



U.S. OFFICE OF SPECIAL COUNSEL

1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

April 22, 2015

The President
The White House
Washington, D.C. 20510

Re: OSC File No. DI-14-3389

Dear Mr. President:

Pursuant to my duties as Special Counsel, enclosed please find the Department of Veteran Affairs' (VA) report based on disclosures of wrongdoing at the Beckley VA Medical Center (Beckley VAMC), Beckley, West Virginia. The Office of Special Counsel (OSC) has reviewed the report and, in accordance with 5 U.S.C. §1213(e), provides the following summary of the allegations and our findings.

The whistleblower, who chose to remain anonymous, alleged that employees at Beckley VAMC engaged in conduct that may constitute a violation of law, rule, or regulation; gross mismanagement; an abuse of authority; and a substantial and specific danger to public health. Specifically, the whistleblower disclosed that Beckley VAMC clinical pharmacy specialists (pharmacists) routinely and improperly reject providers' prescriptions in favor of less expensive medications, and pharmacists working in Beckley VAMC clinics exceed the scope of their practice.

The agency partially substantiated the whistleblower's allegations, concluding that Beckley VAMC encouraged providers to switch patients to older, less expensive medications, based on a pharmacy cost-savings goal for fiscal year 2013 related to atypical antipsychotic medications. In addition, the report acknowledged that a blanket restriction was imposed on continued therapy with aripiprazole or ziprasidone, without any appropriate clinical determination regarding changes to patients' drug regimens. The report recommended that the facility immediately stop this practice. The facility committed to conducting a clinical care review of the conditions and medical records of all patients who were discontinued from medications without review. The report did not substantiate the whistleblower's allegation that pharmacists improperly prescribe medications in clinics. During OSC's final review of this matter, the whistleblower disclosed additional allegations suggesting that related wrongdoing may still be occurring at Beckley VAMC. I have requested a supplemental report addressing these allegations that is due on May 11, 2015. Based on my review, I have determined that the initial report meets all statutory requirements and that the findings appear to be reasonable. However, I am closing this matter conditionally, pending the receipt of the agency's supplemental report.

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The whistleblower's allegations were referred to then-Acting Secretary Sloan D. Gibson, to conduct an investigation pursuant to 5 U.S.C. §1213(c) and (d). Acting Secretary Gibson asked the Under Secretary for Health to refer the whistleblower's allegations to the Office of the Medical Inspector. Chief of Staff Jose D. Riojas was delegated with the authority to review and sign the report. On January 9, 2015, Mr. Riojas submitted the agency's report to OSC. Pursuant to 5 U.S.C. §1213(e)(1), the whistleblower provided comments on the agency report on February 6, 2015. As required by 5 U.S.C. §1213(e)(3), I am now transmitting the report and the whistleblower's comments to you.¹

I. The Whistleblower's Disclosures

A. Pharmacists Improperly Reject Prescription Orders

The whistleblower alleged that Beckley VAMC pharmacists frequently rejected providers' prescription orders based exclusively on cost. The VA National Formulary (VANF) oversees the administration of prescription drugs within the VA health care system. The VANF's mission is to provide high quality pharmaceutical products and care to eligible veterans. According to the whistleblower, VANF regulations and policies are the only restrictions on providers' prescription authority.

The VANF maintains a list of drugs that must be available for prescription at all VA facilities. Veterans Health Administration (VHA) policy states that individual facilities cannot independently remove VANF approved drugs from this list. *See* VHA Handbook 1108.8. § 3. In addition, facilities cannot restrict drugs based solely on economics, and they cannot prevent patients with legitimate medical needs from receiving these medications. *See* VHA Handbook 1108.8 § 17.b and 17.aa. Further, VHA policy states: "Authorized medications... must be provided to eligible veterans when a prescription is completed by an authorized provider." *See* VHA Handbook 1108.05 § 7(a)(3)(h).

When requesting a non-VANF approved medication, the provider must follow an established non-formulary use procedure. *See* VHA Handbook 1108.08 § 17.q. The whistleblower explained that at Beckley VAMC, this requires filling out a "Special Drug Request" (SDR) form, which facility pharmacists review.

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 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).

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According to the whistleblower, when Beckley VAMC providers requested newer VANF approved drugs such as Venlafaxine SA or aripiprazole, the pharmacy mandated that providers first attempt to use older, less expensive medications. The whistleblower stated that older psychiatric medications, such as chlorpromazine, risperidone, and quetiapine can cause or worsen existing conditions, such as metabolic syndrome.

