

Veterans Health Administration

Audit of
Consolidated Mail
Outpatient Pharmacy
Program

ACRONYMS

CMOP Consolidated Mail Outpatient Pharmacy

COR Contracting Officer's Representative

FY Fiscal Year

MHV My HealtheVet

OIG Office of Inspector General

PIV Personal Identity Verification

QMSI Quality Manufacturing Systems Incorporated

VA Department of Veterans Affairs
VHA Veterans Health Administration

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Highlights: Audit of VHA's Consolidated Mail Outpatient Pharmacy Program

Why We Did This Audit

In September 2015, the Office of Inspector General received a congressional request to conduct a review of the prescription processing and delivery timeliness for the Veterans Health Administration's (VHA) Consolidated Mail Outpatient Pharmacy (CMOP) Program.

What We Found

VHA CMOPs had automated controls and place pharmacists in ensure to pharmaceuticals were secure and safely processed. However, at one of seven CMOPs, the Logistics Officer and Director or Associate Director did not review and approve inventory adjustments from the individual pill-dispensing system as required by national policy. This occurred because the Director believed there was a minimal risk for theft and thus did not follow the policy. This CMOP had implemented these controls to minimize the risk for potential loss, theft, and diversion of pharmaceuticals.

We determined that more than 99 percent of veterans received their prescription packages within this CMOP's 10-day timeliness goal. This is calculated from the time the CMOP receives the prescription order to delivery of the package to the veteran. We also found that prescription-tracking information on VA's My HealtheVet allowed veterans who are VA patients to access their prescription information and track prescriptions filled by CMOPs.

Finally, the CMOP Program had quality metrics in place to monitor and address its performance. The Program met the core quality metrics during the period of July 1 through December 31, 2015. However, there were discrepancies with the accuracy of the data reported by the CMOPs to the National Office.

What We Recommended

We recommended the Under Secretary for Health ensure the CMOP Logistics Officer and Director or Associate Director review and sign all inventory adjustment documentation monthly and the CMOP National Office implement a mechanism to validate self-reported data to help ensure the reliability of its core quality metrics.

Agency Comments

The Under Secretary for Health concurred with our findings and requested closure of the recommendations, based upon the actions taken as a result of our audit. The documentation provided was sufficient to close the recommendations.

LARRY M. REINKEMEYER Assistant Inspector General for Audits and Evaluations

Lerry M. Reinkonger

VA OIG 15-05255-422 November 2, 2016

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INTRODUCTION

Objective

In September 2015, we received a congressional request to conduct a review of the prescription processing and delivery timeliness for the Veterans Health Administration's (VHA) Consolidated Mail Outpatient Pharmacy (CMOP) Program. We addressed the following questions from the request as part of a comprehensive national audit:

- 1. Are controls in place to help ensure pharmaceuticals are secure and safely processed?
- 2. Are prescription orders processed for delivery within the established time frames?
- 3. Is prescription-tracking information accessible and reliable to veterans?
- 4. Are quality metrics in place to monitor and address program performance?

CMOP Function

CMOP functions as a virtual extension of VA medical facility pharmacies by delivering prescription medications and supplies directly to veteran patients. The seven CMOPs operate under the direction of VHA's Pharmacy Benefits Management Service. The CMOP National Office is located in Leavenworth, KS, and provides fiscal and logistics oversight and support to the CMOPs. Appendix B lists all seven CMOP locations.

Using automated order processing and delivery systems, seven CMOPs support the 18 Veterans Integrated Service Networks by processing and delivering pharmaceuticals to veteran patients throughout the United States. The goal is to deliver medications and supplies to the patient within 10 calendar days of the provider or patient request.

Workload and Budget

In fiscal year (FY) 2015, VA reported spending nearly \$6.1 billion on pharmaceuticals and delivering about 145 million prescribed medication and supplies to nearly 5 million veterans. VA reported that of the \$6.1 billion, the CMOPs represented approximately \$2.8 billion of spending on pharmaceuticals in FY 2015.

