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DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

February 3, 2016

The Honorable Carolyn N. Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

RE: OSC File No. DI-15-1216:

Dear Ms. Lerner:

I am responding to your letter regarding allegations made by a whistleblower at the Veterans Affairs (VA) Greater Los Angeles Health Care System, specifically the West Los Angeles facility (hereafter, the Medical Center), in Los Angeles, California, and its Santa Maria Community-Based Outpatient Clinic (hereafter, the Santa Maria CBOC) in Santa Maria, California. The whistleblower alleged that understaffing and issues with delays and backlogs of prescriptions processed through the CBOC and the Medical Center have resulted in actions that constitute a violation of law, VA directives, and a substantial and specific danger to public health. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as described in 5 United States Code § 1213(d)(5).

When this referral was received, the Under Secretary for Health was assigned to review this matter and prepare a report in compliance with Section 1213. He, in turn, directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. The report substantiates all three allegations; the initial two and an additional one received during the site visit. VA identified conduct that may have constituted a substantial and specific danger to public health and safety and also violated Veterans Health Administration (VHA) policy. The report includes seven recommendations to the Medical Center and four to VHA. We will send your office follow-up information describing actions that have been taken by the Medical Center and other entities to implement these recommendations.

Thank you for the opportunity to respond.

Sincerely,


Robert D. Snyder
Interim Chief of Staff

Enclosure

**DEPARTMENT OF VETERANS AFFAIRS
Washington, DC**

**Report to the
Office of Special Counsel (OSC)
OSC File Number DI-15-1216**

**Department of Veterans Affairs
Greater Los Angeles Health Care System, Los Angeles,
California and
Santa Maria Community-Based Outpatient Clinic
Santa Maria, California**



Report Date: December 7, 2015

TRIM 2015-D-5475

Executive Summary

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the VA Greater Los Angeles (GLA) Health Care System, specifically the West Los Angeles facility (hereafter, the Medical Center), in Los Angeles, California, and the Santa Maria Community-Based Outpatient Clinic (hereafter, the Santa Maria CBOC), in Santa Maria, California; one of the Medical Center's clinics. [REDACTED] (hereafter, the whistleblower), who consented to the release of his name, alleged that there is understaffing and issues with delays and backlogs of prescriptions processed through the Santa Maria CBOC and the Medical Center, and that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. VA conducted a site visit to the Medical Center September 22-24, 2015.

Specific Allegations of the Whistleblower

1. There is an unreasonable delay in the approval, processing, and delivery of prescriptions through the Santa Maria CBOC, which has resulted in a persistent backlog of prescriptions.
2. This delay prevents patients suffering from significant mental health disorders from receiving prescribed medications in a consistent and timely manner.

Additional Allegation

Chronic understaffing is causing the persistent backlog of prescriptions.

The whistleblower reports that "one pharmacist at the CBOC must electronically approve all prescriptions for both the Santa Maria and San Luis Obispo CBOCs, which together serve 8,000 patients."

VA **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. VA was **not able to substantiate allegations** when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of findings, VA makes the following conclusions and recommendations.

Conclusions for Allegations 1 and 2

- **VA substantiates** that there was an unreasonable delay in processing and delivery of prescriptions through the Santa Maria CBOC, as evidenced by chart reviews of patient cases provided by the whistleblower, analysis of the medication processing data, witness accounts, and documentation of patient complaints.
- VA found that delays in processing and mail delivery have the potential to cause patient harm from delay in treatment or abrupt discontinuation of psychiatric pharmacotherapy, as evidenced in one patient case.
- Delays in mail delivery prescription processing exceeded the requirement established in the Veterans Health Administration (VHA) Handbook 1108.05 and local standard operating procedure (SOP) 10B-119-20, *Ambulatory Prescriptions*, that all original prescriptions and refill requests for formulary medications identified for mail delivery must be processed for filing within 2 working days of receipt.
- The backlog report data for the GLA Health Care System is likely inaccurate, resulting from prescription orders backlogged at least 7 days having been transferred to a separate spreadsheet for a temporary time period. This process is not permitted by applicable VHA policy.
- Associate Chief of Pharmacy and Ambulatory Care acknowledged not reporting to the Medical Center Director the actual number of pending prescriptions backlogged at least 7 days. Given this reporting failure, consecutive weeks of such backlogs could not, in turn, have been reported by the Director to the Veterans Integrated Services Network (VISN) Director, and if it persisted more than 4 consecutive weeks, to the VHA Pharmacy Benefits Management (PBM) Strategic Health Group, as required by applicable policy. In addition, the former practice of moving prescription orders from the electronic "pending" status to a local spreadsheet, where they are classified as being "on-hold," violated VHA documentation requirements and procedures set forth in VHA Handbook 1108.05.

