals purchased in FY 2008.

The Charleston and Dallas CMOPs established physical security controls to prevent the unauthorized physical removal of pharmaceuticals from CMOPs. However, inventory management controls used to account for and prevent diversion of non-controlled pharmaceuticals could be further improved and inventory system access controls need strengthening.

The Charleston and Dallas CMOPs did not perform a complete or consistent physical count of their entire pharmaceutical inventory as required by VHA inventory management criteria and guidelines. For example, at the Charleston CMOP, 14 of the 18 pharmaceutical line items we reviewed had positive variances. The existence of these variances demonstrated the unreliability and inaccuracy of the CMOPs inventory records and positive variances can enable pilferage and diversion of pharmaceuticals to go undetected.

The CMOP inventory management system provided by Quality Manufacturing Systems Incorporated (QMSI) did not always effectively track pharmaceutical dispensing. The CMOPs lacked policy and controls necessary to monitor and control pharmaceutical inventory adjustments. Adjustments were made without restricting the quantity of adjustments made, and an independent validation or verification of adjustments was not performed.

In addition, the CMOPs did not comply with VA requirements for non-controlled pharmaceuticals held for return credit, and the potential exists for the credited amount to be significant. Finally, the CMOPs did not ensure adequate separation of duties over critical system functions and lacked adequate Econolink system access controls. The lack of compliance with inventory management criteria and controls put the CMOPs non-controlled pharmaceutical inventories at risk for diversion. Accountability for

pharmaceutical inventories cannot be reasonably assured without strengthening inventory management and system access controls.

In conclusion, physical inventories act as a check on the effectiveness of other inventory controls. Therefore, significant differences between what is computed as the ending inventory and what is actually available need to be independently reviewed and resolved before inventory records are adjusted. CMOPs did not always perform a complete physical count or consistently estimate their entire inventories, and QMSI software did not always accurately account for all pharmaceuticals dispensed. Therefore, CMOPs cannot accurately account for their inventory, calculate an accurate shrinkage rate, or an inventory turn rate. Inadequate CMOP inventory management controls place non-controlled pharmaceuticals in CMOP inventories at increased risk of theft and diversion.

## **Background**

The primary mission of the VA CMOP program is to provide pharmaceuticals to VA Medical Center patients using automated order processing and delivery systems. Seven CMOPs support all 21 Veteran Integrated Service Networks (VISNs) by mailing pharmaceuticals to veteran patients throughout the United States. The seven VA CMOPS operate under the direction of VHA's Pharmacy Benefits Management (PBM) Service. The national CMOP business office in Leavenworth, KS provides fiscal and logistics oversight and support to the CMOPs.

CMOPs are a virtual extension of medical center pharmacies and assist VA facilities by providing seamless pharmaceutical delivery to patients. In FY 2008, the VA dispensed 125.9 million prescriptions for VA patients, of which approximately 97.4 million (77 percent) were dispensed by the CMOPs. Furthermore, the CMOPs' pharmaceutical purchases totaled approximately \$2.3 billion. According to CMOP officials, approximately \$2.26 billion (98 percent) was used for the purchase of non-controlled pharmaceuticals.

CMOPs manage their pharmaceutical inventory with two different systems to order, receive, and dispense pharmaceuticals delivered to VA patients—the McKesson Prime Vendor System (Econolink) and QMSI. The prime vendor provides pharmaceuticals and medical supplies to regionally grouped military and federal customers, including VHA, from commercial distributors using a proprietary ordering system. QMSI is responsible for the software at five of the seven CMOPs and controls most of the production system while providing the majority of the user functionality.

## **CMOP Inventory Management and System Access Controls Need Strengthening to Ensure Accountability of Non-Controlled Pharmaceutical Inventories**

Improvements were needed to ensure adequate accountability of non-controlled pharmaceuticals in an effective and efficient manner. The Charleston and Dallas CMOPs established physical security controls to prevent the unauthorized physical removal of pharmaceuticals from CMOPs. However, the audit disclosed the Charleston and Dallas CMOPs were not complying with VHA inventory management criteria by not performing a complete and consistent physical count of their entire pharmaceutical inventory. Also, the QMSI software did not always adequately track the dispensing of pharmaceuticals. Furthermore, the CMOPs did not establish a policy for controlling and monitoring adjustments to pharmaceutical inventory, secure and account for non-controlled pharmaceuticals held for return credit, and segregate critical system functions or control and monitor Econolink system access.

Our inventory analysis, interviews, observations, and evaluations of CMOP processes and facilities revealed two primary issues: (1) inadequate inventory management controls over non-controlled pharmaceuticals diminishes CMOP inventory accountability and (2) weak internal controls over system access to non-controlled pharmaceuticals increased the risk of diversion.

### **Conclusion**

Access controls over specific non-controlled pharmaceuticals stored in the controlled substances vault and cage were adequate, and physical security controls were established to prevent the unauthorized physical removal of pharmaceuticals from CMOPs. However, the Charleston and Dallas CMOPs did not adequately account for their non-controlled pharmaceutical inventories in an effective and efficient manner. This impacted their ability to manage and safeguard their non-controlled pharmaceutical inventories. Inadequate CMOP inventory management controls, such as noncompliance with existing VA criteria and the lack of a policy for controlling and monitoring adjustments, and weak internal controls over system access to non-controlled pharmaceuticals increase VA's risk of non-controlled pharmaceuticals being diverted and pilfered. As such, CMOPs need to establish inventory management controls and strengthen system access controls to help ensure adequate accountability over all non-controlled pharmaceutical inventories.

### **Recommendations**

1. We recommend the Under Secretary for Health require the Deputy Chief Consultant PBM/CMOP to enforce the annual wall-to-wall physical inventory requirements.

2. We recommend the Under Secretary for Health require the Deputy Chief Consultant PBM/CMOP perform a complete inventory analysis to develop and implement a plan of action to mitigate significant variances.
3. We recommend the Under Secretary for Health require the Deputy Chief Consultant PBM/CMOP develop policy and establish controls to monitor and control adjustments to pharmaceutical inventory records.
4. We recommend the Under Secretary for Health require the Deputy Chief Consultant PBM/CMOP enforce policy compliance for returned and expired pharmaceuticals.
5. We recommend the Under Secretary for Health require the Deputy Chief Consultant PBM/CMOP establish and implement procedures to prevent a single individual from ordering, receiving, and adjusting against the same pharmaceutical.
6. We recommend the Under Secretary for Health disable all prime vendor generic user IDs and passwords and establish individual user IDs and passwords for ordering and receiving pharmaceuticals.

## **Management Comments and OIG Response**

The Under Secretary for Health concurred with all our findings and recommendations. VHA instituted a plan for quarterly wall-to-wall physical inventories at each of the seven CMOPs and required each CMOP Director to certify they were in compliance with the policy for returned and expired pharmaceuticals. In addition, VHA agreed to develop a statement of work to rewrite the CMOP inventory management software to ensure complete and accurate tracking of inventory.

Furthermore, VHA agreed to develop a national CMOP inventory management policy and establish a monthly review process of completed adjustments. VHA will also establish and enforce procedures that restrict a single individual from ordering, receiving, and adjusting against the same pharmaceutical. Finally, the Under Secretary for Health will ensure that all prime vendor generic user IDs and passwords for ordering and receiving pharmaceuticals are disabled, and the Deputy Chief Consultant PBM/CMOP will include, in the national CMOP inventory management policy, guidance and a requirement for an annual review.