RESULTS AND RECOMMENDATIONS

Finding 1 Controls Are in Place To Help Ensure Pharmaceuticals Are Secure and Safely Processed

VHA CMOPs had automated controls and pharmacists in place to help ensure pharmaceuticals were secure and safely processed. We evaluated the prescription processing at the seven CMOPs to access the sufficiency of physical security, inventory management, and pharmaceutical safety. Generally, adequate controls were in place and the CMOP Program provided reasonable assurance that pharmaceuticals were dispensed safely.

However, at one of seven CMOPs, the Logistics Officer and Director or Associate Director did not review and approve inventory adjustments from the individual pill-dispensing system as required by CMOP *Inventory Management and Control* (770-90-004-P) national policy issued October 21, 2015. The CMOP Director stated that because production staff cannot access the pills in this dispensing system, there was a minimal risk for theft. The controls that require a review and approval of all adjustments help minimize the risk for potential loss, theft, and diversion of pharmaceuticals.

Physical Security

CMOP After-Hour Access to Facility and Production Floor memo (NAT 00-015) dated December 27, 2013, requires that physical security must be continuously maintained at the facility and restricted areas. To comply with policy, CMOP directors limit the issuance of door keys, security cards, and numerical combination locks to only those employees who require access to the facility or restricted areas. Access controls include the use of a key card or personal identity verification (PIV) badge to enter the building and the restricted areas. Restricted areas include:

- Production areas that process prescriptions, dispense, verify, label, and pack pharmaceuticals for delivery
- Controlled substances storage areas
- Loading docks

We observed employees appropriately using PIV badges to access the building and restricted areas. During site visits to the CMOPs, we attempted to access restricted areas to test the effectiveness of CMOP controls. We used an OIG-issued PIV badge and a CMOP visitor key card to attempt access. Using either of these, we were unable to gain entry into the main entrance of the CMOP, loading docks, and production areas. Furthermore, we randomly selected CMOP employees to use their PIV badges to enter the restricted loading dock area to which they had not been provided access.

When employees attempted entry to the areas we had selected, their access was denied. As a result, we determined controls were working as designed.

To ensure physical security of the facilities, CMOPs are equipped with video surveillance systems. CMOPs' facility managers strategically placed cameras inside and outside the facilities. Cameras located inside were positioned in production, receiving, warehouses, and administrative areas. Surveillance cameras were also mounted on loading and unloading docks. The facility managers monitor the video surveillance system weekly to ensure proper operation while recording. In the event a security incident occurs, the Director, Associate Director, or Facility Manager has the ability to review the video recordings for the previous 30 days.

We reviewed recorded video from the different areas of the CMOPs including the production and receiving areas, loading docks, and storage areas for controlled substances. We concluded the video surveillance equipment worked properly and the placement of the cameras ensured maximum coverage of the monitored areas, both inside and outside the facilities.

Inventory Management

Inventory management controls included wall-to-wall quarterly inventories, and monthly inventory variance monitoring and reporting. Wall-to-wall inventories are a physical count of all the medication and supplies dispensed for patients at the CMOPs. Each CMOP completed the required quarterly wall-to-wall inventory. Monthly inventory variance monitoring and reporting provides assurance that procurement, inventory management, and dispensing activities are being monitored for accuracy. Monitoring also helps to detect product diversion within the CMOP for selected medications and supplies, such as controlled pharmaceuticals.

We reviewed the wall-to-wall and monthly inventory documentation and results that included initial counts, beginning inventory reports, recounts, and reconciliations. We found that inventory adjustments were reviewed at least monthly. For six of the seven CMOPs, the Logistics Officer and Director or Associate Director reviewed and approved all inventory adjustments and adjustment documentation monthly as required by CMOP *Inventory Management and Control* national policy.

For the one remaining facility, the Logistics Officer and Director reviewed adjustments completed by the logistics staff. However, adjustments from the individual pill-dispensing system were completed by production area employees and reviewed by a pharmacy supervisor. The Director stated that the potential risk for theft was minimal because production staff cannot access the pills in this system. The CMOP pharmacy technicians opened and emptied the manufacturers' pill bottles into large canisters. When filled, the canisters are locked and placed on the individual pill-dispensing system. The controls requiring the Logistics Officer and Director to review and approve

the adjustments help minimize the risk for potential loss, theft, and diversion of pharmaceuticals. During our site visit, the CMOP Logistics Officer and Director told us they plan to comply with policy by reviewing and approving individual pill-dispensing adjustments.