Recommendations to the Medical Center

1. Ensure that the Chief of Pharmacy and other pharmacy leadership review VHA Handbook 1108.05 and Medical Center SOP 10B-119-20 regarding the medication prescription processing time with all pharmacy and clinical staff at the Medical Center, the Santa Maria CBOC, and other clinics.
2. Track, trend, and report data on the greater than 7-day backlog report to the Medical Center, VISN Director, and to the VHA PBM Strategic Health Group, as specified in the Handbook.
3. Conduct a review of Veteran complaint data regarding delayed medication prescriptions and follow up with patients to ensure that none were harmed.

Recommendations to VHA

1. Ensure that the Assistant Deputy Under Secretary for Health for Clinical Operations, with support from the VHA Chief Consultant of PBM Services, conducts a review of the Medical Center's Pharmacy Service, specifically the processing and delivery of patient medication prescriptions identified for mail delivery, and review the tracking, trending, and documentation of prescription processing backlogs according to VHA Handbook 1108.05.
2. Ensure Medical Center compliance with VHA PBM policies, including accurate reporting of pending prescription backlogs via the PBM pending prescription backlog reporting tool.

Conclusion for the Additional Allegation

VA **substantiates** that chronic understaffing contributes to the persistent 7-day backlog of prescriptions to be delivered by mail.

Recommendations to the Medical Center:

1. Develop a plan to provide immediate on-site or remote coverage for the PharmD vacancy at the Santa Maria CBOC and fill all authorized vacancies for pharmacists and CBOC staff members to meet Patient Aligned Care Team (PACT) panel requirements as set forth in VHA Handbook 1101.10.
2. Ensure that the process in place to assist with the prescription processing and dispensing functions previously managed by the Santa Maria CBOC PharmD is sufficient to support her successors.
3. Formally recognize the existence of the pharmacy inventory and the on-site prescription services occurring at the Santa Maria CBOC to allow strategic planning for necessary resources to support its pharmacy staff members and to ensure that all applicable mandates, regulations, policies, and procedures are being met. Otherwise, they should immediately cease all dispensing services at the Santa Maria CBOC.
4. Conduct site visits to the CBOC on a routine basis and schedule monthly staff meetings with CBOC staff.

Recommendations to VHA

1. The Assistant Deputy Under Secretary for Health for Clinical Operations, with support from VHA PBM, should conduct a review to determine management accountability for the delays in patients receiving medications by mail.
2. VHA should conduct a Workforce Management Review of all pharmacy services governed by the Medical Center to ensure an adequate organizational structure and staffing coverage.

Summary Statement

VA has developed this report, in consultation with other VHA and VA offices, to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, VA's Office of General Counsel (OGC) has provided a legal review, VHA Human Resources (HR) has examined personnel issues to establish accountability, and the Office of Accountability Review (OAR) has reviewed the report and has or will address potential senior leadership accountability. VA found violations of VA and VHA policy.

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I. Introduction

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the VA Greater Los Angeles (GLA) Health Care System, specifically the West Los Angeles facility (hereafter, the Medical Center), in Los Angeles, California, and the Santa Maria Community-Based Outpatient Clinic (hereafter, the Santa Maria CBOC), in Santa Maria, California; one of the Medical Center's clinics. [REDACTED] (hereafter, the whistleblower), who consented to the release of his name, alleged that there is understaffing and issues with delays and backlogs of prescriptions processed through the Santa Maria CBOC and the Medical Center, and that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. VA conducted a site visit to the Medical Center September 22–24, 2015.

II. Facility Profile

The Medical Center is the largest integrated health care organization in VA. It is one component of the VA Desert Pacific Health Care Network, Veterans Integrated Service Network (VISN) 22, offering services to Veterans residing in Southern California and Southern Nevada. The Medical Center consists of a tertiary care facility, 3 ambulatory care centers, and 10 outpatient clinics (including the Santa Maria CBOC), serving Veterans residing throughout 5 counties: Los Angeles, Ventura, Kern, Santa Barbara, and San Luis Obispo. The Medical Center is affiliated with the Schools of Medicine of both the University of California at Los Angeles and the University of Southern California, as well as with more than 45 colleges, universities, and vocational schools in 17 different medical, nursing, paramedical, and administrative programs.

III. Specific Allegation of the Whistleblower

1. There is an unreasonable delay in the approval, processing, and delivery of prescriptions through the Santa Maria CBOC, which has resulted in a persistent backlog of prescriptions.
2. This delay prevents patients suffering from significant mental health disorders from receiving prescribed medications in a consistent and timely manner.

IV. Conduct of Investigation

The VA team conducting the investigation consisted of [REDACTED] MD, Senior Medical Investigator (an internist) of OMI; [REDACTED] RN, Clinical Program Manager, of OMI; [REDACTED] PharmD, Clinical Pharmacy Specialist, Primary Care, VA Health Care System, Salt Lake City, Utah; and [REDACTED] Chief, Human Resources Management Services VA Portland Health Care System, Portland, Oregon. We also

consulted with [REDACTED] Chief Consultant; and [REDACTED] PharmD, Deputy Chief Consultant, PBM Services, VA Central Office.

We reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A. We toured the Medical Center's Primary Care Clinics and operating rooms, the Santa Maria CBOC, and held entrance and exit briefings with Medical Center leadership.

