U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

August 25, 2015

The President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-14-2175

Dear Mr. President:

Pursuant to my duties as Special Counsel, enclosed please find the Department of Veterans Affairs' (VA) report, based on disclosures of a violation of law, rule, or regulation and a substantial and specific danger to public health by officials at the Wilmington VA Medical Center (Wilmington VAMC), Wilmington, Delaware, reported to the Office of Special Counsel (OSC). OSC has reviewed the report and, in accordance with 5 U.S.C. § 1213(e), provides the following summary of the allegations, the whistleblower's comments, and my findings.

The whistleblower, Olufemi Olatunji, is a registered nurse and the substance abuse program coordinator in the Buprenorphine/Naloxone Clinic (clinic) at the Wilmington VAMC. He alleged that the treatment practices of Kevin McGuire, M.D., interim chief of psychiatry, and Dr. McGuire's management of the substance abuse treatment program did not comply with agency policy on the treatment of patients with opioid use disorder.

The investigation did not substantiate that Dr. McGuire's treatment practices or the Wilmington VAMC's opioid use treatment program as implemented violated a law, rule, or regulation or created a substantial and specific danger to public health. The report includes, however, recommendations for revisions to agency documents and the review of a provider's treatment. The VA confirmed these recommendations have been implemented. I have determined that the report contains all of the information required by statute and that the agency's findings are reasonable.

OSC referred the allegations to then-Acting Secretary Sloan D. Gibson for investigation pursuant to 5 U.S.C. § 1213(c) and (d). Acting Secretary Gibson requested that the Office of the Medical Inspector (OMI) conduct the investigation. Then-VA Chief of Staff Jose D. Riojas submitted OMI's report to OSC on behalf of the Secretary. Mr. Olatunji commented on the report pursuant to 5 U.S.C. § 1213(e)(1). As required by 5 U.S.C. § 1213(e)(3), I am now transmitting the agency report and Mr. Olatunji's comments to you.[1]

[1]The Office of Special Counsel (OSC) is authorized by law to receive disclosures of information from federal employees alleging violations of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of

The Disclosures

Mr. Olatunji reported that the clinic treats approximately 60 patients with a staff of four psychiatrists. Upon entry into the treatment program, patients sign a Buprenorphine/Naxolene Treatment Agreement and agree to cease use of alcohol, opiates and other illicit substances such as cocaine, marijuana and amphetamines. Mr. Olatunji explained that patients were informed that under the agreement and Wilmington VAMC policy, those who continue to test positive for illicit substances would be removed from the treatment program due to the inherent danger of combining buprenorphine/naloxone with those substances.

Mr. Olatunji disclosed that Dr. McGuire did not remove patients who tested positive for illicit substances from the treatment program and, instead, prescribed higher doses of buprenorphine/naloxone. Mr. Olatunji maintained that the use of illicit substances while taking the buprenorphine/naxolene could result in life-threatening respiratory difficulties. And, despite the risk to patients, Dr. McGuire continued to prescribe buprenorphine/naxolene to those who failed drug screening tests. In May 2014, a patient of Dr. McGuire's with a history of heroin and oxycodone use was admitted to the Intensive Care Unit. Mr. Olatunji contended that the patient's condition could have been precipitated or complicated by his continued use of both buprenorphine/naloxone and other opiates.

Mr. Olatunji also reported that in May 2014, representatives of the Joint Commission reviewed the facility and informed Dr. McGuire that his practice did not comply with facility policy. Finally, Mr. Olatunji noted that Dr. McGuire's patients seemed to have a lower success rate in the treatment program.

The Report of the Department of Veterans Affairs

The investigation concluded that the local Standard Operating Procedure in use at the Wilmington VAMC, identified as Buprenorphine/Naloxene Induction/Maintenance Treatment (Suboxone SOP), did not conform to VA policy. The VA explained that it does not have a policy that dictates treatment for opioid use disorder and, instead, relies on comprehensive guidelines for patient evaluation and therapeutic options based on the VA/ Department of Defense (DoD) Evidence Based Clinical Practice Guideline Management of Substance Abuse Disorders, and the Substance Abuse and Mental Health Services Treatment Improvement Protocol 40. The investigation determined that Dr. McGuire's treatment practices conformed to these guidelines.

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authority, or a substantial and specific danger to public health and safety. 5 U.S.C. § 1213(a) and (b). OSC does not have the authority to investigate a whistleblower's disclosure; rather, if the Special Counsel determines that there is a substantial likelihood that one of the aforementioned conditions exists, she is required to advise the appropriate agency head of her determination, and the agency head is required to conduct an investigation of the allegations and submit a written report. 5 U.S.C. § 1213(c). Upon receipt, the Special Counsel reviews the agency report to determine whether it contains all of the information required by statute and that the findings of the head of the agency appear to be reasonable. 5 U.S.C. § 1213(e)(2). The Special Counsel will determine that the agency's investigative findings and conclusions appear reasonable if they are credible, consistent, and complete based upon the facts in the disclosure, the agency report, and the comments offered by the whistleblower under 5 U.S.C. § 1213(e)(1).