Pharmaceutical Safety

Controls were in place to ensure that pharmaceuticals were dispensed safely before delivery to the veteran. The CMOPs identified Quality Manufacturing Systems Incorporated (QMSI) as their production system and explained how the system works. The system directs prescription orders to the most effective production area for prompt, efficient filling. QMSI communicates with the software that controls the automated dispensing machines to ensure accuracy and safety. QMSI and the dispensing machines software use bar code technology, radio frequency identification, and numerical inventory location assignments to allow automated and independent product quality verification.

We observed that QMSI rejected bottles of medications when an incorrect weight was detected or when the bar code did not scan correctly. Furthermore, when an order was incorrectly scanned or incomplete, the system stopped production until action was taken. A supervisor was required to review and clear the error before the order could continue processing.

The production area cannot dispense medications and supplies without review and approval from a licensed pharmacist. Pharmacists are required to verify all prescriptions to ensure prescriptions are filled with the correct drug, the dosage and quantity are accurate, and the medication is for the appropriate patient. We observed pharmacists performing verification duties at the CMOPs, such as reviewing medications for damage and ensuring the associated directions for use are included with the medications. We determined that the controls were working as intended.

Conclusion

Controls over pharmaceuticals are essential for the CMOPs to help ensure veterans receive correct prescriptions, prevent unauthorized CMOP facility access, and reduce the risk of pilferage. Through observation of the CMOP facility, tests of the security controls, and review of the CMOPs inventories, we found controls were generally in place to adequately secure and safely process ordered prescriptions. It is essential that all CMOP staff fully comply with policies to help ensure continued safety and security of the pharmaceuticals at the CMOPs.

Recommendation

1. We recommended the Under Secretary for Health ensure the Consolidated Mail Outpatient Pharmacies' Logistics Officer and Director or Associate Director review all inventory adjustments and approve adjustment documentation monthly as required by CMOP *Inventory Management and Control* national policy.

Management Comments and OIG Response

The Under Secretary for Heath concurred with our finding and recommendation and requested closure of this recommendation based upon actions taken as result of our audit. The CMOP Director implemented a monthly process to review all inventory adjustments and approve adjustment documentation as required by CMOP *Inventory Management and Control* national policy.

The actions taken by the Under Secretary and the CMOP Director are responsive to the recommendation. The documentation provided was sufficient to close the recommendation.

Finding 2 Prescription Orders Are Processed for Delivery Within Timeliness Standards

We found that CMOPs processed and delivered pharmaceuticals within the CMOP Program established timeliness standards. Our review of prescription orders from July 1 through December 31, 2015 found that the CMOP Program met its delivery goal. In addition, we found that the CMOPs were adequately monitoring the movement of packages during the delivery process.

Prescription Order Processing and Delivery Timeline The overall goal of the CMOP Program is to deliver medications and supplies to the veteran within 10 calendar days of provider or patient request. Figure 1 shows the time frame for each process included in the 10-calendar day timeline for a CMOP mail outpatient prescription.

Timeline for a VA CMOP **Mail Outpatient Prescription Provider Orders Patient Receives** Medication/Supplies Medication/Supplies 12 to 48 Hrs 1 to 7 Calendar Days 1 to 24 Hrs 10 Hrs Delivery of Product Order Verification **CMOP Filling** to Patient by VAMC and Packing CMOP or CMOP Contractor > Mail Consolidator Delivery Vendor/Partner Transmission of Electronic Order to CMOP Goal: delivery to patient within 10 calendar days of provider or patient request

Figure 1. Timeline for a VA Mail Outpatient Prescription

Source: CMOP National Office, December 12, 2015

Metric for Filling and Packing Prescriptions Met We analyzed and reviewed the CMOP data and determined that the program met the 48-hour timeliness standard to fill and pack prescription orders for delivery to the veteran. We verified the data and determined that program average timeliness ranged between 33 to 41 hours to fill and pack prescription orders for delivery to the veteran from July 1 through December 31, 2015. After the CMOP completes the filling and packing of prescription orders, the packages are sent to the contractor's facility for processing.