VA initially interviewed the whistleblower via teleconference on September 17, 2015. On September 22, 2015, we conducted an entrance briefing with the following individuals:

- [REDACTED] MD, Acting Chief of Staff (CoS)
- [REDACTED] MSN, Acting Nurse Executive
- [REDACTED] Associate Director
- [REDACTED], Health System Specialist (HSS), Office of the Director
- [REDACTED] HSS
- [REDACTED] HSS
- [REDACTED] Chief, Quality Management
- [REDACTED] Associate Chief, Quality Management
- [REDACTED] Associated Director, Ambulatory Care

During the course of our investigation, we interviewed the following Medical Center employees:

- [REDACTED] the whistleblower
- [REDACTED] MD, Acting CoS
- [REDACTED] MSN, Acting Nurse Executive
- [REDACTED] Associated Director, Ambulatory Care
- [REDACTED] MD, Chief of Primary Care (PC)
- [REDACTED] MD, Lead Physician, PC
- [REDACTED] MD, Lead Physician, San Luis Obispo and Santa Maria CBOCs
- [REDACTED] MD, Staff Physician, the Santa Maria CBOC
- [REDACTED] MD, Staff Physician, the Santa Maria CBOC
- [REDACTED] MD, Chief, Mental Health
- [REDACTED] MD, PC Mental Health Clinic
- [REDACTED] DO, Psychiatrist, the Santa Maria CBOC
- [REDACTED] PhD, Psychologist, Team Lead, the Santa Maria CBOC
- [REDACTED] PhD, Psychologist, the Santa Maria CBOC
- [REDACTED] PharmD, Chief, Pharmacy
- [REDACTED] PharmD, Associate Chief, Pharmacy and Ambulatory Care
- [REDACTED] PharmD, Outpatient Pharmacy Supervisor
- [REDACTED] PharmD, the Santa Maria CBOC
- [REDACTED] Certified Pharmacy Technician
- [REDACTED] Management Analyst, the Santa Maria CBOC Manager
- [REDACTED] nurse practitioner (NP), the Santa Maria CBOC
- [REDACTED] NP, the Santa Maria CBOC

- [REDACTED], NP, the Santa Maria CBOC
- [REDACTED] RN, the Santa Maria CBOC
- [REDACTED], Medical Support Assistant (MSA), the Santa Maria CBOC

VA held the exit briefing with the following Medical Center and VISN 22 leadership:

- [REDACTED] PhD, Chief Medical Officer, VISN 22
- [REDACTED] MSN, Quality Management Officer, VISN 22
- [REDACTED] Acting Director
- [REDACTED] MD, Acting CoS
- [REDACTED] Associate Director
- [REDACTED] MSN, Acting Nurse Executive
- [REDACTED], HSS, Office of the Director
- [REDACTED] Associate Director, Ambulatory Care

VI. Findings, Conclusions, and Recommendations

Allegations

1. There is an unreasonable delay in the approval, processing, and delivery of prescriptions through the Santa Maria CBOC, which has resulted in a persistent backlog of prescriptions.
2. This delay prevents patients suffering from significant mental health disorders from receiving prescribed medications in a consistent and timely manner.

Background

Prescriptions are processed for the Medical Center and its associated clinics at several sites. The main sites include:

- the Medical Center, which processes its own prescriptions;
- the VA Sepulveda Ambulatory Care Center, which is assigned to assist with processing of the Santa Maria CBOC prescriptions;
- the VA Los Angeles Ambulatory Care Center (referred to as the "downtown" location by staff members), which is assigned to assist with the processing of Santa Maria, San Luis Obispo, and Oxnard CBOCs prescriptions, and with filling and mailing U.S. Drug Enforcement Administration (DEA) Schedule II prescriptions for the Medical Center.¹

The Bakersfield CBOC has a pharmacy in the clinic, but the Santa Barbara and Santa Maria CBOCs do not.

¹ DEA scheduled substances: Drugs, substances, and certain chemicals used to make drugs are classified into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs are considered the most dangerous class of drugs with a high potential for abuse and potentially severe psychological and/or physical dependence. As the drug schedule changes-- Schedule II, Schedule III, etc., so does the abuse potential-- Schedule V drugs represents the least potential for abuse. A listing of drugs and their schedule are located at Controlled Substance Act (CSA) Scheduling or CSA Scheduling by Alphabetical Order. <http://www.dea.gov/druginfo/ds.shtml>.

