THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

March 21, 2013

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

Dear Ms. Lerner:

I am responding to your letter regarding a whistleblower disclosure at the Department of Veterans Affairs (VA) Outpatient Clinic in Manila, Philippines. The specific allegations were made by Mr. Robert Crawford, Chief Logistics and Facilities Manager. Mr. Crawford alleges that VA Manila Outpatient Clinic officials prescribe and dispense drugs, specifically, controlled substances that are not approved by the United States Food and Drug Administration (FDA), and lack overall specific VA operational directives to address the VA Manila Outpatient Clinic's unique characteristics. You asked me to investigate the whistleblower's allegations and identify any conduct that constituted a violation of law, rule or regulation, gross management or a substantial and specific danger to public health.

I asked the Under Secretary for Health to review this matter and conduct an investigation for purposes of providing your office a report as required under 5 U.S.C. § 1213(c) and (d). He, in turn, directed the Veterans Integrated Service Network 21 to investigate the allegations and report their conclusions and recommendations.

The investigation did find one violation of rules related to reimbursement of non-FDA approved drugs. Based on the findings, four recommendations were also made. The enclosed final report is submitted for your review.

I have reviewed the report and concur with the findings, conclusions, and recommendations. The Veterans Health Administration will monitor the implementation of the recommendations. Thank you for the opportunity to respond to this issue.

Sincerely,

Eric K. Shinseki

Enclosure

Report to the

Office of Special Counsel

OSC File Number DI-12-4217

Department of Veterans Affairs

Sierra Pacific Network 21

Mare Island, California, USA

Veterans Health Administration

Washington, DC

Report Date: February 26, 2013

Executive Summary

The Under Secretary for Health at the Department of Veterans Affairs (VA) requested that the Veterans Integrated Service Network (VISN) 21 investigate a disclosure to the Office of Special Counsel (OSC) by (b) (6) the Chief of Facilities and Logistics Service, at the VA Manila Outpatient Clinic (OPC) in the Republic of the Philippines. (b) (6) alleges that Manila OPC officials prescribe and dispense drugs, specifically, controlled substances that are not approved by the United States (U.S.) Food and Drug Administration (FDA), and lack overall specific VA operational directives to address the Manila OPC's unique characteristics.

Summary of Conclusions

1. VA is implementing a process for the purchase of controlled substances for the Manila OPC from the Pharmaceutical Prime Vendor (PPV) that will bring the OPC into compliance with VA practices. However, at the time the whistleblower made his allegation, VA's purchase of non-U.S. supplied controlled substances in the Philippines was not in compliance with VA policies and regulations concerning FDA approved drugs. The practice at the Manila OPC followed the same procedure established by the VA Foreign Medical Program (FMP) which governs reimbursement for Veterans' service-connected medical care in other foreign countries and would apply to the Philippines were it not for the presence of the VA clinic. The Veterans Health Administration (VHA), VISN 21, and Manila clinic leadership have been proactive in pursuing a long-term solution to this challenging problem of obtaining FDA approved controlled substances for Manila OPC. VA's contracted PPV, McKesson Corporation, the State Department, the Drug Enforcement Agency (DEA), VA National Pharmacy Benefits Management and VA's National Acquisition Center (NAC), have collaborated to implement a process whereby the Manila OPC will obtain U.S. supplied controlled substances from McKesson under its contract similar to VA pharmacies in the United States.

2. VA and VHA Handbooks and Directives are written to guide VA facilities located within the United States, and generally do not take into account the differences of operating a VA clinic in a foreign country. Manila is currently the only VA OPC operated in a foreign country. VHA, VISN 21, and Manila clinic leadership must interpret the Handbooks and Directives as they apply to the specific conditions in Manila, and develop local policies and procedures to operate in a foreign country.

3. Based on the findings and prior to the recent agreement reached with the PPV, the Manila OPC was in violation of the following law, rules, and regulations: 38 Code of Federal Regulations (CFR) 17.38(c)(3) and VHA Handbook 1108.08. However, based on the findings, there was no gross mismanagement, gross waste of funds, or substantial and specific danger to public health and safety.

Summary of Recommendations

1. It is recommended that VISN 21 leadership and the parties involved continue to move forward with implementing a permanent process for procuring, shipping, and receiving controlled substances from the PPV.