The Under Secretary for Health took appropriate actions to implement Recommendations 1 and 4 so we consider these recommendations closed and planned corrective actions for Recommendations 2, 3, 5, and 6 are responsive to our concerns. Finally, we will close these recommendations when all proposed actions have been completed by VHA. Appendix B contains the full text of the Under Secretary's comments.

*(original signed by:)*

BELINDA J. FINN  
Assistant Inspector General  
for Auditing

## Introduction

### Purpose

The Office of Inspector General (OIG) performed this audit to determine whether VA Consolidated Mail Outpatient Pharmacies (CMOPs) accounted for non-controlled pharmaceutical inventories in an effective and efficient manner and whether the CMOPs managed and safeguarded non-controlled pharmaceutical inventories at risk for diversion.

### Background

In 1946, VA became the first organization in the United States to provide medications to patients by mail supporting individual VA medical centers. During the 1970s, VA began consolidating mail prescription workloads from multiple VA medical centers into centralized operations. In 1994, the CMOP located at Leavenworth, KS began processing high volume mail prescription workloads using an automated dispensing system. Since that time, VA expanded its CMOP program to include six additional facilities located in Charleston, SC; Chelmsford, MA; Dallas, TX; Hines, IL; Murfreesboro, TN; and Tucson, AZ.

The mission of CMOPs is to provide high quality, timely, and cost-effective pharmaceuticals to our nation's veterans. CMOPs are a virtual extension of medical center pharmacies and assist VA facilities by providing seamless pharmaceutical delivery to patients. Veterans' pharmaceutical records are maintained at the medical center so that the provider/patient relationship is not interrupted. One of the benefits of CMOP automated pharmaceutical dispensing is that it enables pharmacy personnel at VA medical centers more time to interact and confer with patients seeking prescription counseling.

For their initial prescription needs, patients are provided medications or supplies dispensed directly from VA medical facilities. VA medical facilities electronically transmit prescription information to CMOPs for a faster, more secure means of communicating a patient's pharmaceutical needs and to provide facilities with operational flexibility in pharmaceutical deliveries. Prescription refills are generally dispensed by the CMOP responsible for servicing a particular VA medical facility. VA medical facilities nationwide transmit daily electronic refill requests to the CMOPs for dispensing and direct delivery to the patient. The CMOP completes the prescription process by returning an electronic record, thus verifying patient pharmaceuticals or medical supplies dispensed to the initiating VA medical facility.

To ensure timely prescription deliveries when CMOPs experience production problems such as an emergency shutdown of the production system, prescriptions can be rerouted to another CMOP for processing. If problems or questions arise with the initial

prescription, the prescription data is returned to the transmitting facility for review and resolution. After all issues are resolved, the prescription is received by a CMOP, transferred to the most appropriate CMOP processing area, and then queued for dispensing.

Once the prescription is dispensed, it is labeled by CMOP pharmacy technicians and pharmacy aides in conjunction with the CMOPs' automated dispensing system, which uses barcode technology and radio frequency identification to ensure accurate prescription dispensing. After the prescription is dispensed and labeled, it is routed to a pharmacist for quality verification—examined to ensure the correct product, dose, rate, quantity, and strength was dispensed. Once the patient's prescription is verified, the order is packaged and addressed for delivery. A completed prescription order is then consolidated with others for delivery to patients by the United States Postal Service or an overnight carrier.

Pharmaceuticals dispensed by CMOPs are divided into two categories, controlled and non-controlled. Controlled pharmaceuticals are identified as such by the Drug Enforcement Agency (DEA) and are heavily safeguarded by the Veterans Health Administration (VHA). To reduce the risk of abuse and diversion, VHA requires that CMOPs store controlled pharmaceuticals in separate, secure storage vaults and conduct inventories every 72 hours. In contrast, most non-controlled pharmaceuticals (any pharmaceutical not categorized as controlled) are not subject to the same stringent inventory and oversight controls, even though non-controlled pharmaceuticals make up the bulk of the CMOPs' inventories and account for the majority of CMOP pharmaceutical acquisitions. CMOPs subject some non-controlled pharmaceuticals at risk of diversion, such as erectile dysfunction and oral contraceptive pharmaceuticals, to the same treatment as controlled pharmaceuticals. In FY 2008, CMOPs' pharmaceutical purchases totaled approximately \$2.3 billion. According to CMOP officials, approximately \$2.26 billion (98 percent) was used for the purchase of non-controlled pharmaceuticals.

CMOPs manage their pharmaceutical inventory with two different systems to order, receive, and dispense pharmaceuticals delivered to VA patients—the McKesson Prime Vendor System (Econolink) and the inventory management system of QMSI. Econolink and QMSI descriptions follow:

- **Econolink** Econolink is a client-server based system installed on personal computers and terminals at various medical facilities throughout VA. This application, provided and installed by McKesson, receives and provides pharmaceuticals and other medical supplies to all CMOPs.
- **QMSI** QMSI software, referred to as the inventory management system by the Charleston and Dallas CMOPs, tracks the CMOPs automated and manual dispensing of pharmaceuticals. QMSI is used at five of the seven CMOPs

(including Charleston and Dallas) and controls the majority of the CMOP pharmaceutical production system. The remaining two CMOPs use the Systems Integration Baker software (S/I Baker) for inventory management, which is slated to be replaced by QMSI software.

The process for ordering and receiving pharmaceuticals at all CMOPs follows:

- The inventory management systems generate a daily automatic order file based on prescription demands and CMOP stock levels.
- The automatic order file is reviewed, edited, and imported into Econolink, and orders are electronically transmitted to McKesson.
- McKesson fills the orders and delivers the pharmaceuticals to CMOPs the next day.
- Upon receipt of the pharmaceutical order, CMOP employees scan the bar coded pharmaceuticals into Econolink.
- Econolink exports the scanned receiving data into the inventory management systems which updates CMOP inventory levels

## Scope and Methodology

We reviewed and analyzed current policies, procedures, and internal controls for inventory management for five specific non-controlled pharmaceuticals at risk for diversion. (See Table 1 for the five pharmaceuticals we selected for review and the description of their therapeutic use.) At the Charleston and Dallas CMOPs, we evaluated the effectiveness of CMOPs' physical security controls, conducted an inventory analysis, determined whether controls were established for monitoring and controlling adjustments to pharmaceutical inventory, and assessed CMOP inventory processes. As part of our assessment of the CMOP inventory processes, we evaluated the adequacy of CMOP separation of duties and Econolink system access controls. Our review focused on Charleston and Dallas CMOP pharmaceutical production and inventory operations from February through October 2008.

CMOP Physical Security Controls. We interviewed Charleston and Dallas CMOP personnel to determine whether the CMOPs had established adequate physical security controls over non-controlled pharmaceutical inventories at risk for diversion. Physical security controls are established to prevent the unauthorized physical removal of pharmaceuticals from CMOPs. We validated the adequacy of physical security controls by observing and evaluating operations at both CMOPs, which included observing the controlled pharmaceuticals vault at the Charleston CMOP and the controlled pharmaceuticals cage at the Dallas CMOP. The controlled pharmaceuticals vault and

cage are where the CMOPs store the erectile dysfunction and oral contraceptive pharmaceuticals. Lastly, we reviewed the video surveillance system, at both CMOPs, including the observation of the receipt of pharmaceutical deliveries at one CMOP.

