The Honorable Henry Kerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

Re: Office of Special Counsel File No. DI-19-1176

Dear Mr. Kerner:

I am responding to your April 9, 2019, letter regarding allegations made by a whistleblower, who alleged that employees at the Department of Veterans Affairs (VA) Southern Nevada Healthcare System, engaged in conduct that may constitute a violation of law, rule, or regulation; engaged in gross mismanagement; or created a substantial and specific danger to public health.

The Executive in Charge, Office of the Under Secretary for Health, directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. We investigated this matter from June 24-27, 2019 and substantiated three of the whistleblower’s allegations. We make eight recommendations to the VA Southern Nevada Healthcare System and one recommendation to the Veterans Health Administration.

Thank you for the opportunity to respond.

Sincerely,

Robert L. Wilkie

Enclosure
DEPARTMENT OF VETERANS AFFAIRS

Washington, DC

Report to the
Office of Special Counsel
OSC File Number DI-19-1176

VA Southern Nevada Healthcare System
Las Vegas, Nevada

Report Date: September 12, 2019

TRIM 2019-C-17
Executive Summary

The Office of the Secretary, Department of Veterans Affairs (VA), received a referral from the Office of Special Counsel (OSC) for formal resolution. Subsequently, the Executive in Charge, Veterans Health Administration (VHA), directed that the Office of the Medical Inspector assemble and lead a VA team to investigate allegations concerning the VA Southern Nevada Healthcare System located in Las Vegas, Nevada. The whistleblower, a clinical pharmacist, alleged that Las Vegas employees engaged in conduct that may constitute violation of a law, rule, or regulation; engaged in gross mismanagement; or created a substantial and specific danger to public health or safety. We conducted a site visit to Las Vegas on June 24–27, 2019.

Specific Allegations of the Whistleblower

1. VASNHS’s mail order prescription system is delaying patients’ access to prescription medications.

2. VASNHS’s mail order prescription system is resulting in the destruction of thousands of dollars’ worth of prescription drugs.

3. VASNHS’s mail order prescription system is causing the VA to expend significant resources replacing, processing, and destroying returned prescriptions.

We substantiated allegations when the facts and findings supported that the alleged events or actions took place and did not substantiate allegations when the facts and findings showed the allegations were unfounded. We were not able to substantiate allegations when the available evidence was insufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of the findings, we make the following conclusions and recommendations:

Conclusion(s) for Allegation 1

- We substantiate that Las Vegas’ mail order prescription system has caused delays in Veterans’ access to prescription medications.

- Las Vegas’ requirement for signatures for all schedule II narcotics is contrary to guidance in VHA Directive 1108.01, Controlled Substances Management. This policy results in delays in the delivery of controlled substances when patients are not home to sign for the medications.

- Pharmacy staff were unaware of VHA policies and standard operating procedures (SOP). This resulted in both delaying the delivery of some medications and increasing the possibility of narcotic diversion due to recognizable differences between mailing procedures for different categories of medications.
• We reviewed the Veterans’ records provided by the whistleblower and found one (Veteran J) that may represent a delay in care and possible worsening of condition.

• We found no evidence that consolidation of pharmacy services caused a significant negative impact on the delivery of medications to Veterans.

**Recommendation(s) to Las Vegas**


2. Cease mailing procedures that increase chances of diversion, as discussed in the June 27, 2019, Exit Briefing.

3. Instruct management to directly supervise a complete review of ongoing competencies for all pharmacy staff, including reviews of applicable SOPs and other guidance documents and document completion.

4. Conduct clinical quality reviews of cases involving Veterans J, L, and M.

**Recommendation(s) to VHA**

1. Direct that the Murfreesboro Consolidated Mail Outpatient Pharmacy (CMOP) use mailers identical to those used by Tucson CMOP to decrease the potential for narcotic diversion.

**Conclusion(s) for Allegation 2**

• **We substantiate** that Las Vegas’ mail order prescription system results in the destruction of thousands of dollars in medications. However, national policy requires the destruction of medications that are returned through the mail unless the medications can be re-mailed to the same patient. The cost for returned and destroyed medications compared to medications provided by mail order is proportionately very small.

• The procedure used for documenting and tracking returned medications allows for the possibility of diverting narcotics prior to destruction.

• There is no clear mechanism for the provider to be notified in the event the Veteran fails to receive prescribed medications. We have concerns that providers may determine that prescribed medications are ineffective, rather than unavailable to the Veteran and change prescriptions based on this information.

**Recommendation(s) to Las Vegas**

5. Comply with VHA Directive 1108.01 and return all narcotics to stock to ensure secure tracking of these medications.
6. Use the 'return to stock function' in the Veterans Information Systems and Technology Architecture (VistA) for accountability tracking of all medications returned in the mail. This does not mean adding these items to inventory for re-dispensing.