Mail Contractor Meeting Processing Time Standards In September 2014, VA awarded a national contract to provide standardized services for mail processing to all CMOP locations. The new awardee began performing these services in April 2015.

The CMOP's performance work statement requires the contractor to process every package received from the CMOP within the same business day. We visited all seven mail contractor facilities, located within close proximity to the CMOP, and found that all packages were processed and released to delivery carriers by the end of the business day.

We also validated our observations by calculating the processing time for packages that CMOPs released to the contractor for delivery. Using data for the month of October 2015, we compared the difference between the date and time the CMOP completed the packages to the date and time the contractor released the packages to the delivery carrier. Based on our reviews, we confirmed that the contractor was meeting the requirement to process packages within the same business day as received from the CMOP.

Monitoring Prescription Packages The Contracting Officer's Representative (COR) at each CMOP told us that the current contractor's performance was satisfactory. The CORs also said that there was continuous communication with the contractor and that the contractor promptly addressed CMOPs' issues and concerns.

For example, while monitoring the web-based portal reports, the contractor and a CMOP COR told us that they had identified an issue in August 2015, which impacted delivery times in the northwest states of Oregon, Washington, and Idaho. Packages picked up by the postal service from the mail processing contractor took anywhere from 2 to 3 days to arrive at the local postal facilities. A manager working for the contractor stated that he believed the delivering timeliness was due to the ongoing realignment of regional postal facilities. As a result, in September 2015, the mail processing contractor began using a third-party delivery service to transport packages directly to the local postal facilities. The CMOP COR stated that this improved delivery timeliness of medication and supplies to veterans.

In addition, the mail processing contractor provides the CMOP with quality control reports to proactively monitor and evaluate delivery performance. The daily report describes steps taken to identify delays and to ensure package delivery to the veteran. The mail processing contractor uses a web-based portal to track mailed packages. CMOP and contractor staff have access to the portal and can request reports that assist in monitoring and tracking the status of packages.

¹ We used only the month of October because of the volume of packages included for all 6 months of the audit scope. Also, October was a representative month for prescription orders processed.

Overall CMOP Meeting 10-Day Timeliness Goal We determined that more than 99 percent of veterans received their prescription packages in less than or equal to CMOP's 10 day timeliness goal. This is calculated from the time the CMOP receives the prescription order to delivery of the package to the veteran. Using data for the month of October 2015, we found that about 9.3 of 9.4 million packages met the CMOPs 10-day timeliness goal for delivery. Only 53,132 (0.57 percent) of the 9.4 million packages did not meet the timeliness standard.

Conclusion

We determined that the CMOPs processed and delivered veterans' medication packages within their established performance timeliness standards. Therefore, we did not make any recommendations.

Finding 3 Prescription Tracking Information Is Accessible and Reliable to VA Patients

A veteran who is a VA patient can register for a My HealtheVet (MHV) account to access their prescription tracking information. We verified the tracking information was accessible and reliable to veterans for those prescription orders we reviewed. Also, our review determined tracking information was reported accurately in veterans' MHV accounts.

My Healthe Vet

MHV is a web portal with an extensive health information library, information about VA benefits, and a veteran's personal health record. It also includes electronic services, such as online prescription refill, prescription tracking. MHV is an internet-based personal health resource that enables veterans to access these services 24 hours a day from anywhere. Veterans who register on the web portal can store and access their health profile, which includes family and personal health histories, medications, immunizations, allergies, insurance information, and more. As of September 2015, VA reported 2.8 million VA patients had a registered MHV account.

To access the prescription tracking information in MHV, the veteran and/or VA patient must elect and register for an advanced or premium account. The prescription-tracking feature in MHV allows users to access and view information, including when medications and supplies were shipped and the expected delivery date. MHV includes three account types: basic, advanced, and premium.

- Basic account. Provides limited access to enter information and use journals and other tools to track vital statistic measures. However, no access is provided for prescription tracking or personal information located in VA or Department of Defense systems.
- Advanced account. Provides access to view limited information in VA or Department of Defense records. For access, the user must enter personal registration information, such as date of birth and social security number. However, access to MHV's prescription tracking is only available to VA patients.
- <u>Premium account.</u> Provides VA patients access to all the features available in MHV, including prescription-tracking features.