2. It is recommended that VHA develop a policy that describes the instances and process to obtain non-FDA approved drugs for use in foreign countries. This is needed for a variety of reasons, such as the Southern Hemisphere flu vaccine needed for Manila Veterans which cannot be provided from any FDA approved source; emergency drug supplies available from local wholesalers may or may not be FDA approved; and inpatient and non-VA community care provided through fee-for-service arrangements with medical facilities or private health care providers in the community may prescribe/administer drugs that are not FDA approved. These are examples which still remain as technically noncompliant with VA practices.

3. It is recommended that VISN 21 collaborate with VHA program offices to interpret VHA Directives, Handbooks, and information letters and apply the requirements as appropriate to the Manila OPC.

4. It is recommended that the FMP process for reimbursement of non-FDA approved drugs according to 38 CFR 17.38(c)(3) be clarified.

Final Report to the Office of Special Counsel

I. Summary of Allegations

VA's Under Secretary for Health requested that VISN 21 respond to a disclosure to OSC by (b) (6) (hereafter referred to as the whistleblower), Chief of Facilities and Logistics Service at the VA Manila OPC in the Republic of the Philippines. He alleges that Manila OPC providers prescribe and dispense drugs, specifically, controlled substances that are not approved by FDA and lack overall specific VA operational Directives to address the Manila OPC's unique characteristics.

II. Facility Profile

VA has been in operation in the Philippines since the U.S. Veterans Bureau opened in 1922 (except during the Japanese occupation of WW II), and it is an integral part of the U.S. mission to the Republic of the Philippines. A VA regional office and OPC operate in Manila, Philippines, and both administrations are now co-located on U.S. Embassy grounds. This illustrates the U.S. Government's continuing commitment to Veterans in the Philippines by providing a new state-of-the-art facility that is a safer, more accessible "one-stop-shop" for all Veterans' needs. This is the only VA health care facility located in a foreign country. 38 United States Code (U.S.C.) 1724, 38 CFR 17.35, and VHA Directive 2012-019 provide the authority for delivery of certain outpatient health care services to U.S. Veterans residing or sojourning in the Philippines.

A U.S. military Veteran must have a VA service-connected disability rating to be eligible for care at the Manila OPC. Service-connected U.S. Veterans who receive services through the OPC may be treated for their non service-connected conditions within the available scope of services and resources of the OPC. U.S. Veterans who are not residents of the Philippines but are sojourning in the Philippines and develop unexpected medical conditions may obtain needed outpatient medical services. However, the OPC is not authorized to serve as a sojourning Veteran's primary health care facility in accordance with VHA Directive 2012-019.[1] During fiscal year 2012, the clinic provided services to 5,974 Veterans.

Inpatient and non-VA community care is limited to treatment of service-connected conditions and is provided through fee-for-service arrangements with recognized medical facilities and private health care providers in the community.

III. Conduct of the Investigation

VISN 21 staff has been working on this issue of shipment of controlled substances from a VA source to the Manila OPC since the 1990s. The background and history of this issue was

[1] VHA Directive 2012-019 replaced VHA Directive 2007-006 on July 11, 2012.

gathered from involved staff listed below, as well as the review of documents provided by the claimant who has also been involved in this issue.

1- (b) (6), Chief Pharmacy Executive, VISN 21
2- (b) (6) Deputy Network Director, VISN 21
3- (b) (6) PBM Pharmacy Program Manager, VISN 21
4- (b) (6) Chief of Pharmacy, Manila OPC
5- (b) (6), Regional Counsel
6- (b) (6) Quality Management Officer, VISN 21
7- (b) (6), Chief Medical Officer, VISN 21
8- (b) (6) Network Director, VISN 21
9- (b) (6) Associate Quality Management Officer, VISN 21
10- (b) (6), Director of Operations, VA FMP

IV. Summary of Evidence Obtained from the Investigation

Allegation #1

Manila OPC officials prescribe and dispense drugs, specifically controlled substances that are not approved by FDA.

Definitions

FDA approved drug - A chemical or biological entity approved by FDA for sale and marketing using a new drug application (NDA), abbreviated new drug application (ANDA), or biologics license. Unique new drug approvals are reviewed using the NDA while generic drug approvals are reviewed using an ANDA.

FDA approved indication - This is also called labeled indication. A condition for which an FDA approved drug has been determined to be a safe and effective treatment option. FDA approval for a labeled indication means that the company can include the information in their package insert regarding the use of that drug for that indication. The manufacturer may also claim that the drug is effective for the approved indication, and use this information to market their drug to patients and physicians.