7. Develop procedures to ensure the provider is notified when Veterans fail to receive their prescribed medications.

Conclusion(s) for Allegation 3

- We substantiate that Las Vegas' mail order prescription system is causing VA to expend significant resources replacing, reprocessing, and destroying medications. However, this finding is related to the methods used by Las Vegas to mail schedule II narcotics, not from excessive workload or loss rates from the mail order system in general.

Recommendation(s) to Las Vegas

8. Adopt standard packaging used by the CMOPs and lower mail rates for routine medication delivery from the Las Vegas pharmacy.

VI. Summary Statement

We have developed this report in consultation with other VHA and VA offices to address OSC's concerns that Las Vegas may have violated a law, rule, or regulation; engaged in gross mismanagement; or created a substantial and specific danger to public health or safety. VHA Human Resources has examined personnel issues to establish accountability, and the National Center for Ethics in Health Care has provided a health care ethics review. We found violations of VHA policy at Las Vegas, but none resulting in substantial and specific danger to public health or safety.

1 VistA is the nationwide Veterans clinical and business information system of VA. VistA consists of 180 applications for clinical, financial, and administrative functions, all integrated within a single database, providing a single, authoritative source of data for all Veteran-related care and services. Congress mandates that VA keep Veterans' health records in a single, authoritative, lifelong database, which is VistA.
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I. Introduction

The Office of the Secretary, Department of Veterans Affairs (VA), received a referral from the Office of Special Counsel (OSC) for formal resolution. Subsequently, the Executive in Charge, Veterans Health Administration (VHA), directed that the Office of the Medical Inspector (OMI) assemble and lead a VA team to investigate allegations concerning the VA Southern Nevada Healthcare System located in Las Vegas, Nevada. The whistleblower, a clinical pharmacist, alleged that Las Vegas employees engaged in conduct that may constitute violation of a law, rule, or regulation; engaged in gross mismanagement; or created a substantial and specific danger to public health or safety. We conducted a site visit to Las Vegas on June 24-27, 2019.

II. Facility Profile

The Las Vegas VA Medical Center, part of Veterans Integrated Service Network (VISN) 21, opened in August 2012. It is a one million square foot medical center, located in North Las Vegas. Las Vegas is a 1b High Complexity facility. Initially equipped to serve 90 inpatients, and 120 extended and skilled nursing care patients, it now also provides numerous primary and specialty care services, including a 20-bed inpatient psychiatric ward that opened in 2013. Today, the medical center services more than 61,000 patients who make more than 680,000 outpatient visits per year. Las Vegas’ Veteran population has grown more rapidly than projections, including an increase in Operations Enduring Freedom, Iraqi Freedom and New Dawn (OEF/OIF/OND) Veterans by 10.5 percent.

III. Specific Allegations of the Whistleblower

1. VASNHS’s mail order prescription system is delaying patients’ access to prescription medications.

2. VASNHS’s mail order prescription system is resulting in the destruction of thousands of dollars’ worth of prescription drugs.

3. VASNHS’s mail order prescription system is causing the VA to expend significant resources replacing, processing, and destroying returned prescriptions.

IV. Conduct of Investigation

The VA team conducting the investigation consisted of two Senior Medical Investigators, the Special Advisor to the Principal Deputy Under Secretary for Health, and a Clinical Program Manager, all from OMI; a Chief of Pharmacy, Salisbury VA Medical Center; and a Human Resources (HR) Officer, Miami VA Medical Center. We reviewed relevant policies, procedures, professional standards, reports, memos, and other documents listed in Attachment A. We toured Las Vegas’ Outpatient Pharmacy.

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2 VHA medical centers that are 1b facilities have a medium-high volume, high risk patients, many complex clinical programs, and medium-large research and teaching programs.
mail distribution area at the main facility, and the location of the former satellite pharmacy at the Southwest Primary Care Clinic, and held entrance and exit briefings with leadership.

We initially interviewed the whistleblower via teleconference on May 14, 2019, and in person on June 25, 2019. We also interviewed the following staff:

- Primary Care Providers (3)
- Pharmacy Leadership (4)
- Chief of Staff
- Pharmacist (4)
- Pharmacy Technician (5)
- Chief Financial Officer
- Assistant Financial Officer
- Chief of Quality, Safety, and Value
- Patient Safety Manager

V. Findings, Conclusions, and Recommendations

Allegation 1

VASNHS’s mail order prescription system is delaying patients’ access to prescription medications.