For these reasons, Beckley VAMC providers selected newer VANF approved medications that do not cause these side-effects. The whistleblower contended that when providers placed orders for approved new drugs, pharmacy officials not only required them to fill out SDR forms, but often rejected their orders. The whistleblower also noted that pharmacists have explicitly rejected orders because providers did not first prescribe older, less expensive medicines such as lithium or liothyroxine.

According to the whistleblower, Beckley VAMC pharmacists denied prescription orders and limited prescription durations for Venlafaxine SA, a drug commonly prescribed for the treatment of depression. When the whistleblower made inquiries with the Beckley VAMC Pharmacy and Therapeutics Committee (Committee), he was informed that Venlafaxine SA prescriptions were restricted based exclusively on “cost issues.” The whistleblower also noted that other approved medications such as Geodon, Lamictal, and Cymbalta are limited to 30-day supplies based on cost. The whistleblower explained that by limiting supplies to 30 days, patients are forced to schedule recurring consultations to renew prescriptions, creating a strain on primary care clinics. These practices appear to have no clinical purpose, thereby contravening VHA policy that facilities cannot restrict approved drugs based solely on economic factors.

The whistleblower also noted the acting chief of primary care, Lisa Ward, verbally proposed a policy which would incorporate the number of opiate prescriptions providers order into performance evaluations. The proposed policy would reduce performance ratings for providers based exclusively on the number of opiate prescriptions they wrote, without assessing the clinical appropriateness of these orders. The whistleblower asserted that this policy was an inappropriate mechanism to control excessive opiate prescriptions, and suggested that process would have a chilling effect on providers treating patients with legitimate medical needs for these medications. The whistleblower further alleged that this would ultimately harm patients.

B. VAMC Pharmacists Improperly Prescribe Medications

The whistleblower also disclosed that Beckley VAMC pharmacists act as medical care providers in outpatient primary care clinics. The whistleblower acknowledged that agency policy gives pharmacists prescribing privileges for non-controlled and controlled substances.² However, the whistleblower alleged that the scope of pharmacist-patient encounters at Beckley VAMC violates VHA clinical privileging guidelines.

² 21 U.S.C. § 802 defines a controlled substances as “a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter.” Drugs are placed on schedules according to their potential for

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Under VHA Directive 2009-014, pharmacists must have appropriate state licenses and registrations, and facility directors must implement policies to enable the effective and efficient administration of this authority. VHA Handbook 1100.19 sets administrative and clinical requirements for the privileging of healthcare providers. The Handbook defines “clinical privileging” as: “The process by which a practitioner, licensed for independent practice, is permitted by law...to provide specific medical [services].” Privileges must be within the scope of the practitioner’s license and clinical competence, as determined by education, training, experience and licensure. *See* VHA Handbook 1100.19 § 14.

The whistleblower explained that Beckley VAMC pharmacists see patients in clinical settings. In the Mental Health Clinic, the whistleblower alleged that 35 weekly patient slots are assigned to a pharmacist. The whistleblower reported that pharmacists essentially function as providers, interacting with patients, discussing their conditions and prescribing non-controlled and controlled substances. The whistleblower personally observed these interactions and reviewed patient charts to confirm that pharmacists had prescribed medications to patients. The whistleblower alleged that allowing pharmacists to act in this capacity violated clinical privileging policy and posed a serious danger to patient health. The whistleblower observed that the stated purpose of the policy is to grant medication providing privileges to pharmacists for non-controlled substances, and speculated that the use of pharmacists in clinical settings at Beckley VAMC is associated with efforts to reduce patient wait times.

II. The Agency Report

The report substantiated that the Beckley VAMC Committee encouraged providers to switch patients from aripiprazole or ziprasidone based on a cost savings goal for FY2013 related to atypical antipsychotics. The report noted that this decision was not in compliance with VHA policy on the VANF management process. The report noted that the Mental Health unit representative to the Committee voiced concerns about the blanket restriction on continued therapy with these two drugs, but that these concerns were ultimately ignored. In response, the report recommended that Beckley VAMC take numerous measures to correct this issue. First, the report took issue with the fact that the Committee was chaired by a non-physician, which represents a departure from standard practice at other VHA facilities. The report suggested that policy making and medication oversight could be improved by appointing a physician as the chair of the Committee.