Inventory Analysis. We selected five pharmaceuticals from a list of 46 non-controlled pharmaceuticals considered at risk for diversion that were identified during the *Audit of VHA’s Management of Selected Non-Controlled Drugs*. These 46 pharmaceuticals were considered to be at risk for diversion by experts in the private and public sector (VA OIG, the Federal Drug Administration, the Drug Enforcement Agency, the National Association of Drug Diversion Investigations, the National Association of Boards of Pharmacy, and Kaiser Permanente).

**Table 1. Description of the Five “At Risk” Pharmaceuticals**

Brand Name	Generic Name	Therapeutic Use
Plavix	Clopidogrel	To treat mild heart attacks.
Sustiva	Efavirenz	To treat Human Immunodeficiency Virus (HIV) Type I.
Zyprexa	Olanzapine	To treat certain mental disorders.
Ultram	Tramadol	To relieve moderately severe pain.
Levitra	Vardenafil	To treat erectile dysfunction.

To perform our inventory analysis and review of CMOP controls over non-controlled pharmaceuticals, we obtained the recorded beginning inventory balances, purchases, and dispensed pharmaceutical data and their related product codes from the Charleston and Dallas CMOPs for the five pharmaceuticals identified in Table 1. A product code is an identifier specific to a product, a product’s strength, and a CMOP. The five pharmaceuticals consisted of 18 product codes at the Charleston CMOP and 17 product codes at the Dallas CMOP. We performed one inventory analysis at the Charleston CMOP in September 2008 and two inventory analyses—one in August and the other in October 2008 at the Dallas CMOP. We performed the second inventory analysis at Dallas to determine whether significant variances existed after we obtained an accurate beginning inventory balance from our initial independent physical count conducted in August. We did not conduct a second inventory analysis at the Charleston CMOP because additional testing was considered unnecessary.

We conducted our analysis to determine if the Charleston and Dallas CMOPs were accurately accounting for their non-controlled pharmaceutical inventories and QMSI software was adequately tracking dispensed pharmaceuticals. We compared the OIG computed ending inventory (the CMOP provided beginning inventory plus McKesson provided purchases less dispensed pharmaceuticals identified by QMSI) for the five selected pharmaceuticals to the physical inventory that was on hand based on our physical count. We performed the calculations below as part of our analysis, which resulted in negative and positive variances. Variances occur when the CMOPs' actual ending inventory is lower or higher than what the OIG computed as ending inventory given the number of pills ordered and then dispensed. (See Appendix A for the results of our inventory analysis):

- OIG Computed Ending Inventory = Beginning Inventory + Purchases – Dispensing
- Pill Count Difference = Physical Count – OIG Computed Ending Inventory
- Percent Variance = Pill Count Difference ÷ OIG Computed Ending Inventory

We obtained beginning inventory data from the CMOPs, purchase data from the prime vendor (McKesson), and dispensing data from the QMSI software. We were unable to validate the beginning inventory for each of the pharmaceuticals analyzed because the beginning inventory was the product of continuous adjustments made against the system balance. We were also unable to validate the McKesson purchase data because neither McKesson nor the QMSI software retains purchase order records thus preventing a comparison of purchase orders to receiving documentation. Finally, we could not validate dispensing data because working with actual dispensing data would disrupt CMOP production and subsequently impact the timely delivery of pharmaceuticals to patients.

Pharmaceutical Inventory Adjustments. To determine whether the CMOPs established controls for monitoring and controlling adjustments to pharmaceutical inventory, we interviewed Charleston and Dallas CMOP personnel to: (1) obtain the list of all individuals authorized to adjust pharmaceutical inventory; (2) determine if CMOP staff document the adjustment reason; and (3) determine whether management adequately monitors and tracks adjustments. We also observed the process used at the CMOPs to make adjustments to pharmaceutical inventory balances.

CMOP Inventory Processes. To determine the processes used to manage non-controlled pharmaceuticals at risk for diversion we: (1) interviewed Charleston and Dallas CMOP personnel; (2) identified and evaluated the policies and procedures on the management of pharmaceutical inventories; and (3) observed and evaluated the manner by which the CMOPs purchase, receive, adjust, store, dispense, mail, secure, and monitor returned pharmaceuticals.

Separation of Duties. As part of our assessment of the CMOP inventory processes and at the request of the National Director of CMOP Operations, we determined the adequacy of separation of duties by obtaining the list of employees/users that have access to CMOP pharmacy data systems and interviewing Charleston and Dallas CMOP personnel to determine whether management at either CMOP monitors or tracks user access permissions. Lastly, we analyzed the list to determine the adequacy of the number of employees/users who had authorization to purchase, receive, and adjust pharmaceutical inventories.

System Access Controls. As part of our assessment of the CMOP inventory processes, we observed the Econolink ordering process at both CMOPs and conducted interviews with Charleston and Dallas CMOP personnel. We did not expand testing of the Econolink system access controls to all facilities throughout VA because our audit objectives focused on CMOPs' inventory management. In addition, we did not review the system access controls over the SI/Baker software because this system is not used at the Charleston and Dallas CMOPs.

Use of Computer-Processed Data. We performed a limited assessment of the reliability of the purchase data obtained from McKesson and the dispensing data obtained from QMSI. Our assessment was limited because McKesson and QMSI do not retain purchase order records which did not allow us to compare purchase orders against what was received. Additionally, a validation of dispensing data would have required a disruption of CMOP production and impacted the CMOPs' ability to provide timely delivery of pharmaceuticals to patients. Therefore, we conducted a physical count and inventory analysis of five pharmaceuticals at risk for diversion and their associated product codes. Specifically, we compared what was on hand to what the OIG computed as ending inventory based on the CMOPs' beginning inventory plus purchases less dispensed pharmaceuticals. Since our analysis revealed significant variances between our physical count and what we computed as ending inventory, we concluded that we could not rely upon data obtained from either McKesson's Econolink or QMSI. We have included the results of our analysis as part of a finding within this report.

We conducted our audit from July 2008 through March 2009 in accordance with generally accepted government auditing standards. The 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 the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Results and Conclusions

The Charleston and Dallas CMOPs established physical controls to prevent the unauthorized physical removal of pharmaceuticals from CMOPs. However, inventory management controls used to account for and prevent diversion of non-controlled pharmaceuticals could be further improved. For example, at the Charleston CMOP, 14 of the 18 pharmaceutical line items we reviewed had positive variances. The existence of these variances demonstrated the unreliability and inaccuracy of the CMOPs inventory records. Furthermore, the existence of positive variances can enable pilferage and diversion of pharmaceuticals to go undetected.

Our analysis of CMOP inventories, interviews with CMOP officials, and observations and evaluations of CMOP processes revealed that CMOP inventory management controls for non-controlled pharmaceuticals were inadequate and inventory system access controls needed strengthening. Specifically, we found:

- Inadequate annual wall-to-wall physical inventories of their entire non-controlled pharmaceuticals, as required by VHA.
- Inadequate tracking of dispensed pharmaceuticals by QMSI.
- Significant variances between the OIG computed ending inventory and the pharmaceuticals that CMOPs had on hand.
- Inadequate controls to monitor and control pharmaceutical inventory adjustments and a lack of policy guidance.
- Lack of controls for non-controlled pharmaceuticals held for return credit as required.
- Inadequate separation of duties over critical system functions.
- Inadequate Econolink system access controls.

