



DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

JAN 05 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:

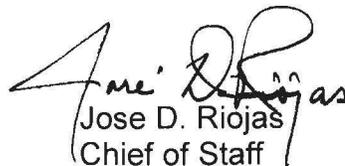
I am responding to your letter regarding allegations made by a whistleblower at the Beckley Department of Veterans Affairs (VA) Medical Center, (hereafter, the Medical Center) in Beckley, West Virginia. The whistleblower alleged that pharmacists are substituting older psychotropic medications for prescribed ones on the basis of economy and were acting as if they were psychiatrists by writing prescriptions in the mental health unit. 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).

The Secretary asked the Under Secretary for Health to refer the whistleblower's allegations to the Office of the Medical Inspector, which conducted a site visit to the Medical Center on September 9-12, 2014. VA substantiated one of the two allegations that pharmacists were substituting prescriptions but did not substantiate that pharmacists were exceeding their scope of practice.

VA made eight recommendations to the Medical Center and one for the Veterans Health Administration. Findings from the investigation are contained in the report, which I am submitting for your review.

Thank you for the opportunity to respond.

Sincerely,


Jose D. Riojas
Chief of Staff

Enclosure

**DEPARTMENT OF VETERANS AFFAIRS
Washington, DC**

**Report to the
Office of Special Counsel
OSC File Number DI-14-3389**

**Department of Veterans Affairs
Beckley Veterans Affairs Medical Center
Beckley, West Virginia**



Report Date: November 3, 2014

TRIM 2014-D-1266

Executive Summary

The Secretary requested that the Veterans Health Administration (VHA) investigate complaints lodged with the Office of Special Counsel (OSC) by an anonymous whistleblower. The Under Secretary of Health (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 Veterans Affairs (VA) Medical Center (VAMC), 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 that alleged Medical Center pharmacists routinely and improperly reject the providers' prescriptions in favor of less expensive medications, and 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.

Specific Allegations of the Whistleblower

1. Medical Center pharmacists were ordered by management to deny provider prescription orders for approved medications based on cost; and
2. Medical Center pharmacists improperly prescribe medications to patients in clinics, and essentially function as psychiatrists.

Conclusions to Allegation 1 (aripiprazole and ziprasidone)

- VA substantiated that the Medical Center's Pharmacy and Therapeutics (P&T) Committee encouraged providers to switch Veterans from aripiprazole or ziprasidone prescribed by other Veterans Health Administration (VHA) providers, based on a Pharmacy cost-savings goal for Fiscal Year 2013 related to atypical antipsychotics. VA's evidence is derived primarily from interviews with mental health (MH) prescribing providers, and perceptions were consistent from one provider to the next. On the basis of these interviews, we believe the preponderance of evidence leads to our substantiating the allegation. Therefore, VA concludes that the P&T Committees' decision was not in compliance with VHA's policy on VA National Formulary (VANF) management process, which prohibits restrictions of VANF medications at the local level based solely on economics and/or without legitimate need for a change in therapy, and thus may have constituted a substantial and specific danger to public health and safety. Although each Veteran had his or her medications reviewed by their MH provider before any adjustment took place, many providers felt that they had no option other than to prescribe some other medication in place of the originally prescribed aripiprazole or ziprasidone. They followed this guidance, despite their disagreement with the change in treatment, citing concerns about the side effects of weight gain and sedation.

- VA substantiated that the MH representative to the P&T Committee voiced concerns to the Committee about the blanket restriction on continued therapy with aripiprazole or ziprasidone for patients who are stable on such medications, including transferred patients who were prescribed these medications at another VA medical center, without a clinical determination of the need to change the patient's therapy. VA is concerned that the P&T Committee did not follow the procedures in VHA Handbook 1108.05, *Outpatient Pharmacy Services*, May 30, 2006, and VHA Handbook 1108.08, *VHA Formulary Management Process*, February 26, 2009.
- Although there is no local policy that requires a physician to serve as Chairperson of the Medical Center P&T Committee, or that prohibits the Chief of Pharmacy from serving in that capacity, the Medical Center could improve its policy making and medication oversight with a physician as chairperson or the Chief of Pharmacy as secretary, as is the practice in other VHA medical centers.

Recommendations to the Medical Center

1. Immediately stop the practice of automatically removing patients from VANF medications (without a legitimate clinical need) initiated by an authorized provider at another VA medical facility, when a patient transfers their care to the Medical Center.
2. Immediately stop the practice of automatically removing Medical Center patients from VANF medications (specifically, aripiprazole or ziprasidone) without a legitimate clinical need.
3. Conduct 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 P&T Committee on April 25, 2013, to restrict use of these medications, to ascertain whether any adverse patient outcomes occurred as a result of discontinuance of the medication.
4. Upon completion of above review, if adverse events are identified related to a patient's clinical care, appropriate disclosures should be made, consistent with the requirements of VHA Handbook 1004.08, *Disclosure of Adverse Events to patients*.
5. Where warranted, appropriate action should be taken against Medical Center leadership and the P&T Committee for approving actions that were not consistent with VHA policy on VANF management and may constitute a substantial and specific risk to public health.
6. Educate Medical Center leadership and the P&T Committee on the policy and procedure requirements outlined in VHA Handbook 1108.05 and 1108.08.
7. Improve local policy making and medication oversight by designating a physician as chairperson of the P&T Committee and the Chief of Pharmacy as secretary.