Background

VHA Directive 1108.07, Pharmacy General Requirements, dated March 10, 2017, states that pharmacy managers are responsible for ensuring that resources allocated to the Pharmacy Service are being utilized in a manner that delivers maximum benefit to patients and guarantees safety, proper medication use, and the delivery of clinical care that closes gaps in any unmet patient needs. Pharmacy managers are required to ensure operational efficiencies, which include the use of centralized and remote prescription processing.

VHA uses the Consolidated Mail Outpatient Pharmacy (CMOP) system as the mail order prescription processing solution, which is regionalized to provide services to specific geographic areas. VHA Handbook 1108.05, Outpatient Pharmacy Services, states that pharmacy leaders are financial stewards responsible for operational efficiencies; namely, limiting routine fills at the pharmacy outpatient window to reduce patient wait times, limiting the number of outpatient pharmacy dispensing sites within the VA medical facility, centralizing staff in one location where possible, and establishing local contracts for retail pharmacy dispensing for starter supplies and urgent medications, to reduce the cost of inventory, space, and staff at community-based outpatient clinics (CBOC). Las Vegas consolidated four primary care pharmacy locations into the main facility, in 2016, in accordance with this recommendation.
VHA Directive 1108.01, *Controlled Substances Management*, dated May 1, 2019, states that only schedule III-V narcotics can be filled by the CMOP. Controlled substances (which includes both narcotics and other medications such as stimulants, etc.) must be maintained in a limited access area such as a vault to increase security. The local facility must fill schedule II narcotics. Mailed packages containing controlled substances cannot have any annotation on the shipping label that identifies the contents. In the event that a Veteran or other authorized representative picks up the controlled substance before leaving the VA medical facility, following an admission or outpatient appointment, Pharmacy Service staff must verify the identity of the person (using photo identification) and a signature is required for release of the medication.

**Findings**

We reviewed the procedures Las Vegas uses for mailing prescriptions to Veterans and found three different locations from which medications are mailed, depending on the type of medication. The CMOP in Tucson, Arizona, supplies medications for non-controlled medication refills and uses Las Vegas’ address as the return address for non-deliverable packages. The CMOP in Murfreesboro, Tennessee, provides schedule III-V narcotics for Las Vegas and uses Las Vegas’ address as the return address for non-deliverable packages. Schedule II narcotics and high-value medications (e.g. HIV medications) are mailed directly from Las Vegas.

Medications that are returned as undeliverable from either CMOP location are received in the Las Vegas mail room and retrieved daily by the controlled substance pharmacy technician. During our site visit, we went to the mail room and observed approximately 20 returned medication packages awaiting pick-up by the pharmacy. Mail room personnel indicated that this was a high number for a day. After retrieving the mail, the controlled substance vault pharmacy technician returns to the pharmacy and sorts it into regular correspondence, non-controlled, and controlled substances. Non-controlled substances go to pharmacy technicians assigned to the call center, and controlled substances are returned to the vault. There is no documentation on the total number of medications returned via mail; however, staff we interviewed stated that this varied between 5 and 20 medication returns daily.

The process for determining which medications were controlled versus non-controlled varied. Some vault technicians stated that they opened the packages to determine what was inside, but most stated that they could tell which were controlled medications by the packaging. Staff in the mail room also indicated they could tell the difference between packages containing controlled and non-controlled medications. Obvious differences in packaging increase the chances of diversion of these medications — a violation of VHA Directive 1108.01. We also observed these differences, which we shared with both pharmacy and facility leadership. Specific details regarding the packaging are not included in this report for security reasons.

Las Vegas requires a signature for receipt of controlled substances in the mail; however, the Murfreesboro CMOP does not as there is no VHA requirement. According to pharmacy leadership, the rationale behind this policy is to manage Veterans with a
history of claiming non-receipt or missing narcotics from mail orders. When questioned about the number of Veterans exhibiting this behavior, staff admitted that there were no tracked metrics, but the number was very low. One manager indicated that he believed the Drug Enforcement Agency (DEA) required signatures on schedule II narcotics; however, he could not produce the source document.

We reviewed the DEA Diversion Control Division Web site. On its Resources pages, title 21 Code of Federal Regulations § 1301.74(e), states:

“When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.... In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.”

We note that VHA Directive 1108.01 requires a signature to pick up narcotics from the pharmacy window but makes no reference to such a requirement for mailed narcotics. The Las Vegas Veteran population is approximately 14 percent OEF/OIF/OND Veterans, who are younger and more likely to be employed, and away from home during normal mail delivery hours. In the event that a Veteran or family member is unable to sign for the schedule II narcotics mailed from Las Vegas, the package is returned to the post office with a note for the Veteran to retrieve it there during normal business hours. Veterans with mobility and transportation issues may also be affected by this policy of requiring signatures. In the event the medication is not signed for, or picked up within a few days, the post office returns the package to Las Vegas for resolution. In some cases, Veterans choose to go to the Las Vegas pharmacy and pick up the medication from the window following failed delivery attempts. Medications other than narcotics not retrieved by the Veteran are processed for destruction after 30 days. This protocol will be discussed under Allegation 2.