As a result, the CMOPs pharmaceutical inventory records did not accurately reflect the pharmaceuticals on hand, thus impacting CMOPs ability to accurately compute and report VA's CMOP shrinkage rate or inventory turn rate. A shrinkage rate is used to determine CMOPs missing pharmaceutical inventory, while the inventory turn rate is the primary measure of the effectiveness of inventory management. In addition, because CMOPs have not ensured accurate and complete inventory control over non-controlled pharmaceuticals, they have potentially increased VA's risk of pilferage and diversion of non-controlled pharmaceuticals.

## **Inadequate Inventory Management Controls of Non-Controlled Pharmaceuticals Diminishes CMOP Inventory Accountability**

The Charleston and Dallas CMOPs did not perform complete and consistent annual physical wall-to-wall inventories for all items, as required, and the QMSI software does not always adequately track pharmaceutical dispensing. Additionally, both CMOPs did not establish a policy for controlling and monitoring adjustments to pharmaceutical inventory or secure and account for non-controlled pharmaceuticals held for return credit, as required. VHA criteria and guidelines exist to ensure CMOPs perform annual wall-to-wall inventories (complete physical counts and/or estimations of open bottle inventory balances) and to manage pharmaceutical return credits. CMOPs need to establish criteria to monitor and control pharmaceutical adjustments.

### **CMOPs Did Not Conduct Required Non-Controlled Pharmaceutical Inventories.**

The Charleston and Dallas CMOPs did not always conduct complete physical counts or consistently estimate inventory quantities of open products during their annual wall-to-wall physical inventory. Also, because of the various shapes and sizes of pills being dispensed by the individual pill dispenser (IPD), QMSI, which controls the majority of the CMOPs production system, does not always adequately track the dispensing of pharmaceuticals.

Physical Counts of CMOP Pharmaceutical Inventory. The Charleston and Dallas CMOPs did not perform an annual wall-to-wall physical inventory, as required, for all items and inconsistently estimated their inventory quantities of open products. VHA Handbook 1761.2, *VHA Inventory Management*, March 19, 2003, requires that an annual wall-to-wall physical inventory be performed for all items. In addition, VHA's *Pharmacy Inventory Guidelines* states that inventory quantities of an open product need to be estimated to the nearest tenth of a bottle. The guidelines further state that inventories can be useful in making accurate projections and determining shrinkage and inventory turn rates. For example, CMOP pharmaceuticals are dispensed by either manual or automated means, including the IPD—an apparatus for dispensing individual dosage units of medication such as tablets or capsules into containers. Charleston and Dallas CMOP personnel informed us they physically count all pharmaceuticals that are manually dispensed, but they do not physically count all pharmaceuticals dispensed from IPD because it is too labor intensive. Charleston, which maintains an inventory of 303 IPDs, counts the top 20 (7 percent) of their high-dollar value IPD dispensed pharmaceuticals and estimates the remaining 283 IPDs to the nearest fourth. Charleston estimates their open product inventory quantities to the nearest fourth of a bottle. Dallas does not estimate the quantities in their IPDs but does estimate their open product inventory quantities to the nearest half bottle. As previously mentioned, VHA criteria for annual wall-to-wall physical inventory requires estimates of open product inventory quantities to the nearest tenth of a bottle.

For CMOPs to provide and ensure a more accurate calculation of their shrinkage rate, inventory turn rate, and ensure accountability over non-controlled pharmaceuticals, they need to perform a complete annual wall-to-wall physical inventory and estimate inventory quantities for open products, as required.

QMSI Software Tracking Dispensed Pharmaceuticals. QMSI software does not always adequately track the dispensing of pharmaceuticals. We performed an inventory analysis at the Charleston CMOP, and at the Dallas CMOP, we performed two inventory analyses—one in August and the other in October 2008. We only performed the second inventory analysis at Dallas to determine whether significant variances existed after we obtained an accurate beginning inventory balance from our initial independent physical count conducted in August (ending inventory amount). We did not conduct two inventory analyses at the Charleston CMOP because additional testing was considered unnecessary.

The Dallas inventory analysis performed in August consisted of the five selected pharmaceuticals and 17 product codes; while the Dallas inventory analysis performed in October was limited to two pharmaceuticals and five product codes. These pharmaceuticals were selected based on the following criteria:

- Pharmaceuticals that had a significant (100 percent or higher) positive variance based on the results of our inventory analysis in August.
- All pharmaceuticals that had a negative variance based on the results of our inventory analysis in August.
- A pharmaceutical with a variance that had been moved from IPD dispensing to manual dispensing as a result of our inventory analysis in August.

(Vardenafil 5mg was dispensed from an IPD and had a negative five percent variance based on the inventory analysis conducted in August. As a result, CMOP staff immediately moved this pharmaceutical from IPD dispensing to manual dispensing. We wanted to determine whether the variance improved as a result of this change.)

Based on our inventory analyses for the time period February 2008 through October 2008, we identified pill variances ranging from -3,092 pills to 192,498 pills valued at an approximate total cost of \$1.1 million. The existence of these variances demonstrated the unreliability and inaccuracy of the CMOPs' inventory records and positive variances can enable pilferage and diversion of pharmaceuticals to go undetected.

A summary of the CMOP inventory analysis conducted at both CMOPs follows:

- Charleston's pill count compared to the OIG computed ending inventory varied from -1,762 pills to 192,498 pills valued at approximately \$997,000 for the five selected pharmaceuticals and 18 product codes.
- In August, Dallas's pill count compared to the OIG computed ending inventory varied from -3,092 pills to 39,017 pills valued at approximately \$86,000 for the five selected pharmaceuticals and 17 product codes.
- In October, Dallas's pill count compared to the OIG computed ending inventory varied from -403 pills to 93 pills valued at approximately \$-410 for two pharmaceuticals and five product codes.

(See Appendix A for the detailed results of the CMOP inventory analysis.)

CMOP personnel could not explain the positive and negative pill variances between the actual pill count and the amounts the OIG computed as ending inventory. However, they indicated that the variances may be the result of QMSI software inaccurately tracking dispensed pills and because an annual wall-to-wall physical inventory was not completed for all pharmaceuticals, which could lead to an inaccurate beginning inventory number. In addition, according to CMOP personnel, some pharmaceuticals do not accurately dispense from the IPD due to the various shapes and sizes of the capsules, which impact QMSI's ability to track what has been dispensed accurately. For example, as previously mentioned, our initial inventory analysis of Vardenafil (5mg) identified a negative five percent variance when dispensed from IPD. This pharmaceutical was moved from IPD to manual dispensing and our subsequent October inventory analysis identified a positive two percent variance for Vardenafil (5mg), potentially indicating that the significant variance change within three months was due to the pharmaceutical being moved from IPD to manual dispensing or because we had obtained an accurate ending inventory count.

Finally, we obtained a QMSI generated "Dispense Activity Report," which provides the amount of pills dispensed for a selected pharmaceutical for Tramadol on August 19 and August 22 covering the time period August 8-18, 2008, and found that QMSI reported a different total amount dispensed for each of the days for which we obtained the reports. For example, on August 19, the report showed approximately 484,000 pills were dispensed; however, on August 22, the report showed approximately 488,000 pills were dispensed for the same period. Therefore, based on our inventory analyses we concluded that ending inventory reported to be on hand by the QMSI software may not always accurately reflect the actual remaining inventory balance.