The report recommended that Beckley VAMC immediately stop automatically removing transfer patients from VANF medications, without a legitimate clinical need, when these medications are prescribed by an authorized provider at another VA medical facility. The report also recommended that the facility immediately stop the practice of automatically removing Beckley VAMC patients from VANF medications, specifically aripiprazole or

abuse, their medical usage, and their safety. Schedule I features the most restricted drugs, while Schedule V contains minimally restricted substances.

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ziprasidone, without a legitimate clinical need. The report called for a clinical care review of the condition and medical records of all patients who were discontinued from aripiprazole or ziprasidone, following the decision of the Committee noted above. The clinical review will assess whether any adverse patient outcomes occurred as a result of medication discontinuation.

The report also recommended that if any adverse events are identified during the review, appropriate disclosures to patients should be made consistent with VA policy. In addition, the report recommended that appropriate disciplinary action be taken against Beckley VAMC leadership and the Committee for approving actions that were not consistent with VHA policy, and which could constitute a substantial and specific danger to public health. The report next recommended that Beckley VAMC leadership and the Committee receive additional training on VANF policy. The report recommended that Beckley VAMC designate a physician as the chair of the Committee, with the chief of pharmacy as secretary. Finally, the report recommended that VHA remind other medical centers of policies and requirements related to the VANF. As of the date of this closure letter, the facility has developed an action plan to carry out these recommendations. This action plan is currently pending approval by the Office of the Medical Inspector and VHA senior management.

The report did not substantiate that Beckley VAMC restricted the prescribing of alprazolam for cost-containment reasons, and found that a restriction requiring psychiatric review was motivated by safety concerns. For these reasons, the report deemed this restriction permissible. In addition, the report did not substantiate that Beckley VAMC restricted the quantity of medication dispensed solely for cost.

The report found noted that Beckley VAMC management did not communicate opioid performance measures to all primary care physicians within ninety days of the start of the fiscal year as required by VHA policy. The report recommended that Beckley VAMC management communicate performance measures to physicians in a timely manner.

With respect to the allegations concerning pharmacists exceeding their scope of practice, the report did not substantiate the whistleblower's allegations. The report noted that Beckley VAMC assigned a single clinical pharmacy specialist (CPS) to work closely with a physician in the pain management clinic. The report explained that in this capacity, the CPS initiated, adjusted, and terminated medications. The report noted that all CPSs' scope of practice agreements were reviewed, and all were found in compliance with VHA policy. A review of the work of the CPS who was detailed to the Pain Management Clinic indicated that this individual was authorized to initiate and adjust lamotrigine, and did so with the supervision of a physician. The report reviewed the medical record of the patient at issue and determined that the care and medications prescribed were appropriate.

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III. The Whistleblower's Comments

The whistleblower disagreed with the conclusions reached in the report, noting that the agency investigation made no effort to review practices in the pharmacy beyond what was addressed in the specific allegations. The whistleblower also asserted that the report mischaracterized the pharmacy's actions. Rather than pharmacists encouraging providers to avoid newer, more expensive medications, the whistleblower asserted that patients' medications were simply switched with no provider input. The whistleblower also felt the agency imposed inappropriate limits on prescription quantities generally, and the prescription of alprazolam specifically. Finally, the whistleblower disputed the report's conclusion that a pharmacist prescribing medications in the pain clinic was acting within the scope of their practice.

IV. The Special Counsel's Findings

I have reviewed the original disclosure, the agency report, and the whistleblower's comments. While the whistleblower had concerns regarding aspects of the agency's report, it appears that the agency took immediate and appropriate measures to resolve the serious allegations that the whistleblower raised. For these reasons, I have determined that the agency's findings appear reasonable and the report meets all statutory requirements. However, as noted above, I am closing this matter conditionally, pending the transmittal a supplemental report addressing the whistleblower's allegations of ongoing wrongdoing.

As required by 5 U.S.C. § 1213(e)(3), I have sent copies of the agency report and the whistleblower's comments to the Chairman and Ranking Members of the Senate and House Committees on Veterans Affairs. I have also filed copies of the agency report and whistleblower comments in our public file, which is available at www.osc.gov. OSC has now conditionally closed this file.

Respectfully,



Carolyn N. Lerner

Enclosures