Delays did occur sporadically and were addressed on a case-by-case basis. For example, narcotic prescriptions have specific start and stop dates, and schedule II narcotics are only dispensed in 30-day quantities. Although Veterans can request refills up to 10 days in advance, new prescriptions are not processed until the next dispensing is due and the prescription will not be dispensed until the due date. The timing of the mail-out date considers the time needed to mail the medication. The desired outcome is that the medication arrives on the same day the previous prescription runs out. In instances in which the medication runs out before delivery, Veterans must contact their ordering provider for a bridge prescription—a limited supply of the medication to cover his/her need until delivery—which can be retrieved at the Las Vegas pharmacy window.

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4 Ibid.
The whistleblower indicated that because of the closing of pharmacy locations in 2016 at the four CBOCs, to consolidate pharmacy services in the main hospital, Veterans suffered due to issues with the mail order pharmacy system. He provided 14 Veteran records from Calendar Year 2017 to present, alleged to have been affected by delays in receiving medications. We present a review of these records in Attachment B.

In compliance with VHA Handbook 1108.05, *Outpatient Pharmacy Services*, Las Vegas consolidated pharmacy services at the main facility to increase efficiency. We interviewed Las Vegas leadership involved in the decision to consolidate and found that each of the four primary care clinic pharmacies required two pharmacists and one pharmacy technician. The workload at each facility was approximately 70-100 prescriptions per day. The main pharmacy requires that each pharmacist completes 400 prescriptions per day significantly more than the 35-50 previously filled per pharmacist in the primary care clinics. Before the consolidation, if one of the staff members in the primary care pharmacies took annual or sick leave, the main pharmacy would have to cover that pharmacy, reducing staffing at the main pharmacy.

During this same period, Las Vegas experienced much greater-than-expected growth, which required more pharmacy support at the main facility. Mandated expansion of clinic hours under VHA Directive 2013-001 also increased staffing requirements for pharmacy services.\(^5\) Closure of the primary care pharmacies eliminated the need to recruit additional personnel for the main pharmacy and negated hiring additional staff at the primary care pharmacies to cover extended hours. These positions were filled using existing staff at the primary care pharmacies, avoiding approximately $1.5 million in additional personnel costs. Shifting prescription delivery to the CMOP, based upon costs from Fiscal Year (FY) 2015, saved $9.98 per prescription (the average cost over four primary care pharmacies amounted to $23.27 while the average cost for CMOP prescriptions was $13.29). Additionally, there were limited medications available at each primary care pharmacy, and Veterans still had to either receive mail order prescriptions or travel to the main hospital for service. After closure of the primary care clinic pharmacies, Las Vegas implemented a contract pharmacy service for high-volume medications that can be picked up at a local pharmacy. This formulary is limited, however, and Veterans still occasionally travel to the main facility or pay for the medications out-of-pocket if they choose to do so.

We reviewed CMOP utilization from 2016 to present and found that the primary care pharmacy closures corresponded with increased CMOP utilization, as well as a general Veteran population increase. At the time of our review, the two CMOPs used by Las Vegas had an average processing time of less than 3 days for FY 2019, as of June 2019 (2.82 calendar days from Murfreesboro and 2.43 days from Tucson). There is no established standard for delivery times, but they are monitored for any deviations and compared to previous performance.

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\(^5\) VHA Directive 2013-001, *Extended Hours Access for Veterans*, January 9, 2013, required that each VHA medical center and clinic treating more than 10,000 unique Veterans per year must provide access to a full range of Primary Care Services, including clinical support services offered during regular hours such as pharmacy that extend beyond regular business hours at least once on weekdays and once every weekend.
Conclusion(s) for Allegation 1

- We substantiate that Las Vegas’ mail order prescription system has caused delays in Veterans’ access to prescription medications.

- Las Vegas’ requirement for signatures for all schedule II narcotics is contrary to guidance in VHA Directive 1108.01 Controlled Substances Management. This policy results in delays in the delivery of controlled substances when patients are not home to sign for the medications.

- Pharmacy staff were unaware of VHA policies and standard operating procedures (SOP). This resulted in both delaying the delivery of some medications and increasing the possibility of narcotic diversion due to recognizable differences between mailing procedures for different categories of medications.

- We reviewed the Veterans’ records provided by the whistleblower and found one (Veteran J) that may represent a delay in care and possible worsening of condition.