The report advised that the local Suboxone SOP is not in compliance with the guidelines because it requires discharge from the program if a patient fails to maintain abstinence from illicit substances. In contrast, the guidelines recommend that patients be treated with an increased dosage of Suboxone to combat continued cravings. Further, the local Suboxone SOP does not comply with 38 Code of Federal Regulations (CFR) 17.107 or VHA Handbook 1160.01 because it recommended discharge for disruptive behavior whereas the CFR and VHA Handbook require an assessment of the disruptive behavior and continued treatment. With respect to the psychiatrists, investigators found that three of the four treating psychiatrists followed the comprehensive guidelines and VA policy and ignored incorrect provisions of the Suboxone SOP. The fourth psychiatrist was unfamiliar with the guidelines, but did not improperly discharge any patients from the treatment program.

The investigation also reviewed the medical records of four patients whom Mr. Olatunji identified as having potentially been adversely affected by the use of both Suboxone and illicit substances. In all cases the investigation concluded that the treatment administered to the patients was consistent with the comprehensive guidelines for the treatment of opioid use disorder; thus, there was no substantial and specific danger to public health.

Investigators confirmed that the Joint Commission conducted an unannounced survey of the facility but determined that the survey did not include any finding that Dr. McGuire's treatment practices violated agency policy. Finally, the investigation found that the Wilmington VAMC's rate of patients receiving opioid agonist therapy was 35.5 % for the third quarter of fiscal year 2014, which exceeds the 29.2% for all VA addiction treatment programs. Thus, the investigation did not conclude that Dr. McGuire's practice rendered the treatment program less effective.

OMI made three recommendations to the facility. OMI recommended that the Wilmington VAMC complete the revision to the Suboxone SOP to ensure it is consistent with comprehensive guidelines and the VHA Handbook. Additionally, any care agreements included in the SOPs should not state that the failure to abstain will result in discharge from the program. Instead, the agreements should explain that a failure to abstain may result in a reassessment of therapeutic options. Finally, OMI recommended that the facility assess the practice of the one psychiatrist who was not familiar with the comprehensive guidelines and provide any training necessary. In May 2015, the VA confirmed that the facility completed these recommended actions.

The Whistleblower's Comments

Mr. Olatunji stated that the report's findings are egregious and objects to the OMI giving advance notice of the investigation to the medical center. He noted that his allegations concerned Dr. McGuire's practice only, not the other psychiatrists', and explained that the other psychiatrists contributed to the Suboxone SOP. Mr. Olatunji highlights that the investigation confirmed that there were patients who continued to use both

buprenorphine/naxolene and illicit substances. He commented that the medical literature on this issue is succinct and that the combination of these substances can produce fatal results.

Finally, Mr. Olatunji states that if the VA/DoD guidelines are to hold any weight, they should be implemented across VA medical centers nationally. He maintains that the investigation was for cosmetic purposes and believes that until the VA is investigated by neutral, preferably non-governmental entities, problems with investigations will persist.

The Special Counsel's Findings

I have reviewed the original disclosure, the agency report, and the whistleblower's comments. I recognize Mr. Olatunji's commitment to patients, especially those who suffer from addiction, and understand his concerns with the implementation of VA/DoD guidelines. However, I am satisfied with the agency's investigation and the corrective measures recommended by OMI. Thus, I have determined that the reports contain all of the information required by statute and find reasonable the agency's conclusions.

As required by 5 U.S.C. § 1213(e)(3), I have sent copies of the unredacted agency reports and the whistleblower's comments to the Chairmen and Ranking Members of the Senate and House Committees on Veterans' Affairs. I have also filed copies of the redacted agency reports and whistleblower's comments in OSC's public file, which is available online at www.osc.gov.[2] This matter is now closed.

Respectfully,

Carolyn N. Lerner

Enclosure

cc: Linda Halliday, Deputy Inspector General

[2]The VA provided OSC with reports containing employee names (enclosed), and redacted reports in which employees' names were removed. The VA has cited Exemption 6 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(6)) as the basis for its redactions to the reports produced in response to 5 U.S.C. § 1213, and requested that OSC post the redacted version of the reports in our public file. OSC objects to the VA's use of FOIA to remove these names because under FOIA, such withholding of information is discretionary, not mandatory, and therefore does not fit within the exceptions to disclosure under 5 U.S.C. § 1219(b), but has agreed to post the redacted version of the reports as an accommodation.