Controlled Substance - Controlled substances consists of drugs and other substances by whatever official name, common name, usual name, chemical name, or designated brand name, that are listed in title 21 CFR Schedule I 1308.11, Schedule II 1308.12, Schedules III 1308.13, Schedule IV 1308.14, and Schedule V 1308.15; 21 CFR 1301; and Title 21 U.S.C. 812 and 827.

PPV - PPV is a concept of support whereby a primary commercial distributor serves as the provider of a broad range of pharmaceuticals to VA facilities and a multitude of other government agencies. Other government agencies which use VA's PPV include, but are not limited to: State Veterans Homes, Indian Health Service, and Bureau of Prisons. Per contract

requirements, the PPV contract is mandatory for VA and is the biggest contract within VA's NAC with approximately $4 billion in annual sales. PPV services over 750 customers in the 50 United States, the Virgin Islands, Saipan, Puerto Rico and Manila, Philippines, for "just-in-time" deliveries of government-contracted pharmaceutical products. Pricing for the majority of the pharmaceutical products distributed through the PPV are established by the Federal Supply Schedule and VA national contracts. Full requirements for the PPV contract can be found at this Web site (http://www.va.gov/oal/business/nc/ppv.asp).

McKesson - McKesson Corporation is the contracted PPV for VA hospitals and clinics.

Findings

The central issue of the whistleblower's allegation is that VA is violating a requirement to provide FDA approved controlled substances to Veterans in Manila. 38 CFR 17.38 describes the VA medical benefits package available to eligible Veterans. The medical benefits package excludes "drugs, biological, and medical devices not approved by the Food and Drug Administration . . . ." (38 CFR 17.38(c)). VHA interprets FDA approved to mean approved "drug" not "indication". There are different ways to determine whether a drug is FDA approved. One way is to look at all original vials or bottles of drug and compare the manufacturer with a list of approved FDA drugs on the FDA Web site (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/). Another option is to use only drugs procured from VA PPV, which is required in most cases by contract to ship only FDA approved drugs. FDA approved drugs are often available in foreign countries, but not all drugs available for purchase in foreign countries are FDA approved.

The majority of drugs procured for use at the Manila OPC are purchased from VA PPV and are, by contract, FDA approved. The only exceptions to this practice are currently controlled substances, flu vaccine, emergencies, and inpatient contracted admissions where drugs are administered by the hospital.

Several issues have been identified that make it impracticable to use only FDA approved drugs in a foreign country setting. There will always be a need to procure a very small percentage of medication on the local market where FDA approval cannot be guaranteed. An example is the need to provide flu vaccine to Veterans per VA policy. The World Health Organization often recommends different influenza strains in flu vaccine administered in the Southern Hemisphere. The vaccine needed for Manila Veterans could not be provided from any FDA approved source. Second, if an emergency drug supply is needed it may be necessary to procure this from local wholesalers. Drugs available from these sources may or may not be FDA approved, but in an emergency, they would be used. Further, VA pays for inpatient and non-VA community care provided through fee-for-service arrangements with medical facilities and private health care providers in the community, and we have no way of knowing if drugs prescribed or administered are FDA approved.

VISN 21 has been working to address the controlled substance issue and the subject of this allegation since the 1990s, and has very recently developed a solution working with PPV, and DEA. A history of the efforts to procure FDA approved controlled substances follows.

The Manila OPC has been procuring controlled substances from local wholesalers since the early 1990s using a Philippine DEA license. Prior to VA adoption of the PPV contract, the Manila OPC procured all of its FDA approved drugs through VA NAC. Once VA moved to the PPV contract in the mid 1990s, all non controlled pharmaceuticals have been procured through this contract and are FDA approved. However, the controlled substance purchases became problematic because the Manila OPC was not registered with the DEA and the PPV was unable to ship controlled substances directly to the clinic. Due to the inability to receive these controlled substances from PPV, the clinic began to procure them locally. At that time they were only dispensing three controlled substances; Valium (diazepam), Ativan (lorazepam) and Librium (chlordiazepoxide). The Clinic procured these controlled substances from Clark Air Force Base and Subic Naval Base hospitals, as well as the U.S. Embassy Clinic. As the Manila OPC enrollment grew and medication needs expanded beyond the three drugs provided, the clinic began procuring from other local sources to include: Mercury Drug (similar to Walgreens), Marsman (a vendor similar to McKesson), or from Roche Philippines. In 2004, the Manila OPC began procuring their controlled substances from Zeullig Pharmaceuticals. Zeullig is a pharmaceutical distributor in the Philippines, similar to McKesson.