The following is an outline of the prescription ordering and filling process at the Medical Center and the Santa Maria CBOC:

- A prescription order is initiated when a Santa Maria CBOC provider enters and signs a medication order in VA's Computerized Patient Record System (CPRS).
- New prescription orders and refill requests are held in a "pending" status awaiting pharmacist processing.
- Pending prescription orders entered by Santa Maria CBOC providers are processed by either the on-site clinical pharmacist (position now vacant) or by pharmacists at the Sepulveda Ambulatory Care Center in Los Angeles. While processing the prescription order, the pharmacist reviews the order for appropriateness (including medication name, dose, directions, duration of therapy, drug-drug interactions, and completion of appropriate laboratory monitoring to assess efficacy/safety of ordered medication) to help ensure the safe and effective provision of medications.
- Once processed, the prescription order converts from "pending" to "active" status, and is then filled and dispensed to the patient in one of two ways:
 - If the VA facility has an on-site pharmacy and the medication is in stock, the patient may pick up the prescription there. This process is commonly referred to as "window pick-up" and provides the patient with medications needed for acute conditions, or in the case of chronic conditions, when it is determined that the patient cannot wait for mail delivery.
 - For routine medications, the medication order is processed for mail delivery to the patient. Some prescriptions are mailed from a VA facility pharmacy, but most medication orders are transmitted to a Consolidated Mail Outpatient Pharmacy (CMOP) for filling and mailing.² Prescription orders designated for mail delivery are held in a suspense file to be filled and mailed from either the Medical Center pharmacy (for more urgent requests or certain special handling items) or from a CMOP facility.
- Medical Center prescriptions for non-controlled substances that are designated for CMOP filling and patient delivery are transmitted to a CMOP facility in Tucson, Arizona. The suspense file for mail-out prescriptions is transmitted to the Tucson CMOP once daily. According to the Chief of Pharmacy, the CMOP typically takes one day to fill a prescription order, one day to consolidate the medications into bags coded with the zip code, and one day to transport them via truck from Tucson to the United States Postal Service (USPS) in Los Angeles. Patients typically receive medications within 5 days after the prescription order is received by the CMOP. Both the PharmD at the Santa Maria CBOC and the Chief of Pharmacy reported that

² CMOP: 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 centers. In 1994, the CMOP at Leavenworth, Kansas began the processing of high volume mail prescription workloads using an integrated, automated dispensing system. Since that time VA has expanded the program to include a total of seven CMOP facilities in Leavenworth, Kansas; Tucson, Arizona; Chelmsford, Massachusetts; Dallas, Texas; Murfreesboro (Nashville), Tennessee; Hines (Chicago), Illinois; and Charleston, South Carolina. <http://www.va.gov/CBO/wfm/cmop.asp>.

the goal is to process pending prescriptions within 5 days, so that patients will receive medications in the mail within a total of 10 days from the date the new prescription or refill request was initiated.

- DEA Schedule II controlled substances are filled and mailed via United Parcel Service (UPS) from the VA Los Angeles Ambulatory Care Center vault. DEA Schedule III through V substances are filled and mailed from the Murfreesboro, Tennessee CMOP.

There are several options for the processing and delivery of urgent CBOC prescription orders. The provider can request the pharmacist to expedite prescription processing to reduce the amount of time that the prescription waits in the pending file. The PharmD receives instant message requests (via Microsoft Lync) on a daily basis from providers at the Santa Maria, San Luis Obispo, and Santa Barbara CBOCs, requesting expedited processing. Once processed (converted from pending to active), the prescription can be transmitted to either the CMOP for regular mail delivery or to the Medical Center pharmacy for expedited mailing.

For urgently needed (same-day) medications, the provider can enter a prescription order for a limited number of medications that are stocked at the Santa Maria CBOC. The Santa Maria CBOC PharmD then dispenses the prescription to the patient from a cabinet on-site. If the patient urgently needs a medication that is not stocked in the clinic, then an alternative method known as the "Heritage Bridge" prescription process is available.³ The Medical Center supports the Santa Maria CBOC through a contract with non-VA pharmacies managed by Heritage Health Solutions, Inc., to provide a short supply (typically 10 days) of medications needed acutely by patients who are not geographically located near a VA pharmacy. The Heritage Bridge contract includes a limited formulary of medications from which providers must choose.

According to VHA Handbook 1108.05, *Outpatient Pharmacy Services*, "all original prescriptions and refill requests for formulary medications that are identified for mail delivery must be processed for filing (sic) within two working days of receipt." The Handbook acknowledges that prescriptions requiring clarification from the provider or non-formulary medication requests may take longer to process. Thus, most formulary medication orders for mail delivery should be converted from "pending" to "active" status within 2 days after the provider has signed the medication order, or within 2 days after the patient has submitted a refill request for an active medication order containing available refills. Reasonable delays in prescription processing (conversion from pending to active status) may be expected if a new prescription order is required (e.g., prescription has run out of refills or the original prescription has expired) or if the

³ Heritage Bridge prescription: A short supply of medications needed acutely for patients who are not geographically located near a VA pharmacy may be filled through a local contract with Heritage Health Solutions. These prescription orders are commonly referred to as "bridge prescriptions" and may be utilized to provide patients with a small supply of medication until the patient receives the remainder of the prescription order via mail order from a VA pharmacy or CMOP. Bridge prescriptions come at a higher cost to VA than prescriptions filled at VA pharmacies or CMOPs and are therefore utilized only when deemed necessary by the provider. Heritage Health Solutions, Inc. contract for the period January 1, 2015–September 30, 2016, signed by a VA contracting representative September 22, 2014.

pharmacist discovers an error in the prescription order and must contact the ordering provider for clarification. The Medical Center local SOP 10B-119-20, *Ambulatory Prescriptions*, echoes the requirement in VHA Handbook 1108.05, stating that "Mail prescriptions will be processed within two working days of receipt."