Review of Tracking Information Prescription tracking information is electronically transmitted each night from the contractor's system to MHV. We obtained a random sample of 100 prescription orders to ensure the tracking information properly transferred into veterans' MHV accounts. We reviewed the sample prescription orders to determine if tracking numbers and delivery addresses' cities and states matched the information included in the websites for the

delivery carriers. We determined that tracking information included in our sample was accurate and enabled sampled veterans to track delivery of their medications and supplies.

The National Web Application is a tool used to communicate between the VA medical facility and CMOP staff. The VA medical facility staff use the National Web Application to enter received issues from veterans regarding prescriptions received from CMOP. We reviewed the National Web Application to identify MHV complaints or other issues submitted by veterans. We found no incidents relating to MHV, and the Director of VHA's Veterans and Consumers Health Informatics Office told us they have not received any complaints.

Conclusion

Prescription tracking information was accessible and reliable. MHV allowed veterans who are VA patients with advanced or premium accounts to access their prescription information and track prescriptions filled by CMOPs. Therefore, we did not make any recommendations.

Finding 4 Quality Metrics Are in Place But Data Reliability Can Be Improved

The CMOP Program had quality metrics in place to monitor and address its performance. The Program met its core quality metrics during the period of July 1 through December 31, 2015. However, there were discrepancies with the accuracy of the data reported by the CMOPs to the National Office. This occurred because the CMOP National Office did not validate the data that each CMOP self-reported. As a result, the CMOP National Office cannot ensure the data used to determine the core quality metrics are accurate and reliable.

Core Quality Measures The CMOP Program has five national quality measures to help monitor adverse events. Adverse events are defined as an incident, injury, or other adverse occurrence directly associated with services provided within the jurisdiction of a CMOP. Each type of adverse event is categorized as one of five quality measures. Three of five measures—wrong patient, wrong product, and wrong quantity—are identified as core quality measures because they have a more direct impact on veterans. This table describes the CMOP Program's five national quality measures.

Table. CMOP Program's National Quality Measures

Quality Measure	Description
Wrong Patient	Package labeled with an incorrect patient name
Wrong Product	Unordered product mailed to a patient
Wrong Quantity	Unordered quantity of product mailed to a patient
Operational Failure	Package with incorrect or missing documents; expiration date issue; damaged due to insufficient packing; correct product with wrong national drug code; missing or loose cap; loose contents in package; patient label issue; product missing from order; product temperature issue; safety cap issue; unlabeled product; or miscellaneous failures
Systems Delivery Failure	Delivered package with incorrect addresses; mail consolidator error; damaged or compromised by delivery carrier; misdelivered; or package not received by veteran within 7 calendar days of date it was packed

Source: CMOP FY 2015 Quality Measures

CMOP provides electronic prescription dispensing data to the appropriate VA medical facility or clinic. Veterans must contact the VA medical facility directly to report adverse events related to mail order prescriptions. The VA medical facility pharmacy staff enter adverse events into the National Web Application to advise CMOPs about incidents related to veterans' prescriptions. Once advised, CMOP staff investigate and make a determination based on a review of the evidence collected and the validity of the event. After the incident has been determined an adverse event, the CMOP staff electronically report it to the CMOP National Office located in Leavenworth, KS.

Discrepancies in Reported Incidents

We compared incidents reported in the National Web Application to those reported to CMOP National Office for July 1 through December 31, 2015. We also reviewed individual incidents from the National Web Application to ensure that errors were valid. Based on our review and analysis of the CMOP Program metrics reports, the CMOPs met the core quality metrics. However, we found that incidents reported on the National Web Application did not always agree with those reported by CMOPs to the National Office. These following examples highlight these discrepancies.

- A CMOP did not report seven wrong quantity incidents that were substantiated during July 2015. Instead, the CMOP reported zero wrong quantity incidents to the National Office. According to the CMOP Quality Assurance Manager, this occurred because of a typographical error when manually transferring data from an internal spreadsheet to the CMOP National Office spreadsheet.
- Another CMOP did not report seven wrong quantity substantiated incidents for July 2015. Instead, the CMOP reported only two of these incidents to the National Office. According to the CMOP Quality Assurance Manager, this occurred because the facility reported the incidents to the National Office in the month they were closed, instead of the month the adverse event was reported on the National Web Application. The CMOP National Quality Manager told us that incidents should be reported during the month received.