In conclusion, physical inventories act as a check on the effectiveness of other inventory controls. Therefore, attempts must be made to determine the causes of significant differences between what is computed as the ending inventory and what is actually

available. CMOPs did not always perform a complete physical count or consistently estimate their entire inventories, and QMSI software did not always accurately account for all pharmaceuticals dispensed from IPD. Therefore, CMOPs cannot accurately account for their inventory, calculate an accurate shrinkage rate or inventory turn rate, and ensure that non-controlled pharmaceuticals are not being diverted and pilfered.

**CMOP Management Needs to Establish a Policy for Controlling and Monitoring Adjustments to Pharmaceutical Inventory.** Charleston and Dallas CMOP management did not effectively control and monitor adjustments made to their pharmaceutical inventory. This occurred because a CMOP specific policy for controlling and monitoring pharmaceutical adjustments does not exist. For example, when the CMOPs conduct a physical count for a particular pharmaceutical and a variance exists between the physical count and the system balance, an adjustment is made to the QMSI system balance for that pharmaceutical. Adjustments are made to reduce or enhance the QMSI system balance so it corresponds to the physical count. There are no restrictions to the number of adjustments an individual can make to pharmaceuticals and there are no limits to the adjustment quantities made against pharmaceuticals. Finally, CMOP management does not independently validate and verify adjustments made to pharmaceutical inventory balances.

Further, at the Charleston CMOP, we found that the adjustment reason codes are not available in QMSI to allow CMOP personnel to document the reason(s) an adjustment is made to a pharmaceutical inventory item. However, the Charleston CMOP implemented a verbal policy requesting staff to document in hard copy the reason adjustments were made to inventory. The Charleston CMOP also presented a proposal to QMSI requesting a modification to the production system that would add a field allowing for a mandatory selection of an adjustment reason. Finally, although the Dallas QMSI maintains an adjustment reason field so that personnel can document inventory adjustments, the Dallas CMOP management was not trending adjustments to determine reasons adjustments were made.

A lack of policy to control and monitor adjustments to pharmaceutical inventory could lead to inaccurate inventory records and the CMOPs inability to accurately account for their pharmaceutical inventory. Furthermore, without controls over adjustments, theft and diversion of drugs can go undetected. Significant inventory adjustments should only be made after supervisory review and authorization.

**Security and Accountability Over Non-Controlled Pharmaceuticals Held for Return Credit Needs Improvement.** CMOPs did not always secure, track, and monitor non-controlled pharmaceuticals held for return credit. Specifically, Charleston and Dallas CMOPs did not always:

- Secure non-controlled pharmaceuticals held for return in a location away from the normal inventory.
- Maintain a detailed list of non-controlled pharmaceuticals held for return.
- Reconcile credits received to the list of non-controlled pharmaceuticals returned.

VHA Directive 2008-021, *Monitoring of Non-Controlled Substance Medication Returns*, April 17, 2008, states non-controlled substance medications held for return credit must be secured, tracked, and monitored to reduce the possibility of fraud and maximize revenues received through credits. Although the CMOPs were aware of the requirements, they had not initiated procedures to ensure compliance with VHA requirements.

At the Charleston CMOP, we found that the *Returned Non-Schedule Drug Report* showed anticipated return values due from vendors that ranged from \$436 to \$147,000 for the 12-month period ending September 2, 2008. During the same period, however, the highest amount credited to the CMOP was only \$22,000. For example, the CMOP might receive a check from the vendor for a credit amount. Since the CMOP would not know for which month the credit applied, because they do not maintain sufficient information about the returned items to reconcile refunds against returns, reconciliation to the vendor *Returned Non-Schedule Drug Report* would not be possible and the potential exists for the refund amount to be significant. Consequently, CMOPs cannot adequately determine if credits received from the vendor were accurately applied to the returned items.

In conclusion, inadequate CMOP inventory management controls place all non-controlled pharmaceuticals at risk of being diverted and pilfered. Additionally, the lack of CMOP inventory management controls impacts the CMOPs' ability to accurately manage and safeguard their non-controlled pharmaceutical inventories; calculate an accurate shrinkage rate or inventory turn rate; and adequately determine if credits received from the vendor were sufficient. Therefore, establishing controls to ensure CMOP compliance with existing VHA criteria and developing and implementing a policy for controlling and monitoring adjustments will help ensure adequate accountability over the CMOPs' non-controlled pharmaceutical inventories.

### **Weak Internal Controls for System Access to Non-Controlled Pharmaceuticals Increase Risk of Diversion**

The Charleston and Dallas CMOPs did not ensure segregation of critical system functions and did not control and monitor Econolink system access. However, VA provides guidance to ensure that adequate separation of duties exists for critical system functions.

**Critical System Functions Need to Be Segregated.** CMOPs did not always ensure adequate separation of duties for users who have Econolink access to order and receive

and QMSI access to order, receive, and adjust pharmaceutical inventories. The *VA Cyber Security Practitioner Reference Guide Version 2.0*, March 30, 2006, defines separation of duties as the practice of dividing the steps of a critical function among different individuals. We identified 33 users at the Charleston CMOP and 28 users at the Dallas CMOP whose combined Econolink and QMSI access allowed them to order, receive, and adjust non-controlled pharmaceutical inventories. In addition, we found that QMSI does not track system user activity to determine if an employee has used all three permissions, which allowed users to order, receive, and adjust against the same pharmaceutical.

This occurred because CMOP management does not monitor or track permissions granted to employees. For example, an employee may be granted multiple permissions to perform their job requirements or to back up another employee who is on leave. Generally, employees with multiple permissions would not pose a separation of duties problem if QMSI was configured to restrict an employee with multiple permissions from ordering, receiving, and adjusting against a single pharmaceutical; however, QMSI does not maintain the automated controls necessary to restrict an employee from using their three permissions against the same pharmaceutical.

To determine the extent to which users with all three permissions were ordering, receiving, and adjusting against the same pharmaceutical, we attempted to obtain user activity for those with multiple system permissions. We discovered that QMSI did not have the capability to identify this type of user activity. Therefore, employees with multiple permissions leave the CMOPs vulnerable to pilferage by maintaining the capability to potentially order, receive, and adjust against a single pharmaceutical given that such user activity, if occurring, is not tracked by the CMOPs. A lack of adequate separation of duties and monitoring of user activity and permissions impacts the CMOPs ability to ensure the accuracy, reliability, and completeness of pharmaceutical inventories and ultimately, their ability to compute realistic shrinkage rates and inventory turn rates. As a result of our review, the Charleston and Dallas CMOPs took action to delete some user permissions to reduce vulnerabilities that result from inadequate separation of duties.

