DEPARTMENT OF VETERANS AFFAIRS
Under Secretary for Health
Washington DC 20420

JUN 11 2015

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-14-3389

Dear Ms. Lerner:

I am responding to your request for supplemental information on the Beckley Department of Veterans Affairs (VA) Medical Center, Beckley, West Virginia (hereafter, the Medical Center), in response to the three additional allegations from the whistleblower presented by your office. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as referenced in 5 United States Code § 1213(d)(5).

To deal with these allegations, the VA team made a follow-up site visit to the Medical Center from April 27 to May 1, 2015, to conduct interviews with over two dozen providers and pharmacists. VA did not substantiate any of the three additional allegations and made no new recommendations. Details of the findings of this site visit may be found in the enclosed supplemental report.

If you have any other questions, I would be pleased to address them.

Sincerely,

Carolyn M. Clancy, MD
Interim Under Secretary for Health

Enclosure

Department of Veterans Affairs
Supplemental Report
to the
Office of Special Counsel
Beckley Veterans Affairs Medical Center
Beckley, West Virginia
OSC File No. DI-14-3389
May 29, 2015

TRIM 2015-D-4108

Background

The Secretary of the Department of Veterans Affairs (VA) requested that the Veterans Health Administration (VHA) investigate complaints lodged with the Office of Special Counsel (OSC) by an anonymous whistleblower. The Interim Under Secretary for Health (I/USH) directed the Office of the Medical Inspector (OMI) to assemble and lead a team to conduct the inquiry. The whistleblower alleged that the Beckley VA Medical Center, Beckley, West Virginia, (hereafter, the Medical Center) engaged in conduct that may constitute a violation of law, rule or regulation, gross mismanagement, an abuse of authority, and a specific danger to public health. The whistleblower further alleged that Medical Center pharmacists routinely and improperly reject providers' prescriptions in favor of less expensive medications, and that clinical pharmacy specialists working in the clinics exceed their scope of practice. The VA team conducted a site visit to the Medical Center on September 9–12, 2014.

Based on its investigation, VA partially substantiated the whistleblower's allegations and made seven recommendations for the Medical Center and one for VHA, all endorsed by the I/USH. OMI and the Office of the Deputy Under Secretary for Health for Operations and Management subsequently reviewed and concurred in the Medical Center's action plan for implementing the recommendations. The Medical Center has fully implemented all of those recommendations. During OSC's final review of this case, the whistleblower alleged that related wrongdoing may still have been/be occurring. OSC referred the additional allegation to VA on April 9, 2015, for investigation and on April 22, 2015, OSC closed this case conditionally pending the results of the supplemental investigation.

In the supplemental report to OSC, the whistleblower alleged:

1. Beckley VAMC Pharmacy Service currently maintains a list of mental health medications designated as "Special Drugs," which require additional written provider justifications in order to prescribe.

2. A spreadsheet maintained by Pharmacy indicates that many of these special drugs are restricted to Beckley VAMC providers exclusively due to their cost, in violation of VHA Handbook 1108.05 and 1108.08. The whistleblower asserted

that these medications are VA National Formulary (VANF) approved, and as such, cost cannot be an exclusive factor in their restriction.

3. The whistleblower detailed that (b) (6), the Chief of Pharmacy, recently directed employees to improperly alter this list to indicate that cost was not a consideration in placing the medications at issue on the restricted drug list.

On April 27 – May 1, 2015, the investigative team conducted a follow-up site visit to investigate these additional allegations. The VA team consisted of (b) (6) MD, Deputy Medical Inspector; (b) (6) RN, BSN, MSN, CPUR, Clinical Program Manager; and (b) (6), PharmD, Deputy Chief Consultant for Professional Pharmacy Practice and Pharmacy Benefit Management Services, VHA. During the visit, VA interviewed the following Medical Center staff:

Interviewed in-person

- (b) (6) RPh, Chief of Pharmacy and Chair of the Pharmacy and Therapeutics (P&T) Committee
- (b) (6) MD, Chief of Staff (CoS)
- (b) (6) MSW, Chief, Mental Health Service Line (MHSL)
- (b) (6), PharmD, Anticoagulation Clinical Pharmacy Specialist
- (b) (6), Physician Assistant (PA), Mental Health (MH)
- (b) (6), PA, MH, Community Based Outpatient Clinic
- (b) (6) PA, MH
- (b) (6), PA, MH
- (b) (6) PA, MH
- (b) (6) Nurse Practitioner (NP), MH
- (b) (6), NP, Assistant Chief, MHSL
- (b) (6), PharmD, Associate Chief Pharmacy
- (b) (6) PA, MH
- (b) (6) MD, MH
- (b) (6) MD, Primary Care Service Line (PCSL)
- (b) (6) NP, PCSL
- (b) (6) MD, PCSL
- (b) (6) RPh
- (b) (6) PharmD
- (b) (6) MD
- (b) (6) RPh
- (b) (6) MD, MH
- (b) (6) PharmD
- (b) (6) PharmD, Automated Data Processing Application Coordinator, Pharmacy
- (b) (6) MD, MH