Overall, these discrepancies did not affect the CMOP Program performance. Based on our analysis, the CMOP Program would have met the core quality measures for July 2015 had these incidents been reported correctly. These discrepancies potentially could have been identified if the National CMOP Office verified the accuracy of the adverse event data received by the CMOPs. According to the CMOP National Office Quality Assurance Manager, the data are not verified or validated for accuracy once they are received because CMOPs are responsible for the accuracy of the information. However, Government Accountability Office Standards for Internal Control in the Federal Government requires management to design controls aimed at validating the propriety and integrity of both the entity and individual

performance measures and indicators. Without controls in place to validate the self-reported data, the CMOP National Office cannot ensure the data used for its core quality metrics are accurate and reliable.

Conclusion

The discrepancies with the accuracy of the data reported by the CMOPs to the National Office we identified were not systemic and did not affect the CMOP Program meeting its performance metrics. However, inaccurately reporting incidents could affect CMOPs not meeting their core quality measures. Strengthening reporting controls through data validation will help ensure reported metrics are accurate and complete.

Recommendation

 We recommended the Under Secretary for Health ensures Consolidated Mail Outpatient Pharmacy National Office implements a mechanism to validate self-reported data to ensure the reliability of its core quality metrics.

Management Comments and OIG Response

The Under Secretary for Heath concurred with our finding and recommendation and requested closure of this recommendation based upon actions taken as result of our audit. The CMOP National Office implemented a policy that requires each CMOP to reconcile the data the local facility reports against a report generated by the CMOP National Office.

The actions taken by the Under Secretary and the CMOP National Office are responsive to the recommendation. The documentation provided was sufficient to close the recommendation.

Appendix A Background

CMOP Established

In 1946, VA became the first organization in the United States to provide medications for its patients using a mail delivery service through individual VA medical facilities. The mission of the CMOPs is to provide accurate, dependable, and timely mail-out pharmacy service as a part of pharmaceutical care to VA patients and medical center customers.

During the 1970s and 1980s, consolidation of mail prescription workloads from multiple VA medical facilities into central operations was initiated on a limited basis. In 1994, the CMOP at Leavenworth, KS, began processing high volume mail prescription using an integrated, automated dispensing system. Since then, the VA has expanded the program to include an additional six facilities.

Prescription Process

The CMOP uses state-of the-art technology and centralizes the workload while maintaining a continuum of care that is invisible to the patient. Figure 2 describes the prescription process from physician order through delivery to patient.

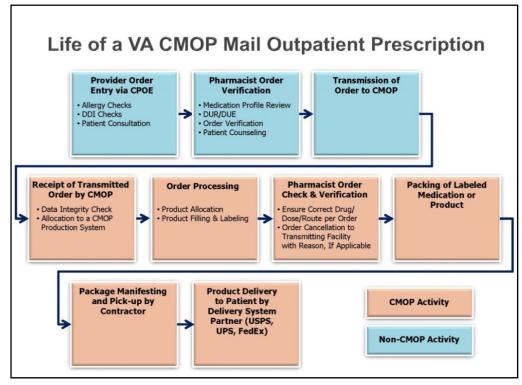


Figure 2. Prescription Processing at the CMOP

Source: CMOP National Program Office.

Image Acronyms: CPOE: Computer Physician Order Entry; DDI: Drug - Drug Interaction; DUR/DUE: Drug Utilization Review/Drug Utilization Evaluation; USPS: United States Postal Service; UPS: United Parcel Service

The mail processing contractor provides these services:

- Package pickup from CMOP facilities
- Pre-payment and affixing postage or delivery charges to packages
- Transfer of packages to the United States Postal Service or third-party delivery carrier
- Timely and controlled management of packages
- Administrative services that ensure delivery of packages, tracking, reporting, and accurate billing

CMOP Awards

In a 2015 independent study conducted by J.D. Power, the CMOP received the highest customer satisfaction score among participating mail-order pharmacies. This annually conducted study measures satisfaction among consumers who filled a mail-order prescription within the last 90-days. Veterans were asked to rate VA on cost competitiveness, delivery, ordering process, and customer service experience. VA also led the mail-order pharmacy industry nationwide from 2010 to 2014.