**CMOP Management Needs to Ensure Access Controls to the Prime Vendor System Exist.** CMOPs did not control access to Econolink, the McKesson Prime Vendor System. Econolink is configured to allow CMOP personnel to use generic identifications (ID) and passwords. Econolink was installed at the Charleston and Dallas CMOPs in 2004 with generic IDs and passwords to provide users with the capability to order and receive pharmaceuticals before they had received their individual IDs and passwords. With the generic Econolink ID and password, CMOPs are at risk for anonymously ordered pharmaceuticals to be adjusted in QMSI and pilfered by employees. For example, an employee can transmit and receive a pharmaceutical ordered in Econolink without being identified as a specific user. The same employee can then use their unique ID and password to adjust QMSI by reducing the inventory balance for the same pharmaceutical and keep or divert the pharmaceutical for personal use. VA Handbook

6500, *Information Security Program*, September 18, 2007, states that VA controls must uniquely identify system users, and each user ID will be associated with a unique password to authenticate the individual. When identification and authentication are used together, they provide an effective means to identify and validate a user's identity prior to granting system access.

At our request, we observed a Dallas CMOP employee successfully transmit a pharmaceutical order using the generic ID and password. The same employee also has permissions to receive and adjust pharmaceutical inventories. We also requested activity data that took place under the generic ID to evaluate the magnitude of its use; however, the CMOPs do not track user activity associated with the generic IDs and passwords. Further, the CMOP management does not review user adjustments in QMSI, as previously mentioned as a finding in this report.

The CMOPs' inability to control access to McKesson's Econolink application poses significant system vulnerability and increases the potential for diversion or pilferage of CMOP pharmaceuticals. As a result of our review, the CMOPs took action to disable the Econolink generic ID and password accounts and assigned specific user IDs at the Charleston and Dallas CMOPs.

In conclusion, inadequate separation of duties over critical system functions and inadequate Econolink system access controls leave the CMOPs vulnerable to non-controlled pharmaceuticals being pilfered and diverted. Weak system access controls impact the CMOPs' ability to adequately manage and safeguard pharmaceutical inventories and compute realistic shrinkage rates and inventory turn rates.

## Other Matters Reported

**Inadequate Access Controls to the Prime Vendor System Could Exist at Pharmacies Throughout the VA.** McKesson, VHA's prime vendor, provides pharmaceuticals and other medical supplies to pharmacies throughout VA. Prior to the pharmacies transitioning to the web-based Supply Management Online Database (SMO), VA medical facilities were using Econolink to order and receive pharmaceuticals. As previously reported, Econolink is configured to allow the use of generic IDs and passwords. During our audit, we learned that at facilities where Econolink is installed, users may still be able to transmit and receive pharmaceutical orders using generic IDs and passwords. As a result of our review, the Chief Consultant, Pharmacy Benefits Management, issued a memorandum to all VA facilities requiring them to disable all active generic IDs and password accounts. However, we do not have absolute assurance that all active Econolink accounts that may exist at facilities throughout the VA have been disabled.

We also attempted to determine whether Econolink is currently installed and active and the magnitude by which pharmaceuticals are ordered and received using the generic ID and password at pharmacies throughout VA. We asked McKesson to provide a list of

user activity, which took place under the generic ID and password VA-wide. McKesson does not maintain the capability to track orders by user. Based on our request, McKesson did provide a listing that identified 371 active Econolink accounts throughout VA. We were later informed that the provided list did not reflect active Econolink accounts. McKesson agreed to provide documentation to support their statement that the originally identified 371 active Econolink accounts were not active throughout VA, but this documentation was never provided. In conclusion, active Econolink accounts could exist throughout the VA, allowing users to order and receive pharmaceuticals using a generic ID and password.

## Conclusion

Access controls over specific non-controlled pharmaceuticals stored in the controlled substances vault and cage were adequate, and physical security controls were established to prevent the unauthorized physical removal of pharmaceuticals from CMOPs. However, the Charleston and Dallas CMOPs did not adequately account for their non-controlled pharmaceutical inventories in an effective and efficient manner. This impacted their ability to manage and safeguard their non-controlled pharmaceutical inventories at risk for diversion. Inadequate CMOP inventory management controls, such as noncompliance with existing VA criteria and the lack of a policy for controlling and monitoring adjustments, and weak internal controls over system access to non-controlled pharmaceuticals potentially increase VA's risk of non-controlled pharmaceuticals being diverted and pilfered. As such, CMOPs need to establish inventory management controls and strengthen system access controls to help ensure adequate accountability over all non-controlled pharmaceutical inventories.

## Recommendations

1. We recommend the Under Secretary for Health require the Deputy Chief Consultant PBM/CMOP enforce the annual wall-to-wall physical inventory requirement.
2. We recommend the Under Secretary for Health require the Deputy Chief Consultant PBM/CMOP perform a complete inventory analysis to develop and implement a plan of action to mitigate significant variances.
3. We recommend the Under Secretary for Health require the Deputy Chief Consultant PBM/CMOP develop policy and establish controls to monitor and control adjustments to pharmaceutical inventory records.
4. We recommend the Under Secretary for Health require the Deputy Chief Consultant PBM/CMOP enforce compliance with the policy for returned and expired pharmaceuticals.

5. We recommend the Under Secretary for Health require the Deputy Chief Consultant PBM/CMOP establish and enforce procedures that restrict a single individual from ordering, receiving, and adjusting against the same pharmaceutical.
6. We recommend the Under Secretary for Health disable all prime vendor generic user IDs and passwords and establish individual user IDs and passwords for ordering and receiving.

## **Management Comments and OIG Response**

The Under Secretary for Health concurred with all our findings and recommendations. VHA instituted a plan for quarterly wall-to-wall physical inventories at each of the seven CMOPs and required each CMOP Director to certify they were in compliance with the policy for returned and expired pharmaceuticals. In addition, VHA agreed to develop a statement of work to rewrite the CMOP inventory management software to ensure complete and accurate tracking of inventory.

Furthermore, VHA agreed to develop a national CMOP inventory management policy and establish a monthly review process of completed adjustments. VHA will also establish and enforce procedures that restrict a single individual from ordering, receiving, and adjusting against the same pharmaceutical. Finally, the Under Secretary for Health will ensure that all prime vendor generic user IDs and passwords for ordering and receiving pharmaceuticals are disabled, and the Deputy Chief Consultant PBM/CMOP will include, in the national CMOP inventory management policy, guidance and a requirement for an annual review.

The Under Secretary for Health took appropriate actions to implement Recommendations 1 and 4 so we consider these recommendations closed and planned corrective actions for Recommendations 2, 3, 5, and 6 are responsive to our concerns. Finally, we will close these recommendations when all proposed actions have been completed by VHA.

Appendix B contains the full text of the Under Secretary's comments.