The Handbook also states that the Chief of Pharmacy Services (or designee) must review the outpatient prescription order pending file and CMOP status to ensure timeliness of services. When a review indicates that a backlog of 7 calendar days exists, a report must immediately be submitted to the facility Director; the report must include recommendations to ensure that all patients receive their medications prior to running out and pending actions to correct the backlog. When backlog reports are submitted to the facility Director for more than 4 consecutive weeks, the Director must submit a report to the VISN Director and to the VHA PBM Strategic Health Group citing: the deficiencies, the unusual circumstances involved, all corrective action taken, and the projected timeline for correction.

Findings

We reviewed the electronic health records (EHR) of six patients whose names were provided by the whistleblower and evaluated a total of eight prescriptions for timeliness of the services provided. We reviewed and retrieved the following data from each EHR:

- Name of the pharmacist that processed the prescription
- Number of days between the date of provider signature and pharmacist processing (i.e., days to convert from pending to active status)
- Number of days from the time the prescription was signed by the provider to the time the prescription was released by the pharmacy to mail
- Documented adverse effects reported from the delay of prescription delivery.

Five of the six patient records contained new prescription orders for a total of six new orders, and two records had refill order requests. Of the six new prescription orders, five orders were written by a CBOC psychiatric provider and one by a CBOC PC provider. The PharmD processed all six of the new prescription orders and one of the refill requests. We found that there was a delay in prescription processing for all 6 new prescription orders, with a median time of 12 days to convert from "pending" to "active" (range: 6 to 13 days). The median time from the date the medication order was written by a provider to the date the prescription was released to mail was 14 days (range: 7 to 27 days).

In one of the above cases, we found data that supported the whistleblower's complaint of a delay of at least 33 days from the day that the new prescription order was signed by the provider to the day that the patient received prescriptions in the mail. In this case, the patient's prescription order remained in "pending" status for 12 days before the PharmD processed it; delivery of the medication was further delayed due to a medication backorder. The patient received a Heritage Bridge prescription for this medication, but not before reportedly running out of the medication for 2 weeks.

We also reviewed backlogged prescriptions data for all of the Medical Center's sites, including the Santa Maria CBOC, over a 1-year period. The data revealed that the overall percentage of prescriptions backlogged 7 calendar days for the Medical Center ranges between 0.28 and 6 percent, which is not unusually high when considering the significant prescription volume of over 130,000 prescriptions per month. However, the percentage of Santa Maria CBOC prescriptions backlogged 7 calendar days ranged higher at 0.63 to 44 percent, with an average monthly prescription volume of 2,200 prescriptions per month. The Medical Center Pharmacy Service confirmed that they do not report to the Medical Center Director when a backlog of 7 calendar days exists, as required by VHA Handbook 1108.05.

Between March and April 2015, there was a significant decline in the percentage of prescriptions on the 7-calendar day backlog report for the Medical Center and all the CBOCs. This decline may represent improved efficiency in prescription processing or may be due to a change in the management of the pending prescription backlog data.

The Medical Center's Associate Chief, Pharmacy and Ambulatory Care, noted on the backlog data spreadsheet: "The pending order greater than 7 calendar day monitor was implemented March 2015 by VA [Central Office]." She stated that, since April 2015, the pharmacy supervisors monitor the backlog report on a daily basis. During these months, they converted the prescriptions on the backlog report from a pending to an "on-hold" status. The on-hold prescriptions were transferred to a spreadsheet and assigned to a pharmacist for processing on the next day. Any prescriptions converted from on-hold to active status were then removed from the spreadsheet. These same prescriptions are now flagged and remain on the backlog report.

According to the Chief Consultant, PBM implemented the backlog monitoring report to ensure that facilities are processing new prescription orders according to policy, VHA Handbook 1108.05. Per the Deputy Chief Consultant, PBM, the prescription backlog monitoring tool was made available to VISN Pharmacy Executives in June 2015 and to Chiefs of Pharmacy in September 2015. The purpose of this tool detailed in the *Outpatient Pending Rx-Business Rules* is to: "Provide trending reports on how many CPRS outpatient pharmacy orders are still in pending status by calendar day and show detailed patient specific report of pending orders by medical center."

The whistleblower estimates that over the past 2 years, he has addressed Veterans' complaints regarding delays in receiving prescriptions at least 2 to 3 times a day. We found that assertion to be generally corroborated by relevant objective evidence of records. More specifically, over the past 3 years, VA has received 34 letters from Congressional members related to their constituents' complaints about the delays in receiving medications from the GLA Health Care System. In addition, VA's patient advocate tracking system reflects that approximately 136 patient complaints related to delays in receiving medications from the GLA Health Care System. After thoroughly reviewing this data, we were still unable to determine if the cause for the delays in processing the subject prescription orders and refill requests was due to provider-related error (requiring the reviewing pharmacist to obtain clarification) or to processing delays on the part of Pharmacy Service. In addition, most of the providers

at the Santa Maria CBOC, the Santa Maria CBOC Manager, and the Medical Center Pharmacy Supervisor all stated that they had received complaints frequently from various patients who had not received their mail delivery prescriptions in a timely manner. This often resulted in the responsible provider having to place prescription orders (for bridge amounts of medication) with the Heritage pharmacy, as discussed above.