Previous Reviews

VA OIG conducted an audit of VA's CMOPs in 2009.² The audit assessed if CMOPs 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. We found that inventory management controls used to account for and prevent diversion of non-controlled pharmaceuticals could be further improved and that inventory system access controls needed strengthening.

² Audit of VA's Consolidated Mail Outpatient Pharmacy Inventory Accountability Report No.08-02730-133, May 28, 2009

Appendix B Scope and Methodology

Scope

We conducted our audit work from October 2015 through July 2016 to address a congressional request to review prescription processing and delivery timeliness for VHA's CMOP Program. To accomplish the audit objective, we conducted site visits at all seven CMOP facilities located in:

- Charleston, SC
- Chelmsford, MA
- Dallas, TX
- Hines, IL
- Leavenworth, KS
- Murfreesboro, TN
- Tucson, AZ

Methodology

We reviewed and analyzed applicable policies, procedures, and guidelines related to the CMOPs pharmaceutical processing, delivery timeliness, and quality assurance. We conducted interviews with directors, logistics officers, pharmacists, and quality assurance managers from all the CMOPs, including the CMOP National Office to obtain information on the Program. We also conducted site visits and interviews at all the contractor's mail processing facilities. We reviewed applicable program controls to determine the adequacy of internal controls as they relate to the audit objective.

Security and Safety Controls We observed all seven CMOP facilities access and video surveillance systems. We reviewed documentation for wall-to-wall inventories, monthly inventory variance monitoring and reporting, and inventory adjustments completed from July 1 through December 31, 2015. We also observed and reviewed prescription verification procedures to determine the adequacy of safety controls.

Delivery Time Frames

We obtained and analyzed relevant program data to assess CMOP Program's timeliness of prescription processing and delivery. We conducted analysis of the universe of mail prescription packages the CMOPs shipped during the month of October 2015, totaling about 9.4 million packages. We used only the month of October because of the volume of packages included for all 6 months of the audit scope. Also, October was a representative month of prescription orders processed. From our data analysis, we were able to verify shipping and performance data included in the CMOP Program's Core Metrics and Delivery Performance Reports.

Once the CMOP Program data and reports were verified as accurate, we used these data to review and analyze the entire scope of packages processed and

shipped from July 1 through December 31, 2015, to determine if CMOPs were meeting timeliness standards.

We visited the CMOP and mail processing facilities to learn the responsibilities and procedures used to process, sort, and ship the CMOP's prescription packages to the veterans. We also evaluated package processing timeliness at the mail processing contractor's facilities and assessed whether the contractor was meeting the obligation that all received CMOP packages are sent out to mail carriers within the same day.

My Healthe Vet

We obtained a random sample of 100 prescription records containing tracking information from MHV staff to determine if prescription-tracking information was accessible and reliable to veterans. We conducted interviews with the directors and staff of the CMOP National Office and VHA Veterans and Consumers Health Informatics Office to gain an understanding of how veterans' prescription tracking information flows from CMOP to MHV systems and how veterans gain access to MHV.

Quality Metrics

We reviewed and compared incidents reported on the CMOP National Quality Measures Dashboard, the CMOP Program's Data Collection Log, and the National Web Application for July 1 through December 31, 2015, to determine whether quality metrics were in place to monitor and address CMOP Program performance. We also reviewed individual incidents from the National Web Application to ensure that there were valid reasons for reported errors that were not substantiated.

Fraud Assessment

We did not identify any instances of fraud during this audit. The audit team assessed the risk that fraud, violations of legal and regulatory requirements, and abuse could occur during this audit. The audit team exercised due diligence in staying alert to any fraud indicators by taking actions, such as:

- Reviewed previous investigations that were a representation of fraud or theft cases involving CMOP facilities and CMOP prescriptions.
- Determined if CMOP management assessed and responded to fraud risk as it pertains to the Program.