Since the mid 1990s, the Manila OPC, former VHA Western Region leaders, and subsequent VISN 21 leaders pursued many options to obtain FDA approved controlled substances. These options included purchasing from Clark U.S. Air Force Base in the Philippines, the local Philippine Government Veterans Memorial Medical Center, or having a VISN 21 facility procure and ship the needed drugs; however, none of these options were successful. Reasons cited were: closure of Clark Air Force Base, restructuring of the NAC, and the inability to export from a VISN 21 stateside facility due to DEA regulations. The only option available to support patient care was to continue the purchase of controlled substances with local pharmaceutical vendors. These medications were ordered and procured by the local contracting staff and dispensed by the clinic pharmacist based on a prescription written by practitioners who are credentialed and privileged in the Manila OPC following its local medical staff bylaws.

As far back as the 1990s, the Manila OPC and VISN 21 leadership engaged the assistance of VA's Office of Inspector General, VA's Office of Acquisition and Materiel Management, DEA, VA NAC, McKesson, VA National Pharmacy Benefits Management, and VA Regional Counsel to establish a way to procure the medications through the PPV contracted provider. The primary reason given by DEA for not issuing a license to the Manila OPC was that the OPC was not physically located within the U.S. Embassy grounds. Prior to 2011, the Manila OPC was in leased space in Pasay City, Philippines.

In February 2011, the Manila OPC relocated to newly constructed space within the U.S. Embassy grounds. In April 2011, the whistleblower was undergoing new employee orientation at the VISN office during which time the issue regarding controlled substance procurement was discussed. During the conversation with VISN staff, the whistleblower stated that he had worked on these kinds of issues in past positions while employed by the Department of Defense and Defense Logistics Agency. When he arrived in Manila, he began to pursue a DEA license for the clinic in conjunction with VISN staff and Regional Counsel. The whistleblower coordinated

discussions with DEA, PPV and NAC. In September 2011, the DEA license for the Manila clinic was approved.

Once the clinic obtained its DEA license in September 2011, staff informed McKesson that they were now ready to order and accept controlled substances from PPV. The clinic and VISN leadership's understanding was that two necessary requirements were in place to make this happen: 1) the Manila OPC was now on Embassy grounds with a Diplomatic Post Office (DPO) address, and 2) they were registered with DEA. (DEA Registration Number FD2835328). VISN leadership was then notified by McKesson that according to their legal department, McKesson was required to register as an exporter and the Manila clinic as an importer. This solution was not pursued due to the lengthy process of shipment involving the import/export and the potential for pilferage and drug degradation from heat during delivery. In September 2012, VISN 21 contacted DEA's Registration Office and discovered that if controlled substances were shipped via a State Department diplomatic pouch system from McKesson to the new Embassy address, they could avoid the lengthy import/export process. This information was substantiated by McKesson legal counsel after they contacted DEA and received the same information. As a result, McKesson legal counsel reversed their position on using the import/export process. VISN 21, McKesson, NAC and the State Department held a conference call in October 2012, to discuss a plan to move forward using the State Department diplomatic freight process to ship controlled substances from PPV to Manila. Upon testing a shipment to Manila using the diplomatic freight process, the State Department discovered that the shipping address was a DPO zip code. This presented another issue in that the DPO zip code is reserved for the use of sending and receiving personal mail only for U.S. Embassy employees. In addition, the State Department noted that with the DPO zip code as the mailing address they would be handing off the freight to the U.S. Postal System and this would be no different than PPV handing shipments off to the U.S. Postal System directly. The VISN Pharmacy Benefits Manager contacted DEA once again to ask if there was any prohibition on sending controlled substances from the PPV to the Manila OPC using a military mailing address. On January 28, 2013, another conference call was held involving the interested parties, and DEA representatives responded that there would be no prohibition in sending shipments to the Manila OPC located on U.S. Embassy grounds using a military zip code. The Manila OPC obtained a Fleet Post Office zip code and tested a shipment of non-controlled substances. On February 19, 2013, the Manila OPC requested a change of address for their DEA license. As of March 1, 2013, controlled substances are ordered through and shipped by PPV.