## CMOP Inventory Analysis Results

**Table 1. Charleston CMOP Inventory Analysis Results September 2008**

Generic/Brand Name and Strength			Physical Pill Count <sup>1</sup>	OIG Computed Ending Inventory <sup>2</sup>	Pill Count Difference (Variance) <sup>3</sup>	Inventory Value of Pill Count Difference <sup>4</sup>	Percent Variance <sup>5</sup>
<b>Olanzapine/ Zyprexa</b>	Olanzapine	20 mg	49,975	49,602	373	\$5,020	1%
	Olanzapine	15 mg	42,557	40,180	2,377	\$24,498	6%
	Olanzapine	10 mg	13,548	5,671	7,877	\$54,490	139%
	Olanzapine	7.5 mg	2,550	1,490	1,060	\$5,920	71%
	Olanzapine	5 mg	7,233	-5,956	13,189	\$59,445	-221%
	Olanzapine	2.5 mg	1,288	3,050	-1,762	-\$6,735	-58%
	Rapid	20 mg	210	-30	240	\$3,324	-800%
	Rapid	15 mg	390	330	60	\$623	18%
	Rapid	10 mg	480	-90	570	\$3,943	-633%
	Rapid	5 mg	540	480	60	\$276	13%
<b>Vardenafil/ Levitra</b>	Vardenafil	20 mg	127,477	73,304	54,173	\$133,211	74%
	Vardenafil	10 mg	30,408	27,773	2,635	\$6,479	9%
	Vardenafil	5 mg	330	294	36	\$89	12%
	Vardenafil	2.5 mg	290	15	275	\$676	1833%
<b>Clopidogrel</b>	Clopidogrel	75 mg	485,096	298,853	186,243	\$508,754	62%
<b>Tramadol</b>	Tramadol	50 mg	718,727	526,229	192,498	\$4,391	37%
<b>Efavirenz</b>	Efavirenz	200 mg	47,790	3,855	43,935	\$139,142	1140%
	Efavirenz	600 mg	9,600	3,887	5,713	\$53,609	147%
<b>Total</b>						<b>\$997,156</b>	

<sup>1</sup>The physical pill count was performed to determine the amount of pills the CMOPs had on hand.

<sup>2</sup>Computed using CMOP provided beginning inventory plus purchases less dispensed pharmaceuticals.

<sup>3</sup>Pill count difference is the difference between the physical pill count and the OIG computed ending inventory.

<sup>4</sup>Inventory value was computed by multiplying the cost per pill by the pill count difference.

<sup>5</sup>Percent variance was computed by dividing the pill count difference into the OIG computed ending inventory.

**Table 2. Dallas CMOP Inventory Analysis Results August 2008**

Generic/Brand Name and Strength			Physical Pill Count <sup>1</sup>	OIG Computed Ending Inventory <sup>2</sup>	Pill Count Difference (variance) <sup>3</sup>	Inventory Value of Pill Count Difference <sup>4</sup>	Percent Variance <sup>5</sup>
<b>Olanzapine/ Zyprexa</b>	Olanzapine	20 mg	3,766	1,786	1,980	\$27,423	111%
	Olanzapine	15 mg	3,655	2,769	886	\$9,131	32%
	Olanzapine	10 mg	5,334	4,200	1,134	\$7,689	27%
	Olanzapine	7.5 mg	1,149	1,127	22	\$123	2%
	Olanzapine	5 mg	1,591	4,683	-3,092	-\$13,936	-66%
	Olanzapine	2.5 mg	1,891	1,867	24	\$93	1%
	Rapid	20 mg	0	0	0	\$0	0%
	Rapid	15 mg	30	0	30	\$312	0%
	Rapid	10 mg	360	360	0	\$0	0%
	Rapid	5 mg	30	54	-24	-\$110	-44%
<b>Vardenafil/ Levitra</b>	Vardenafil	20 mg	37,192	34,282	2,910	\$7,156	8%
	Vardenafil	10 mg	1,051	40	1,011	\$2,486	2528%
	Vardenafil	5 mg	298	314	-16	-\$39	-5%
	Vardenafil <sup>6</sup>	2.5 mg	N/A	N/A	N/A	\$0	N/A
<b>Clopidogrel</b>	Clopidogrel	75 mg	72,319	56,086	16,233	\$44,343	29%
<b>Tramadol</b>	Tramadol	50 mg	1,056,970	1,017,953	39,017	\$890	4%
<b>Efavirenz</b>	Efavirenz	200 mg	266	266	0	\$0	0%
	Efavirenz	600 mg	1,050	990	60	\$563	6%
<b>Total</b>						<b>\$86,124</b>	

<sup>1</sup>The physical pill count was performed to determine the amount of pills the CMOPs actually had on hand.

<sup>2</sup> Computed using CMOP provided beginning inventory plus purchases less dispensed pharmaceuticals.

<sup>3</sup>Pill count difference is the difference between the physical pill count and the OIG computed ending inventory.

<sup>4</sup>Inventory value was computed by multiplying the cost per pill by the pill count difference.

<sup>5</sup>Percent variance was computed by dividing the pill count difference into the OIG computed ending inventory.

<sup>6</sup>The Dallas CMOP did not carry Vardenafil in the 2.5 mg dosage.

**Table 3. Dallas CMOP Inventory Analysis Results October 2008**

Generic/Brand Name and Strength		Physical Pill Count <sup>1</sup>	OIG Computed Ending Inventory <sup>2</sup>	Pill Count Difference (variance) <sup>3</sup>	Inventory Value of Pill Count Difference <sup>4</sup>	Percent Variance <sup>5</sup>
<b>Olanzapine/ Zyprexa</b>	Olanzapine 20 mg	2,622	2,529	93	\$1,288	4%
	Olanzapine 5 mg	618	1,021	-403	-\$1,816	-39%
	Olanzapine Rapid 5 mg	180	150	30	\$138	20%
<b>Vardenafil</b>	Vardenafil 10 mg	3,373	3,385	-12	-\$30	0%
	Vardenafil 5 mg	224	220	4	\$10	2%
				<b>Total</b>	<b>-\$410</b>	

<sup>1</sup>The physical count was performed to determine the amount of pills the CMOPs actually had on hand.

<sup>2</sup>Computed using CMOP provided beginning inventory plus purchases less dispensed pharmaceuticals.

<sup>3</sup>Pill count difference is the difference between the physical pill count and the OIG computed ending inventory.

<sup>4</sup>Inventory value was computed by multiplying the cost per pill by the pill count difference.

<sup>5</sup>Percent variance was computed by dividing the pill count difference into the OIG computed ending inventory.

## Under Secretary for Health Comments

Department of  
Veterans Affairs

Memorandum

Date: APR 30 2009

From: Under Secretary for Health (10)

Subj.: *OIG Draft Report, Audit of VA Consolidated Mail Outpatient Pharmacies Inventory Accountability*, Project No. 2008-02730-R6-0169 (WebCIMS 427106)

To: Assistant Inspector General for Auditing (52)

1. I have reviewed the draft report, and I concur with the recommendations and findings. As the findings suggest, VA's Consolidated Mail Outpatient Pharmacies (CMOP) physical security controls adequately prevents the unauthorized removal of pharmaceuticals from CMOPs. However, I agree that CMOP inventory management controls and inventory system access controls need further improvement and strengthening to better safeguard non-controlled pharmaceuticals in CMOPs.
2. To ensure that all CMOPs adequately account for non-controlled pharmaceutical inventories in an effective and efficient manner, the Deputy Chief Consultant, Pharmacy Benefits Management/Consolidated Mail Outpatient Pharmacies (PBM/CMOP) has instituted a plan for quarterly wall-to-wall physical inventories at each of the seven CMOP facilities. In addition, the Deputy Chief Consultant, PBM/CMOP is developing a National CMOP Inventory Management Policy to establish clear roles and responsibilities and standardize CMOP inventory management policies and procedures.
3. Lastly, your report states that the current CMOP inventory management system did not always effectively track pharmaceutical dispensing. I agree that the inventory management software requires enhancements to more accurately track inventory variances. To this end, the Deputy Chief Consultant, PBM/CMOP will work with National Acquisition Center contracting staff and staff from VA's Office of Information and Technology (OI&T) to develop a statement of work to rewrite the CMOP inventory management software to ensure complete and accurate inventory tracking. Implementation of the software changes is dependent on OI&T funding and execution; therefore, I will place emphasis on this need and highly prioritize this requirement. In the interim, VHA has improved CMOP inventory procedures and physical security to mitigate inventory variances to the extent possible.