- We found no evidence that consolidation of pharmacy services caused a significant negative impact on the delivery of medications to Veterans.

Recommendation(s) to Las Vegas


2. Cease mailing procedures that increase chances of diversion, as discussed in the June 27, 2019, Exit Briefing.

3. Instruct management to directly supervise a complete review of ongoing competencies for all pharmacy staff, including reviews of applicable SOPs and other guidance documents and document completion.

4. Conduct clinical quality reviews of cases involving Veterans J, L, and M.

Recommendation(s) to VHA

1. Direct that the Murfreesboro CMOP use mailers identical to those used by the Tucson CMOP to decrease the potential for narcotic diversion.

Allegation 2

VASNHS’s mail order prescription system is resulting in the destruction of thousands of dollars’ worth of prescription drugs.
Background

VHA Directive 1108.01, *Controlled Substances Management*, states that in the event of a non-deliverable package containing narcotics, pharmacy may attempt to contact the patient to arrange pick-up or re-mail of the returned prescriptions. If the Veteran cannot be contacted and arrangements made for resending or pick up within 5 business days, the pharmacy must log the medication for disposal. Pharmacy may not place contents of returned prescriptions back into stock. VHA Handbook 1108.05, *Outpatient Pharmacy Services*, states that pharmacy is prohibited from accepting any outdated or otherwise returned medications directly from the patient or their authorized representative. VHA Directive 1108.08, *Formulary Management Process*, November 2, 2016, states that pharmacies must not restock into inventory, nor reissue to another patient, any CMOP or locally dispensed prescription medication that has been returned as undeliverable. Medical Center Memorandum (MCM) 119-16-03, *Medication Return Policy*, June 2016, states that medications dispensed to patients cannot be reissued once returned.

Findings

We reviewed Excel spreadsheet records Las Vegas provided for both controlled and non-controlled substance returns from 2016 to present. There were 4,034 controlled substance returns (2,756 were destroyed or 68.3 percent) and 4,858 non-controlled substance returns (1,218 were destroyed or 25 percent) in this period. We also reviewed an Excel spreadsheet the whistleblower provided, containing returned controlled substances and found that there were 3,451 total returns for 2016 to present. Because this number was lower, we used the higher, facility-provided data in the following calculations. Using CMOP average medication costs as of May 2019 of $25.31 per medication, the total cost of destruction for this 3-year period was $100,581. The total expenditure for medications from Las Vegas for FYs 2016 through 2019 year-to-date was $64,279,323 and $120,736,545 for CMOP medications, for a combined total of $185,015,868. Destroyed medications represent 0.05 percent (5 in 10,000) of the total expenditures for medications in this period.

Returned medications are logged on two different Excel files located on a shared drive for the pharmacy. These spreadsheets are not password-protected or secured by any other methods and can be modified by anyone who has access to this drive. Las Vegas' policy for documenting returned controlled substances includes logging the medication onto the spreadsheet with the Veteran's name, prescription number and medication name, and populating the comment section with an explanation on actions taken to resolve the issue. There is no count of the amount of medication returned (other than individual dose) on this spreadsheet; however, the original prescription number would allow an auditor to compare prescribed to returned amounts. Interviewees told us that they retrieve the medications from the mail room as previously described, then log information off the prescription label into the spreadsheet. Controlled substances are kept in the narcotic vault in a collection bin awaiting disposition. If Las Vegas pharmacy's staff are unable to reach the Veteran within 5 business days, the pharmacist logs a controlled medication for destruction and
completes a note in the medical record for controlled medication only. There is no indication on the pharmacy menu that the medication was not received by the Veteran; the provider would need to read the note entered by the pharmacist. There is no pharmacist note made in the medical record for non-controlled medications.

VHA Directive 1108.01 states that all controlled substances expired or otherwise determined to be unusable must be removed from active stock and stored separately until destroyed or turned over to a reverse distributor for destruction. The medication must be recorded into the Controlled Substance Hold for Destruction Report and verified by two pharmacy employees before being placed into a sealed evidence bag. Las Vegas does not enter into stock controlled substances returned from the CMOP (schedule III-V) or the locally filled and mailed schedule II medications. As a result, the only evidence of the existence of these medications prior to their entry into the Controlled Substance Hold for Destruction Report is the unsecured Excel spreadsheet. This period is approximately 5 business days, and although the medication is secured in the narcotic vault, there is no unmodifiable tracking of the medication prior to the Hold for Destruction note. This is concerning because it presents an opportunity for diverting medications, especially those provided by the CMOP. For non-controlled medications, there is only the Excel spreadsheet to document their existence, and there is no documentation in the medical record showing that the Veteran failed to receive the medication.

