DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

JUN 03 2013

In Reply Refer To:

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-12-4217 Supplemental Report

Dear Ms. Lerner:

The Office of Special Counsel (OSC) requested additional information on the Department of Veterans Affairs (VA) Sierra Pacific Network 21 report of February 26, 2013, responding to a whistleblower's allegations regarding practices at the Manila Outpatient Clinic (Manila OPC). The Under Secretary for Health asked the Office of the Medical Inspector (OMI) to conduct a follow-up investigation to address the supplemental questions. Their findings are contained in the enclosed supplemental report.

OMI made one recommendation for the Manila OPC. Upon receipt of this supplemental report, the Manila OPC will prepare an action plan for the Deputy Under Secretary for Health for Operations and Management's (DUSHOM) approval. OMI, along with the DUSHOM, will monitor the facility's action plan until completion.

Sincerely,

RL Jesse

Robert L. Jesse, M.D., Ph.D.
Principal Deputy
Under Secretary for Health

Enclosure

Supplement to the Report to the Office of Special Counsel regarding OSC File No. DI-12-4217, Department of Veterans Affairs, Sierra Pacific Network 21, Mare Island, California, USA

This supplemental report clarifies questions raised by the Office of Special Counsel (OSC) regarding the subject report.

OSC Comment #1: The whistleblower has confirmed that he was never interviewed by the VISN 21 investigators in this matter. It is OSC's policy that, where the whistleblower has consented to the release of his name as (b) (6) has, the agency investigators must interview the whistleblower. We therefore request that the investigators interview (b) (6) as soon as possible.

VA Response #1: In response to the request by the Under Secretary for Health, the Office of the Medical Inspector (OMI) completed an investigation into the outstanding issues as detailed above. On May 17, 2013, (b) (6), Medical Inspector; (b) (6), Medical Investigator; and (b) (6), Chief Consultant, Pharmacy Benefits Management, completed an interview of the whistleblower, (b) (6) (b) (6), Chief, Logistics and Facility Support Division, Manila, Philippines. (b) (6) informed the investigative team that all steps required to purchase controlled medications from the PPV for the Manila OPC have been fully implemented, and that the Manila OPC received its first shipment of controlled medications on May 15, 2013. The Manila OPC personnel are no longer purchasing any controlled medications from local vendors as the PPV purchasing process has been completely implemented.

OSC Comment #2: (b) (6) has advised the OSC that the process outlined in the agency report for purchasing controlled medications from the Pharmaceutical Prime Vendor (PPV) for the Manila Outpatient Clinic (hereafter, the Manila OPC) has not been fully implemented. Although the report states that the process was initiated March 1, 2013, Manila OPC personnel have advised (b) (6) that they are still purchasing the majority of controlled medications from local vendors rather than through the PPV. The OSC requests specific information regarding the status of implementation of the PPV purchasing process, including any obstacles preventing full implementation and action taken to resolve these issues. The OSC also requests an update on the status of any other corrective action, such as the development of and/or changes to VA and VHA policies, directives, and standard operating procedures that apply to the Manila OPC.

VA Response #2: The Manila OPC is the only VHA facility operating in a foreign country. There are unique circumstances that affect clinical operations in a foreign country. VA directives, policies and handbooks are written for VHA facilities located within the United States, and may not include consideration for the unique circumstances of this clinic on U.S. Embassy grounds in the Philippines. When VA directives, policies, and handbooks are created or revised and the VISN and/or Manila OPC leadership determines that there will be problems with compliance, the VA/VHA program office is contacted to discuss those issues. The program office makes the

determination to allow modifications of processes, or exclusion of the Manila OPC from the directive, policy or handbook. This is a robust process that is currently ongoing in several clinical areas.

OSC Comment #3: The agency report states that, based on the findings, there was no gross mismanagement, gross waste of funds, or substantial and specific danger to public health or safety. However, the report does not provide details concerning the findings on which these determinations were made. The OSC requests additional information concerning the evidence and information the investigators relied on to reach these conclusions, including: 1) the evidence collected and used to determine that the non-FDA approved controlled medications dispensed to Manila OPC patients did not pose a health risk to these patients; 2) whether patients who received non-FDA approved drugs from the Manila OPC were notified or consulted regarding the non-compliant distribution of these drugs; and 3) information collected regarding any cost savings or projected cost savings as a result of the new process implemented to obtain controlled medications through the PPV versus local vendors.

VHA Response #3: In response to concerns regarding gross mismanagement and gross waste of funds, OMI reviewed the actual costs associated with the procurement of controlled medications outside of the PPV in comparison to projected costs if purchased through the PPV for fiscal year 2012. That year, the Manila OPC spent a total of $3,332,035 on all medications. It spent $943,386 on non-PPV controlled medications. If purchased through the PPV, the projected cost to procure these medications would have been $287,738 resulting in a cost savings of $655,648. Now that the PPV purchasing process has been completely implemented, the Manila OPC will realize these cost savings. By spending this money, the Manila OPC was able to continue to provide care for our Veterans while simultaneously addressing the medicolegal issues of procuring controlled medications in a foreign country through the PPV program. Prior to the implementation of this aspect of the PPV program, the Manila OPC would not have been able to provide adequate care to our Veterans without local purchasing. These actions do not represent gross mismanagement or gross waste of funds; the Manila OPC was putting Veterans first.

In response to concerns regarding substantial and specific danger to public health or safety regarding the use of non-PPV controlled medications, the Chief Consultant, Pharmacy Benefits Management and OMI reviewed the Adverse Drug Events Reporting System and found zero reported instances of adverse drug events for the Manila OPC. OMI has no evidence that Veterans who received locally obtained medications were specifically notified of their procurement source. OMI found no evidence of danger to public health and safety; however, there is a concern that the report of zero adverse events for all medications at the Manila OPC raises questions of their reporting practices and the validity of the data.

Recommendation

The Manila OPC should:

Review their Adverse Drug Event policy and procedures with regards to mandatory reporting, educate and train staff on proper use of the Adverse Drug Events Reporting System, and monitor the report to ensure compliance.