Data Reliability

In performing our audit work, we relied on computer-processed data obtained from CMOP's Central Database and program created spreadsheets. We assessed the accuracy of these CMOP data. We used the Statistical Analysis System server to provide a summary of the data analysis to evaluate package processing timeliness at the mail consolidator's facility and for the CMOPs for the month of October. We compared our data analysis conducted on raw data from the CMOP's Central Database with the National CMOP Program Office's Delivery Performance and Consolidated Core Metrics Reports to determine and verify if data in these reports were reliable.

We also compared data from CMOP's Central Database for the National Web Application to CMOP's National Data Collection Log and Dashboard to determine completeness and accuracy of data reported for core quality metrics. Finally, we assessed the completeness and accuracy of CMOP-provided spreadsheets, by reviewing for missing and duplicate records and data outside of scope, to determine data reliability. Based on our reliability assessments, we concluded that these data were appropriate and sufficient for the purposes of our audit.

Government Standards

Our assessment of internal controls focused on those controls relating to our audit objectives. We conducted this performance audit in accordance with generally accepted government auditing standards. These 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 objective. The evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Appendix C Management Comments

Department of Veterans Affairs Memorandum

Date: August 24, 2016

From: Under Secretary for Health (10)

Subject: Office of Inspector General Draft Report, Audit of Consolidated Mail Outpatient Pharmacy

Program (CMOP) (2015-05255-R4-0029) (VAIQ 7722799)

To: Assistant Inspector General for Audits and Evaluations (52)

- 1. Thank you for the opportunity to review the draft report. I concur with the report, the findings, and the recommendations.
- 2. We are pleased that you highlighted in the report that more than 99 percent of Veterans received their prescription packages in less than or equal to CMOP's 10 day timeliness goal. Thank you for acknowledging that prescription tracking information was accessible and reliable.
- 3. The CMOP system has maintained the highest customer satisfaction score for the entire mail order industry for the past 6 years based on customer satisfaction surveys completed by J.D. Power. For fiscal year 2016, the CMOP system is on track to dispense over 119 million prescriptions to our Veterans. The CMOP system processes approximately 80 percent of the VA outpatient prescriptions.
- 4. The CMOP system developed a process through My HealtheVet to enable Veterans to track their prescription deliveries and to see a photo of the actual medication dispensed by CMOP.
- 5. Developing an action plan in response to OIG's recommendations provides the CMOP program with an opportunity to make the program stronger.
- 6. If you have any questions, please email Karen Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRSAction@va.gov.

(original signed by:)

David J. Shulkin, M.D.

Attachment

For accessibility, the format of the original documents in this appendix has been modified to fit in this document.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA) Action Plan

Office of Inspector General (OIG) Draft Report: Audit of VHA's Consolidated Mail Outpatient Pharmacy (CMOP) Program (2015-05255-R4-0029) (VAIQ 7722799)

Date of Draft Report: July 27, 2016

Recommendations/ Status Completion Date

Actions

<u>Recommendation 1</u>: We recommended the Under Secretary for Health ensures the Consolidated Mail Outpatient Pharmacies' Logistics Officer and Director or Associate Director review all inventory adjustments and approve adjustment documentation monthly as required by CMOP Inventory Management and Control national policy.

VHA Comments: Concur

The OIG report indicated that 6 of the 7 CMOPs were completing the review of inventory adjustments but that the Tucson CMOP did not have such a process in place. On July 9, 2016, the Tucson CMOP established and implemented a monthly process to review all inventory adjustments and approve adjustment documentation as required by CMOP Inventory Management and Control national policy.

To close this recommendation, VHA will provide the components and verification of the review.

Status: Complete Completion Date: July 2016

Recommendation 2: We recommended the Under Secretary for Health ensures Consolidated Mail Outpatient Pharmacy National Office implements a mechanism to validate self-reported data to ensure the reliability of its core quality metrics.

VHA Comments: Concur.

On July 11, 2016, CMOP implemented a policy that requires each CMOP to reconcile the data the local facility reports against a report generated by the CMOP National Office. The results of these reconciliations will be collected and reviewed by the CMOP National Quality Manager with any discrepancies reported to the CMOP Executive Leadership Council for action and follow up.

To close this recommendation, VHA will provide the results of the review.

Status: Complete Completion Date: July 2016

Appendix D OIG Contact and Staff Acknowledgments

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