Interviewed by Phone

- b) (6) MD, MH and P&T Liaison for MH (Located at Richmond, VAMC)
- b) (6) PharmD, MH Clinical Pharmacy Specialist (CPS)
- b) (6) PA, MH

Allegation 1

Beckley VAMC Pharmacy Service currently maintains a list of mental health medications designated as "Special Drugs", which require additional written provider justifications in order to prescribe.

VHA Handbook 1108.08, VHA Formulary Management Process, describes the process for making medications available to Veterans through formulary management. The VANF lists the medications that must be available for prescription at all VA facilities. These medications cannot be withheld from Veterans based on local decisions made by a VISN or individual medical center solely for economic or administrative reasons. VHA designed the formulary management process to provide pharmaceutical products of the highest quality and best value, while ensuring the portability and standardization of this benefit to all eligible Veterans.

The Handbook outlines procedures for the restriction of selected medications listed on the VANF:

> Restrictions to prescribing can be established for VANF items that require close monitoring to ensure appropriate use. For example, in the case of anti-infectives, facility level restrictions intended to prevent resistance are permissible. Restrictions may include evidence-based guidelines or prescribing privileges for providers with specific expertise. Restrictions are not to be based solely on economics, nor are they to be so limiting as to prevent patients with legitimate medical needs from receiving these medications and supplies.

VHA Handbook 1108.08 at paragraph 17.aa., page 15. In addition, the Handbook forbids VA medical centers from discontinuing medications ordered at another VA medical center solely for administrative reasons:

> There will be no administrative action taken to discontinue pharmacotherapy initiated by an authorized provider at one VA medical center, when a patient transfers their care to a second VA medical center or when care is transferred back to the primary facility.

VHA Handbook 1108.08 at paragraph 17.t., page 14, first sentence.

In addition, VHA Handbook 1108.05 Outpatient Pharmacy Services, May 30, 2006, outlines procedures for VA Medical Centers' Pharmacy and Therapeutics (P&T) Committees to restrict the quantity of selected medications dispensed. At paragraph 5.d., the policy provides that no prescription can be filled for more than a 90-day supply

and that no prescription may exceed 12 months of therapy, including refills. Yet, for some prescriptions, a 30-day supply or less may be established, as described in that provision. This provision in the Handbook further directs that: "In all instances, the [P&T Committee] must consider safety, patient care needs, and VISN resources when establishing such guidelines or restrictions." (See VHA Handbook 1108.05 at paragraph 5.d, page 3).

At all VA medical centers, Pharmacy Service is responsible for maintaining the pharmacy drug file (the Veterans Health Information Systems and Technology Architecture (VistA) drug file), which lists all medications available locally, including mental health drugs. Pharmacy Service is also responsible for implementing P&T Committee-approved restrictions on prescribing mental health drugs and implementing those restrictions by identifying restricted medications in the Computerized Patient Record System (CPRS), the software used by providers to prescribe medications. In cases where a provider prescribes a medication that is restricted, he or she enters a restricted drug request (RDR). When this occurs, the provider will see an indicator in the CPRS that he or she must complete the RDR before such a medication can be dispensed. This notification is meant to remind the provider to complete a consultation outlining the patient's need for the medication. The consultation is reviewed by Pharmacy Service and is either approved with the medication dispensed to the patient, or is disapproved with a notification returned to the requesting provider. If a request is disapproved, instructions for appeal to the Medical Center's CoS for final decision are also provided.