Conclusion(s) for Allegation 2

- We substantiate that Las Vegas’ mail order prescription system results in the destruction of thousands of dollars in medications. However, national policy requires the destruction of medications that are returned through the mail unless the medications can be re-mailed to the same patient. The cost for returned and destroyed medications compared to medications provided by mail order is proportionately very small.

- The procedure used for documenting and tracking returned medications allows for the possibility of diverting narcotics prior to destruction.

- There is no clear mechanism for the provider to be notified in the event the Veteran fails to receive prescribed medications. We have concerns that providers may determine that prescribed medications are ineffective, rather than unavailable, to the Veteran and change prescriptions based on this information.

Recommendation(s) to Las Vegas

5. Comply with VHA Directive 1108.01 and return all narcotics to stock to ensure secure tracking of these medications.

6. Use the 'return to stock function' in the Veterans Information Systems and Technology Architecture (VistA) for accountability tracking of all medications.
returned in the mail. This does not mean adding these items to inventory for re-dispensing.6

7. Develop procedures to ensure the provider is notified when Veterans fail to receive their prescribed medications.

Allegation 3

VASNHS’s mail order prescription system is causing the VA to expend significant resources replacing, processing, and destroying returned prescriptions.

Findings

We analyzed the data used in Allegation 2, and determined that from 2016 to present, there were 1,837 returned controlled and non-controlled medications that pharmacy staff attempted to arrange pick-up by or remailing to Veterans. Interviewees indicated that the process of destroying, replacing, and remailing returned medications is one task in the 21 different stations to which they are assigned on a weekly basis. During the site visit, we observed a call center staffed with approximately 12 pharmacy technicians whose duties include calling Veterans to verify addresses for resending packages and processing refills supplied by Las Vegas.

There is no documentation of how much time is allocated to each of the myriad tasks in each of the assigned duty stations. We used an estimate of average pharmacy technician salary cost per hour ($30.54 in FY 2018) and an estimated time to resolution of 15 minutes for each medication reprocessed. With an average of 10 returns per day (see Allegation 1), we estimate the resource cost of 150 minutes or $76 per day. Destruction of controlled and non-controlled medications was discussed in Allegation 2.

We manually separated high-cost medications listed under the heading “destruction” on the Excel spreadsheet records used in Allegation 2 for the period of January to June 2019, and identified 22 items. The total cost of the medication from this list, assuming a prescription for a 30-day supply, was $1,106.

As indicated in Allegation 1, Las Vegas requires a signature for controlled substances mailed to the Veteran’s home, which results in unnecessary medication returns and increases the cost of processing and redelivery. After reviewing the cost center expenditures from FY 2016 to present, we found that Las Vegas pharmacy spent approximately $716,000 per year (average over 4 years) for medication and some medical equipment (e.g., catheters). Las Vegas uses the Endicia postal franking system to mail parcels from the pharmacy, which can be changed to accommodate different postal rates. Nationally, the average cost for mailed parcels packaging is $2.60 using this system (price is dependent on the size and weight of the package). The national average mail cost for a CMOP package is $3.10 (as of May 2019).

6 VistA is the nationwide Veterans clinical and business information system of VA. VistA consists of 180 applications for clinical, financial, and administrative functions, all integrated within a single database, providing a single, authoritative source of data for all Veteran-related care and services. Congress mandates that VA keep Veterans’ health records in a single, authoritative, lifelong database, which is VistA.
whistleblower indicated the cost of mailing packages from Las Vegas pharmacy was $11.99 per package, which includes additional costs for signature at delivery. We requested actual costs from Las Vegas, which indicated that the cost range for this mail service is $12.83 to $13.58 per parcel. Overnight delivery is not used at Las Vegas. Interviewees indicated that routine mail delivery was less than 2 days in the Las Vegas area; however, more rural areas took longer.

The whistleblower also expressed concern that the equipment that was previously used in the primary care clinic pharmacies was still there and not being used, specifically the four automated prescription dispensing and checking devices (ScriptPro 100). We requested documentation on the status of this equipment and found all four accounted for, with two going to the Greater Los Angeles VA Healthcare System; one to the Bakersfield VA facility, all in 2017; and another transferred to UNICOR in 2018.

Conclusion(s) for Allegation 3

- We substantiate that Las Vegas’ mail order prescription system is causing VA to expend significant resources replacing, reprocessing, and destroying medications. However, this finding is related to the methods used by Las Vegas to mail schedule II narcotics, not from excessive workload or loss rates from the mail order system in general.

Recommendation(s) to Las Vegas

8. Adopt standard packaging used by the CMOPs and lower mail rates for routine medication delivery from the Las Vegas pharmacy.