The whistleblower referred to practices of the FMP in his allegations. To address these concerns, VISN staff contacted the Director of Operations for VA FMP. FMP developed procedures to receive claims from Veterans with service-connected conditions from any foreign country (other than the Philippines). Claims for pharmaceuticals are reviewed by staff utilizing a Web based commercial product called Micromedex® which is a common industry drug information reference. It includes FDA labeled indications, as well as off labeled uses. To process claims, FMP does not consider the source of the pharmaceutical or the manufacturer's process, but only if the claim is for an FDA approved indication in the process of approval and reimbursement. FMP has been interpreting the term "FDA approval" as "FDA approved indications."

At the Manila OPC, a controlled substance is purchased through contracting by a warranted contracting officer, and is prescribed only after the Veteran is evaluated by a credentialed and privileged provider and then the medication is prescribed for the appropriate indicated clinical use. It is then dispensed by a clinic pharmacist. Though VA has now worked out a solution for PPV to deliver controlled substances to the Manila OPC, based on the VA FMP understanding of FDA approval, the pharmaceuticals dispensed at the Manila clinic were FDA approved for the uses for which they are prescribed.

Conclusion

VA now has a process for the purchase of controlled substances for the Manila OPC that is in compliance with VA regulation and policy, which started March 1, 2013. However, at the time the whistleblower made his allegation, VA's purchase of controlled substances in the Philippines was not in compliance with VA policies and regulations concerning FDA approved drugs. The practice at the Manila OPC did follow the same procedures established by VA FMP which governs reimbursement for service-connected medical care in other foreign countries, and would apply to the Philippines were it not for the presence of the VA clinic. VHA, VISN 21 and Manila clinic leadership have been proactive in pursuing a long-term solution to this challenging problem. VA's contracted PPV, McKesson Corporation, the State Department, DEA, VA National Pharmacy Benefits Management and VA's NAC have worked together to establish a process, which started March 1, 2013, whereby the Manila OPC can obtain U.S. supplied controlled substances from McKesson under its contract similar to VA pharmacies in the United States. While there will always be a need to obtain drugs from the local community, which may or may not be from an "approved FDA" source for reasons previously stated, all drugs are properly prescribed for Veterans for their "FDA approved" indications.

Recommendation

1. It is recommended that VISN 21 leadership and the parties involved continue to move forward with implementing a permanent process for procuring, shipping and receiving controlled substances from PPV.

2. It is recommended that VHA develop a policy that describes the instances and process to obtain non-FDA approved drugs for use in foreign countries. This is needed for a variety of reasons, such as the Southern Hemisphere flu vaccine needed for Manila Veterans which cannot be provided from any FDA approved source; emergency drug supplies available from local wholesalers may or may not be FDA approved; and inpatient and non-VA community care provided through fee-for-service arrangements with medical facilities or private health care providers in the community may prescribe/administer drugs that are not FDA approved. These are examples which still remain as technically noncompliant with VA practices.

3. It is recommended that the FMP process for reimbursing for non-FDA approved drugs according to 38 CFR 17.38(c)(3) be clarified.

Allegation #2

Lack overall specific VA operational directives to address the Manila Outpatient Clinic's unique characteristics

Findings

VA and VHA Handbooks and Directives are written to guide VA facilities located within the United States and generally do not take into account the differences of operating a VA clinic in a foreign country, of which Manila is the only one. VHA, VISN 21 and Manila OPC leadership have been interpreting the Handbooks and Directives as they apply to the specific conditions in Manila, and developing local policies and procedures since the inception of the Manila OPC.

Conclusions

There is a lack of overall specific VA and VHA Directives that address the Manila OPC since VA and VHA Handbooks and Directives are written to guide VA facilities located within the United States. In lieu of having the differences addressed in the specific VA and VHA Directives, as well as the CFR, VISN 21 and Manila clinic leadership interpret and develop local policies and standard operating procedures collaborating with VHA and program offices when necessary to ensure an efficient, effective safe operation.

Recommendation

It is recommended that VISN 21 collaborate with the VHA program offices to interpret VHA Directives, Handbooks, and information letters and apply the requirements as appropriate to the Manila OPC.

Attachment
Documents Reviewed

Foreign Medical Program Policy Manual. http://www.va.gov/hac/forbeneficiaries/fmp/fmp.asp
http://www.fda.gov/Drugs/informationondrugs/ucm079436.htm

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/default.htm

http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm

http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194989.htm