Conclusions for Allegations 1 and 2

- **VA substantiates** that there was an unreasonable delay in processing and delivery of prescriptions through the Santa Maria CBOC, as evidenced by chart reviews of patient cases provided by the whistleblower, analysis of the medication processing data, witness accounts, and documentation of patient complaints.
- VA found that delays in processing and mail delivery have the potential to cause patient harm from delay in treatment or abrupt discontinuation of psychiatric pharmacotherapy, as evidenced in one patient case.
- Delays in mail delivery prescription processing exceeded the requirement established in VHA Handbook 1108.05 and local SOP 10B-119-20, *Ambulatory Prescriptions*, that all original prescriptions and refill requests for formulary medications that are identified for mail delivery must be processed for filing within 2 working days of receipt.
- The backlog report data for the GLA Health Care System is likely inaccurate, resulting from prescription orders backlogged at least 7 days having been transferred to a separate spreadsheet for a temporary time period. This process is not permitted by applicable VHA policy.
- Associate Chief, Pharmacy and Ambulatory Care, acknowledged not reporting to the Medical Center Director the actual number of pending prescriptions backlogged at least 7 days. Given this reporting failure, consecutive weeks of such backlogs could not, in turn, have been reported by the Director to the VISN Director, and if it persisted more than 4 consecutive weeks, to the VHA PBM Strategic Health Group, as required by applicable policy. In addition, the former practice of moving prescription orders from the electronic "pending" status to a local spreadsheet where they are classified as being "on-hold" violated VHA documentation requirements and procedures set forth in VHA Handbook 1108.05.

Recommendations to the Medical Center

1. Ensure that the Chief of Pharmacy and other pharmacy leadership review VHA Handbook 1108.05 and Medical Center SOP 10B-119-20 regarding the medication prescription processing time with all pharmacy and clinical staff at the Medical Center, Santa Maria CBOC, and other clinics.
2. Track, trend, and report data on 7 calendar day backlog to the Medical Center, VISN Director, and to the VHA PBM Strategic Health Group, as specified in the Handbook.
3. Conduct a review of Veteran complaint data regarding delayed medication prescriptions and follow up with patients to ensure that none were harmed.

Recommendations to VHA

1. Ensure that the Assistant Deputy Under Secretary for Health for Clinical Operations, with support from the VHA Chief Consultant, PBM office, conducts a review of the Medical Center's Pharmacy Service, specifically the processing and delivery of patient medication prescriptions identified for mail delivery, and review the tracking, trending, and documentation of prescription processing backlogs according to VHA Handbook 1108.05.
2. Ensure Medical Center compliance with VHA PBM policies, including accurate reporting of pending prescription backlog via the PBM pending prescription backlog reporting tool.

Additional Allegation

Chronic understaffing is causing the persistent backlog of prescriptions.

The whistleblower reports that "one pharmacist at the CBOC must electronically approve all prescriptions for both the Santa Maria and San Luis Obispo CBOCs, which together serve 8,000 patients."

Background

In the past year, there has been instability and turnover in all of the Medical Center's key leadership positions. The Medical Center Director's position has been vacant since November 13, 2014, (during our site visit, a fourth person was serving as the Acting Medical Center Director and was about to end his 120-day assignment the day after the completion of our site visit). The previous Associate Director resigned on November 13, 2013. Two Acting Associate Directors filled this position until August 24, 2014, when a new permanent current Associate Director assumed his duties. The Acting CoS and Acting Nurse Executive have been in their roles since September 6, 2015.

Prior to our site visit, VA requested organizational charts for Mental Health, PC (including Ambulatory Care where the Santa Maria CBOC and other clinics fall), and Pharmacy. During the visit, we were provided a copy of the Pharmacy organizational chart and a copy of the proposed Mental Health Service Line organizational chart, but there were none available for PC, Ambulatory Care, or most other service lines in the Medical Center.

In accordance with VA Handbook 5003, Part II, Chapter 5, field facility Directors are responsible for ensuring that organizational and functional charts are developed and updated for their respective organizations.

Findings

The Santa Maria CBOC is assigned 1 PharmD who has been working there for the past 5 years. This PharmD served as a member of the PACT at the Santa Maria CBOC, where she provided medical management to patients scheduled in diabetes and Hepatitis C clinics. In addition to providing clinical pharmacy services, the PharmD also performed prescription management duties ordinarily assigned to a registered pharmacist. The Chief, Pharmacy, reported that there were plans to have an on-site pharmacy during the initial construction of the Santa Maria CBOC, but this did not occur due to an administrative decision of Medical Center leadership.