Different and more streamlined procedures apply to situations where a medication that is locally restricted (at the Medical Center) was originally prescribed for a patient by a VA provider at another VA medical facility. Since the original VA site visit in September 2014, the Medical Center has emphasized through clarification with the Pharmacy Service and local providers that medications on the VANF that have a local RDR restriction but were initiated by a provider at another VA medical facility are to be continued unless the Medical Center provider determines that the medication is no longer clinically appropriate. When provision of a locally restricted medication is to be continued, the ordering Medical Center provider notifies the Pharmacy Service that the patient had been receiving the medication at another facility. When entering these orders into the system, the Medical Center provider will still see the RDR requirement in the CPRS because this prompt has not been modified to differentiate between prescription orders originating from Medical Center providers and those which continue, on medical grounds, but were initiated by VA providers at other VA medical facilities. Based on local guidance, Medical Center providers who are continuing such medication orders do not need to complete the RDR consultation form before the medication can be dispensed. This notification (with its tacit determination by the Medical Center provider that the medication is still needed) is less comprehensive than the fully completed consultation required in all other cases, but we underscore that, in making the request, the Medical Center provider is effectively documenting that the provision of the medication is still medically necessary based on his or her medical judgement. Such orders are not subject to Pharmacy Service approval prior to dispensing. In

interviews, some mental health providers admitted completing a consultation every time they renewed an order for a locally restricted drug that had initially been prescribed by another VA provider elsewhere in the VA system, when only a notification to Pharmacy Service was necessary.

Neither the mental health prescribing providers nor the pharmacists we interviewed were aware of the existence of a list of mental health medications requiring an RDR before the medication could be dispensed. The Medical Center Pharmacy Service could create such a list of mental health medications for providers by running a report at any time, but we were told they had not done so.

In November 2014, subsequent to the original VA site visit, the Medical Center Pharmacy Service initiated a review of all medications requiring an RDR (hereafter, Pharmacy Review) to see whether inclusion of each medication on the list was still appropriate. Medications no longer being restricted were to be removed from the list. The results of the Pharmacy Review were approved on May 13, 2015.

Conclusion

VA did not substantiate the allegation that Medical Center Pharmacy Service maintains a separate medication list of mental health drugs that require justification before they can be dispensed. VA concluded that the allegation may stem from the fact that an alternate streamlined process exists for processing of a locally restricted medication where: 1) the medication is included on the VANF but is locally restricted; and 2) the medication in question was originally prescribed for the patient by a VA provider at another VA medical facility. In these cases, the patient's Medical Center provider need only determine that continuation of the locally restricted drug is still necessary and provide the requisite notification of its prior use to Pharmacy Service. In contrast, a request for the dispensing of a locally restricted drug that is originated by a Medical Center provider is subject to local procedures, including the provision of a complete consultation and approval by Pharmacy Service, as described above. This dual process may be interpreted by some as requiring additional justification or approval in some cases but not all, thus creating the appearance of an ad hoc or changing approach being taken at the facility as concerns the requesting of locally restricted medications. The fact that VA's prescribing software program uses the same format for both types of cases may also have prompted the allegation.

Allegation 2

A spreadsheet maintained by the Pharmacy indicates that many of these special drugs are restricted to Beckley VAMC providers exclusively due to their cost, in violation of VHA Handbook 1108.05 and 1108.08. The whistleblower asserted that these medications are VANF approved, and as such, cost cannot be an exclusive factor in their restriction.

VA interviewed all of the mental health prescribing providers, the clinical pharmacy specialists, and the pharmacy managers. All of them denied knowledge of any such

spreadsheet listing drugs restricted to Medical Center providers due to cost exclusively. In all of the interviews we had with these individuals, no one knew of or had heard of such a spreadsheet.

VA found that pharmacists charged with conducting the Pharmacy Review understood that cost was not to be the sole criterion for retaining the RDR requirement on locally restricted medications, consistent with the guidance in VHA Handbook 1108.08.

Conclusion

VA did not substantiate the allegation that the Medical Center Pharmacy Service improperly restricts the dispensing of mental health drugs included on the list of locally restricted medications exclusively due to their cost.

Allegation 3

The Chief of Pharmacy recently directed employees to improperly alter this list to indicate that cost was not a consideration in placing the medications at issue on the restricted drug list.

The team interviewed mental health providers and pharmacy personnel, and heard no evidence that the Chief, Pharmacy Service, directed her employees to alter any local list of restricted mental health medications to indicate that reasons --other than cost -- justified their restricted use. We found that this Chief, when setting up the Pharmacy Review, provided oral guidance consistent with VHA policy as set forth in VHA Handbook 1108.08. The team did not receive or locate any written evidence or documentation that would support the allegation.

Conclusion

VA did not substantiate the allegation that the Chief of Pharmacy directed her employees to alter any local list of restricted drugs to remove cost as the exclusive basis for the inclusion of certain mental health drugs on any such list. Moreover, as regards medications currently included on the recently approved list of restricted drugs, VA concluded the facility followed VHA Handbook 1108.08 in how it identified restricted medications.