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OIG Draft Report, *Audit of VA Consolidated Mail Outpatient Pharmacies Inventory Accountability*, Project No. 2008-02730-R6-0169 (WebCIMS 427106)

4. Thank you for the opportunity to review the report and provide comments. Attached is VHA's complete plan of corrective action. I would be glad to discuss any concerns or comments you may have about this response or the action plan. If you have any questions, please have a member of your staff contact Margaret Seleski, Director, Management Review Service (10B5) at (202) 461-8470.



Michael J. Kussman, MD, MS, MACP

Attachment

**VETERANS HEALTH ADMINISTRATION  
Action Plan  
OIG Draft Report, Audit of VA Consolidated Mail Outpatient Pharmacies  
Inventory Accountability  
Project No. 2008-02730-R6-0169**

Recommendations/ Actions	Status	Completion Date
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**We recommended that the Under Secretary for Health:**

**Recommended Improvement Action(s) 1: Require the Deputy Chief Consultant PBM/CMOP enforce the annual wall to wall physical inventory requirement.**

Concur

The Deputy Chief Consultant, Pharmacy Benefits Management/Consolidated Mail Outpatient Pharmacies (PBM/CMOP) has instituted a plan for quarterly wall-to-wall physical inventories at each of the seven CMOP facilities. The Deputy Chief Consultant issued specific guidance to each CMOP Director at the February 2009 CMOP Executive Leadership Council meeting on the procedures to use to conduct the inventories. Subsequently, he issued a memo to reinforce the guidance to CMOP Directors on 4/8/09. The first CMOP wide quarterly inventory was completed in March 2009.

Completed

3/31/09

**Recommended Improvement Action(s) 2: Require the Deputy Chief Consultant PBM/CMOP perform a complete inventory analysis to develop and implement a plan of action to mitigate significant variances.**

Concur

Each CMOP currently tracks medication inventory using inventory management software. However, the software requires improvement to more accurately track inventory variances. The Deputy Chief Consultant, Pharmacy Benefits Management/Consolidated Mail Outpatient Pharmacies (PBM/CMOP) will work with National Acquisition Center contracting staff and staff from VA's Office of Information and Technology (OI&T) to develop a statement of work to rewrite the CMOP inventory management software to ensure complete and accurate tracking of inventory. The Deputy Chief Consultant, PBM/CMOP will include the software rewrite in the CMOP FY 2010 OI&T budget submission. Implementation of the software changes is dependent on OI&T funding and execution of this project. Subsequent to establishing a clear contract scope and receiving funding, software rewrite and implementation is projected for completion by 9/30/10. To mitigate inventory variances to the extent possible in the interim, CMOPs have taken the following actions:

Page 2

VHA Action Plan, OIG Draft Report, *Audit of VA Consolidated Mail Outpatient Pharmacies Inventory Accountability*, Project No. 2008-02730-R6-0169

- 1) Since 5/12/08, CMOPs have conducted weekly inventory cycle counts of four high cost, high volume, or problem prone medications.
- 2) Increased wall-to-wall physical inventories from annually to quarterly, with the first quarterly inventory completed in March 2009.
- 3) Increased physical security of CMOP buildings by installing security turnstiles that all employees must use to enter and exit each CMOP. The Great Lakes CMOP was the final facility to complete this process in March 2009.

In Progress

9/30/10

**Recommended Improvement Action(s) 3: Require the Deputy Chief Consultant PBM/CMOP develop policy and establish controls to monitor and control adjustments to pharmaceutical inventory records.**

Concur

The Deputy Chief Consultant, Pharmacy Benefits Management/Consolidated Mail Outpatient Pharmacies (PBM/CMOP) is developing a National CMOP Inventory Management Policy that requires each CMOP Director to limit the number of personnel with the capability to perform inventory adjustments. The Deputy Chief Consultant has also established a monthly review process of completed adjustments. CMOP Directors and CMOP Chief Logistics Officers will conduct the monthly review, which will include all inventory adjustments made during a calendar month.

In Progress

5/31/09

**Recommended Improvement Action(s) 4: Require the Deputy Chief Consultant PBM/CMOP enforce compliance with the policy for returned and expired pharmaceuticals.**

Concur

The Deputy Chief Consultant, Pharmacy Benefits Management/Consolidated Mail Outpatient Pharmacies (PBM/CMOP) communicated the requirements of the policy for returned and expired pharmaceuticals, contained in VHA Directive 2008-021 "Monitoring of Non-controlled Substance Medication Returns," to each CMOP Director in April 2008 via the CMOP Executive Leadership Council. The Deputy Chief Consultant, required all CMOPs to certify compliance with the Directive, and in December 2008, each CMOP Director certified that they were in compliance.

Completed

12/31/08

Page 3

VHA Action Plan, OIG Draft Report, *Audit of VA Consolidated Mail Outpatient Pharmacies Inventory Accountability*, Project No. 2008-02730-R6-0169

**Recommended Improvement Action(s) 5: Require the Deputy Chief Consultant PBM/CMOP establish and enforce procedures that restrict a single individual from ordering, receiving, and adjusting against the same pharmaceutical.**

Concur

The Deputy Chief Consultant, Pharmacy Benefits Management/Consolidated Mail Outpatient Pharmacies (PBM/CMOP) communicated this requirement at the October 2008 CMOP Executive Leadership Council, and at that time, each CMOP Director verbally certified that they are in compliance with procedures to restrict a single individual from ordering, receiving and adjusting inventory for the same medication. Subsequently, the Deputy Chief Consultant issued a memo to reinforce this guidance to CMOP Directors on 4/9/09. The Deputy Chief Consultant will also include the procedures to enforce this restriction, including the requirement for an annual review, in the National CMOP Inventory Management Policy.

In Progress

5/31/09

**Recommended Improvement Action(s) 6: Disable all prime vendor generic user IDs and passwords and establish individual user IDs and passwords for ordering and receiving pharmaceuticals.**

Concur

The Deputy Chief Consultant, Pharmacy Benefits Management/Consolidated Mail Outpatient Pharmacies (PBM/CMOP) communicated this requirement to each CMOP Director at the October 2008 CMOP Executive Leadership Council meeting, and at that time, each CMOP Director certified that they had eliminated generic user IDs and passwords for prime vendor software access. In addition, the Deputy Chief Consultant, CMOP discussed this requirement at a Veterans Integrated Service Network (VISN) Pharmacy Formulary Leaders meeting as well as on a monthly VACO Chiefs of Pharmacy call. The Deputy Under Secretary for Health for Operations and Management reinforced this requirement by sending an email on 12/1/08 to all VISN Pharmacy Executives and Chiefs of Pharmacy instructing them to disable generic user IDs and passwords at all VA pharmacy ordering locations. Lastly, the Deputy Chief Consultant, will include this guidance, including the requirement for an annual review, in the National CMOP Inventory Management Policy.

In Progress

5/31/09

## OIG Contact and Staff Acknowledgments

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OIG Contact	Mario Carbone (214) 253-3301
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Acknowledgments	Theresa Cinciripini Clenes Duhon Glen Gowans John Houston Michael Jacobs Heather Jones Kristin Nichols Chau Pham Sally Stevens
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