When interviewed about the whistleblower's allegations, the Chief, Pharmacy, stated that he was unaware of any delays in the approval, processing, or delivery by mail of prescriptions to patients. He said that whenever there is a backup in the processing of such prescription orders, pharmacists assigned to the Sepulveda Clinic assisted with processing. He described the Santa Maria CBOC PharmD duties as those of a PACT Clinical Pharmacy Specialist and not those of a staff pharmacist who dispensed medications.⁴ In contrast to the more traditional prescription dispensing role, a Clinical Pharmacy Specialist practices independently under a scope of practice and provides direct patient care. He also stated that the PharmD dispensed only specialty medications to CBOC patients. The Ambulatory Care Director also reported that he was unaware that there was a delay in medications being processed for mail delivery.

CBOC leadership and all CBOC staff members whom we interviewed reported significant issues with chronic understaffing of health care providers and other clinicians, in addition to pharmacist positions. All agreed that the PharmD was a hardworking, dedicated employee and were complimentary of the services she provided to Veterans. They all stated that she was overworked and they expressed the opinion that management needed to hire a staff pharmacist to help her with processing prescriptions for delivery by mail. The PharmD assigned to the Santa Maria CBOC submitted a request to transfer to another VA, effective October 9, 2015. Staff reported that she was leaving because she was overwhelmed with the amount of work and had

⁴ The VHA Patient Aligned Care Team (PACT) Handbook recommends the staffing ratio of one Clinical Pharmacy Specialist (GS-13) per 3 PACT teams (or 3,600 patients) to provide clinical pharmacy services, yet the CBOC pharmacist was clinically supporting providers at multiple CBOCs that provide care for over 8,000 Veterans.

to no avail, requested assistance from her supervisor and others in leadership numerous times.

The PharmD reported that her regular duties at the Santa Maria CBOC included conducting 20 to 25 individual medication management visits with diabetic patients; teaching group diabetes education classes; conducting shared medical appointments; dispensing stock medications; and providing information pertaining to drug profiles to providers at the Santa Maria, San Luis Obispo, and Santa Barbara CBOCs. In addition, she was required to travel to the San Luis Obispo CBOC on a monthly basis to provide group diabetes education classes. She confirmed that, in an attempt to decrease costs, she encouraged providers to reduce the use of the Heritage Bridge prescriptions for their patients. In addition to these duties, the PharmD managed the pharmaceutical inventory in the Santa Maria CBOC and was responsible for ordering medications, receiving deliveries, keeping track of all inventory, and regularly monitoring account balances "to manage the budget."

In the case of medications dispensed in the Santa Maria CBOC, upon receiving a prescription order from a provider, the PharmD processed the prescription (rendering it active), printed a label in her office, and dispensed the medication from the pharmacy stock. Dispensing a medication includes placing the label with instructions on the medication package and counseling the patient on its appropriate use.

The PharmD also dispensed refrigerated medications to Santa Maria and San Luis Obispo patients who live in the area, but who do not have a street address, which is required for medication deliveries by UPS and USPS. The PharmD also dispensed Hepatitis C medications to patients who were seen at the Santa Maria CBOC Telehealth clinics on Tuesdays, and smoking cessation medications on Wednesdays. In order to prevent disruption in service to these two populations of patients, the PharmD refrained from taking leave on Tuesdays and Wednesdays.

The whistleblower reported that the PharmD was frequently overwhelmed in approving prescription orders but described her as being "conscientious and working to meet the needs of the Veterans." Until 3 years ago, she was processing prescriptions for the Santa Maria, San Luis Obispo, and Santa Barbara CBOCs. She processed over 16,069 (approximately 61 percent) of the total Santa Maria CBOC prescriptions during the period from September 1, 2014, to August 29, 2015, averaging 309 prescriptions processed per week, including mail delivery and CBOC window pick-up. She reported that the pending prescriptions are solely her responsibility to process, that she often cannot keep up with demand, and that the Sepulveda Clinic pharmacists assist her with processing the medication prescription orders when her pending file exceeds 500. She denied being provided pharmacy coverage when on leave; however, the Chief, Pharmacy, and Associate Chief, Pharmacy, Ambulatory Care, stated that the Santa Maria CBOC is supported by Sepulveda regardless of the number of prescriptions in the pending file.

According to HR documentation, there was a second clinical pharmacist recruitment approved in July 2014 with one applicant. Pharmacy leadership opted not to select this applicant, choosing to fill the open position with Pharmacy residents. The permanent position was never filled. The PharmD performed the duties of three pharmacists, including traditional dispensing and prescription processing duties that can be performed by a GS-12 pharmacist.

The PharmD provided VA with multiple emails dating back to March 2013, documenting her requests for assistance with pending prescriptions and dispensing functions multiple times over the past several years. The PharmD frequently requested help with the dispensing functions from a staff pharmacist from both Ambulatory Care and Pharmacy Management, yet there is no documentation found regarding any attempts to recruit a pharmacist for the Santa Maria CBOC.