VI. Summary Statement

We have developed this report in consultation with other VHA and VA offices to address OSC’s concerns that Las Vegas may have violated a law, rule, or regulation; engaged in gross mismanagement; or created a substantial and specific danger to public health or safety. VHA HR has examined personnel issues to establish accountability, and the National Center for Ethics in Health Care has provided a health care ethics review. We found violations of VHA policy at Las Vegas, but none resulting in substantial and specific danger to public health or safety.
Attachment A

Documents in addition to the electronic medical records reviewed.

VHA Directive 1108.01, Controlled Substances Management, May 1, 2019.


VHA Handbook 1108.05, Outpatient Pharmacy Services, June 16, 2016.


MCM 119-16-03 Medication Return Policy, June 2016.

Controlled and non-controlled medication return spreadsheets.

Financial records relating to CMOP and pharmacy costs.

Various emails between pharmacy, finance personnel, and leadership.
Attachment B

Veteran A allegedly failed to receive his injectable insulin in the mail and, as a result, went to the Emergency Department (ED). We reviewed the record and found that on Date 2019, Las Vegas had refilled and mailed the insulin to the Veteran. The Veteran did present to the ED on Date 2019; however, this was for a cardiac dysrhythmia, not related to a high glucose level. There were no ED visits for this Veteran in the 3 months prior to Date 2019. We also found a note relating to a missing Levothyroxine (thyroid hormone replacement) prescription dated Date 2019. The note showed that the Veteran had not received his Levothyroxine in the mail even though records indicate it was sent on Date 2019. Of note, the Veteran was admitted to the hospital from Date through Date 2019, which encompasses the time the medication should have arrived via mail.

Veteran B was in palliative care and receiving pain medications including Oxydode. There did not appear to be any issue with refills of this medication. According to notes written by the palliative care provider, the Veteran reported adequate pain relief and expressed no concerns. A pharmacist reviewed the record and noted concerns about a high dose of a sleeping pill (Zolpidem), which they thought inappropriate for the Veteran’s age and recommended a lower dosage. The decision was appealed, and a pharmacist agreed with the higher dose on a trial basis.

Veteran C has dual eligibility within the Tricare system in the Department of Defense (DoD) and has prescriptions from both systems. There was one instance in which the Veteran ran out of Metformin on or about Date 2019 (a DoD prescription), and Las Vegas wrote a new prescription on Date 2019, which was mailed Date 2019. It is unclear from the record what caused the delay in medication delivery. There is no evidence of any issues with this incident.

Veteran D is on chronic opioids and requested a refill on Date 2019, which was approved with a start date of Date 2019 (at the end of the previous 30-day prescription). The medication was mailed out on Date 2019, but the Veteran did not receive it until Date 2019. On the same day, the Veteran called her patient-aligned care team (PACT) angry about the missing prescription and hung up prior to resolution. According to the whistleblower, this individual went to an ED sometime between Date and Date for opioid withdrawal symptoms; however, there is no evidence of this in the record.

Veteran E requested an Etanercept (a medication used to treat autoimmune diseases) refill on Date 2019, which was provided at the Las Vegas window. The Veteran had previously received a shipment on Date 2019 for four refills of other medications; evidence shows that he requested these via phone. The whistleblower indicated that approximately 90 days of Etanercept had been lost in the mail. We couldn’t find evidence that the Veteran had requested a refill of Etanercept before the Date 2019, shipment, which would explain why it did not arrive with the other medications. We found no evidence of this medication being lost in the mail.
Veteran F had ongoing issues with the Home Health Aid and pain management programs. Relevant to this case, he had peripheral neuropathy (a chronic painful condition affecting peripheral nerves), which was treated with Gabapentin, and Enacarbil, a medication more commonly used to treat restless legs syndrome and post-herpetic neuralgia. Upon review by the pharmacist, there was discussion about use of this medication as it was not Food and Drug Administration (FDA)-approved for treatment of peripheral neuropathy. An appeal was disapproved in favor of an FDA-approved medication. We found no issues with the mail order pharmacy process.

Veteran G had no issues related to the mail order pharmacy. He recently had a medication changed from Naproxen to Celebrex, which was picked up at the Las Vegas pharmacy window. He had previously used the mail order system in Date 2018.

Veteran H was identified as a patient who failed to receive a Sertraline prescription and subsequently had an intensive care unit admission for Serotonin Syndrome. According to the record, this admission occurred approximately 3 years earlier. The Veteran requested a change to the 30-day prescription to a 90-day prescription presumably to make it easier for him to remember to order refills. Even though this request was supported by the pharmacist on Date 2019, it was denied by the provider because, in Date 2019, the Veteran had reported active suicidal ideations (SI) with a plan to overdose on illicit drugs (Heroin). This recent SI event precluded dispensing greater than a 30-day supply of the medication because of concerns regarding his safety. There was no delay in delivery of the medication, and the absence of Sertraline would not cause Serotonin Syndrome as this is a risk from overdose or interaction.