The VHA PACT Handbook recommends the staffing ratio of one Clinical Pharmacy Specialist (GS-13) per 3 PACT panels (or 3,600 patients) to provide clinical pharmacy services, yet the Santa Maria CBOC pharmacist was clinically supporting providers at multiple CBOCs that provide care for over 8,000 Veterans.

To further evaluate the Santa Maria CBOC staffing concerns, the VA investigative team's HR Specialist conducted interviews with several HR leaders and reviewed HR documents, including the vacancies and pending recruitment requests for the Santa Maria CBOC. Of the nine positions actively under recruitment, only four are replacements for vacated positions. According to the Personnel Distribution List for the Santa Maria CBOC, there are currently 10 vacancies that are vice positions, and 5 new positions under recruitment. VA found that positions in active recruitment have experienced significant delay. Several positions were approved for recruitment over 1 year ago (even dating as far back as July 2014), but the VA team could not find any evidence of any recruitment actions. HR interviewees shared that "active recruitment" means that the position has been approved to fill, not that there is recruitment activity associated with the position. Positions not in active recruitment include replacements for three physicians, one clinical pharmacist, and one supervisory MSA, all of whom who vacated their positions.

Of note, the PharmD and one Nurse Practitioner are no longer employed at the Santa Maria CBOC, and Medical Center leadership has not approved any recruitment actions pending completion of the organization charts.

The Santa Maria CBOC PharmD announced her departure on September 8, 2015. A clinical pharmacist volunteered, and was subsequently assigned by the Chief, Pharmacy, to work at the Santa Maria CBOC on a temporary basis until November 6, 2015. This clinical pharmacist decided not to extend this temporary assignment, so the Chief, Pharmacy, is assigning clinical pharmacists when these staff members are available. According to the functional statement, it is the responsibility of the Chief to ensure that all pharmacy operations comply with internal and external

mandates and all DEA, VA, Medical Center, and other applicable Federal regulations, policies, and procedures.

Conclusion for the Additional Allegation

VA substantiates that chronic understaffing contributes to the persistent 7-day backlog of prescriptions to be delivered by mail.

Recommendations to the Medical Center:

1. Develop a plan to provide immediate on-site or remote coverage for the PharmD vacancy at the Santa Maria CBOC, and fill all authorized vacancies for pharmacists and CBOC staff members to meet PACT panel requirements as set forth in VHA Handbook 1101.10.
2. Ensure that the process in place to assist with the prescription processing and dispensing functions previously managed by the Santa Maria CBOC PharmD is sufficient to support her successors.
3. Formally recognize the existence of the pharmacy inventory and the on-site prescription services occurring at the Santa Maria CBOC to allow strategic planning for necessary resources to support its pharmacy staff members and to ensure that all applicable mandates, regulations, policies, and procedures are being met. Otherwise, they should immediately cease all dispensing services at the Santa Maria CBOC.
4. Conduct site visits to the CBOCs on a routine basis and schedule monthly staff meetings with CBOC staff.

Recommendations to VHA

3. The Assistant Deputy Under Secretary for Health for Clinical Operations, with support from VHA PBM, should conduct a review to determine management accountability for the delays in patients receiving medications by mail.
4. VHA should conduct a Workforce Management Review of all pharmacy services governed by the Medical Center to ensure an adequate organizational structure and staffing coverage.

Summary Statement

VA has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, OGC has provided a legal review, VHA HR has examined personnel issues to establish accountability, and OAR has reviewed the report and has or will address potential senior leadership accountability. VA found violations of VA and VHA policy.

Attachment A

Documents in addition to patient EHRs reviewed.

VHA Handbook 1108.11, *Clinical Pharmacy Services*, July 1, 2015.

VHA Handbook 1101.10, *Patient Aligned Care Team (PACT) Handbook*, February 5, 2014.

VHA Handbook 1108.05, *Outpatient Pharmacy Services*, May 30, 2006.

VHA Handbook 1108.05, *Veterans Health Administration Transmittal Sheet, Outpatient Pharmacy Services, 9 a. Utilization of VA pharmacies*, May 30, 2006.

VHA Handbook 5005/64, *Staffing*, April 17, 2013.

VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010.

Medical Center SOP 10B-119-30, *Medication Safety Pharmacy*.

Medical Center SOP 10B 10B-119-12, *Medication Errors Pharmacy*.

Medical Center Pharmacy Policy 00-10B-119-53, *Scope of Practice Privileges for Clinical Pharmacy Specialist*.

Medical Center Pharmacy Policy 00-10B-119-55, *Adverse Drug Event Reporting Pharmacy*.

Medical Center SOP 10B-119-20, *Ambulatory Prescriptions*, April 2014.

Medical Center SOP 00-10B-119-27, *Patient Medication Bridge Supply*, April 2012.

Heritage Health Solutions, Inc. Contract (for the period 1/1/2015 – 9/30/16); signed by VA representative September 22, 2015.

Medical Center Memorandum, *Heritage Medication List*, April 3, 2015.