Veteran I had no pharmacy notes or issues identified related to pharmacy in the search period indicated above.

Veteran J saw his PACT provider on Date 2019, and had multiple laboratory tests completed. Among the tests was a urine culture that was positive for bacteria, suggesting a urinary infection requiring treatment. As the cultures take 48 hours to grow, the results were provided to the Veteran on Date 2019, including the need for an antibiotic. The orders were verified by a pharmacist on Date 2019; however, on Date the Veteran presented to the ED for a reported fever, even though he was afebrile at the time of the visit. He indicated to the nurse that he thought the PACT provider had ordered medications, but he never received them in the mail. He reported to the pharmacy where he was supplied with medications on that same day. The pharmacy note indicated that the Veteran received other medications in the mail after

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7 While this medication was not FDA-approved for the treatment of peripheral neuropathy, it is not uncommon for a physician to prescribe a medication "off-label," meaning that the FDA has not specifically studied the drug in patients with the conditions being treated.

8 Sertraline is a selective serotonin reuptake inhibitor (SSRI), which causes an increase in endogenous serotonin by reducing its uptake. https:// toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs=hstdb;term=%20DOCNO+7037.

9 A life-threatening syndrome consisting of hyperthermia, tremor, and convulsions can develop when sertraline is ingested with tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs), carbamazepine, lithium or serotonergic substances. Reducing the dose of an SSRI would decrease endogenous serotonin by increasing uptake. https:// toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs=hstdb;term=%20DOCNO+7037.
this PACT appointment on [Date]. The order for antibiotics did not exist until after the positive culture was available on [Date]. Of note, this Veteran represents a delay in care and a potential worsening of condition related to the delay.

**Veteran K** had a note written by pharmacy staff indicating that the Veteran stated that it was hard for him to call in prescriptions due to his hearing deficit. The note also indicates that the Veteran lives approximately 30 miles away from the main facility, and travel to the facility to pick up missing medication is a significant burden. There is no indication of clinical concern in these notes.

**Veteran L** required a partial refill of insulin on [Date] 2019, because, although the pharmacy mailed the insulin on [Date] 2019, it did not reach him in time. An earlier event occurred on [Date] 2019, when the Veteran received care for pulmonary issues requiring Azithromycin and steroids to treat as an outpatient. The Veteran picked up one prescription at the window on April 11, and a second (refill) was mailed to him on [Date]. On [Date], after failing outpatient treatment, the Veteran was admitted to the hospital and left against medical advice on [Date] 2019. He was not on Azithromycin during the hospitalization. A note written on [Date] 2019, indicated that he “failed recent outpatient [Azithromycin Z-Pak] and Prednisone taper.” There is no indication of pharmacy delivery failure in this April event; however, the May event represents a delay.

**Veteran M** was hospitalized on [Date] 2019, because of an assault and was discovered to have tachycardia caused by new onset atrial fibrillation. He had no prior cardiac history. He was discharged on [Date] on a beta blocker and mailed a full prescription on [Date] 2019. On [Date], the Veteran returned to the pharmacy as he had run out of the supplied medication, and the mailed prescription had not yet arrived. There was no indication of worsening condition relating to the delayed mail order prescription.

**Veteran N** was admitted for liver abscess and required pain management. We found no indication of problems relating to pharmacy in the record.
Key to Investigators and Interviewees

Investigative Team

- M.D., Chief Medical Investigator
- M.D., JD, Senior Medical Investigator
- MS, RN, Senior Advisor to the Principal Deputy Under Secretary for Health
- DNP, RN, Clinical Program Manager
- PharmD, Chief of Pharmacy, Salisbury VA Medical Center
- MBA, Supervisory HR Specialist, Employee Relations/Labor Relations, Miami VA Medical Center

Interviewees

- M.D., Primary Care Physician
- NP, Primary Care Nurse Practitioner
- M.D., Primary Care Physician
- Pharmacy Clinical Supervisor
- PharmD, Pharmacist (whistleblower)
- Pharmacy Technician
- PharmD, Pharmacist
- Pharmacy Technician
- PharmD, Outpatient Pharmacist Supervisor
- PharmD, Pharmacist
- Pharmacy Technician
- Pharmacy Technician
- PharmD, Pharmacist
- Pharmacy Technician
- Chief Financial Officer
- Assistant Financial Officer (former Budget Analyst)
- PharmD, Associate Chief of Pharmacy
- RPh, Chief of Pharmacy
- Chief of Quality, Safety, Value
- M.D., Chief of Staff
- Patient Safety Manager