Recommendations for VHA

8. Remind and reinforce other Medical Centers on the policy and procedure requirements outlined in VHA Handbooks 1108.05 and 1108.08.

Conclusion (alprazolam)

- VA did not substantiate that the Medical Center restricted the prescribing of alprazolam for cost containment reasons, and that the restriction requiring psychiatric review was motivated by safety concerns and therefore was allowable according to VHA Handbook 1108.05.
- Have VHA Program Office review existing policies governing prescribing practices.

Recommendation for the Medical Center

None

Conclusion (quantity of medication)

- VA did not substantiate that the Medical Center restricted the quantity of medication dispensed solely for cost. The restriction limiting the prescription quantity was motivated by safety concerns as well as cost concerns and therefore allowable under VHA Handbook 1108.05.

Recommendation to the Medical Center

None

Conclusion (performance measure)

- VA substantiated that management did not communicate the opioid performance measure to all Primary Care (PC) physicians within 90 days of the beginning of the FY, as required by VHA policy.

Recommendation to the Medical Center

9. In accordance with VHA policy, ensure performance measures are communicated to physicians in a timely manner.

Conclusion to Allegation 2

- VA did not substantiate that pharmacists improperly prescribe medications to patients in clinics, and essentially function as psychiatrists.

Recommendation to the Medical Center

None

Summary Statement

The VA team has developed this report in consultation with other VA and VHA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement, an abuse of authority, or risked public health or safety. In particular, the Office of General Counsel (OGC) has provided a legal review and the Office of Accountability Review (OAR) has examined the issues from a human resources perspective, establishing individual accountability, when appropriate, for improper personnel practices. VA found actions that constitute a violation of VA and VHA policy and pose a substantial and specific danger to public health and safety.

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I. Introduction

The Secretary requested that the VHA investigate complaints lodged with OSC by an anonymous whistleblower. The USH directed OMI to assemble and lead a team to conduct the inquiry. The whistleblower alleged that 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 the providers' prescriptions in favor of less expensive medications, and clinical pharmacy specialists working in the clinics exceed their scope of practice

II. Facility Profile

Part of the Veterans Integrated Service Network (VISN) 6, the Medical Center is a 40-bed general medical and surgical facility without an inpatient psychiatry service. Its 50-bed community living center offers skilled nursing care, post-acute rehabilitation and restorative care, and palliative and respite care for eligible Veterans. The Medical Center also operates a home-based primary care program, providing services to Veterans in nine counties (Raleigh, Wyoming, Mercer, Summers, Fayette, Greenbrier, Monroe, and Pocahontas in West Virginia and Alleghany in Virginia).

III. Specific Allegations of the Whistleblower

1. Beckley VAMC pharmacists were ordered by management to deny provider prescription orders for approved medications based on cost; and
2. Beckley VAMC pharmacists improperly prescribe medications to patients in clinics, and essentially function as psychiatrists.

IV. Conduct of the Investigation

The VA team consisted of (b)(6) Deputy Medical Inspector; (b)(6) (b)(6) Clinical Program Manager, both of OMI; (b)(6), Human Resources Specialist (Employee Relations/Labor Relations), Huntington VA Medical Center, and (b)(6) PharmD, Deputy Chief Consultant for Professional Pharmacy Practice and Pharmacy Benefit Management Services, VHA. VA reviewed relevant Medical Center policies, procedures, reports, memoranda, and other documents, a full list of which is in Attachment A. On September 9, 2014, the team held an entrance briefing with the Medical Center Director, Associate Director, Chief of Staff (COS), Director for Patient Care Services, Chief of Pharmacy Services, and Quality Management Coordinator. Apart from the Chief of Pharmacy, the same individuals attended the exit briefing on September 12. During the visit, VA toured the inpatient and outpatient pharmacy and interviewed the following Medical Center staff:

Interviewed in-person

- (b)(6) Chief of Pharmacy and Chair of the P&T Committee
- (b)(6) MD, COS
- (b)(6) Chief, Mental Health Service Line (MHSL)
- (b)(6) Associate COS, Primary Care Service Line (PCSL)
- (b)(6) Anticoagulation Clinical Pharmacy Specialist
- (b)(6) Physician Assistant (PA), Mental Health (MH)
- (b)(6) CBOC
- (b)(6) MH
- (b)(6) Clinical Care Coordinator, PCSL
- (b)(6) NP, Assistant Chief, MHSL
- (b)(6) PA, MH
- (b)(6), Nurse Practitioner (NP), MH
- (b)(6), Associate Chief Pharmacy
- (b)(6) Clinical Psychologist, MH: CBOC
- (b)(6), Psychologist, MH, Home based Primary Care
- (b)(6) Antimicrobial Steward
- (b)(6)
- (b)(6) (Pain Management Clinic to June 1, 2014; presently MH)
- (b)(6), Physician, MH
- (b)(6), PA, MH
- (b)(6), PCSL
- (b)(6), NP, PCSL
- (b)(6), MD, PCSL

Interviewed by Phone

- (b)(6), MD, MH and P&T Liaison for MH (Located at Richmond, VAMC)
- (b)(6), MH

V. Findings, Conclusions, and Recommendations

Allegation 1

Background

VHA Policy and National Clinical Guidance

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.

Further, the Handbook says the P&T Committee is responsible for performing all functions set by *The Joint Commission Accreditation Manual for Hospitals* and by the American Society of Health-System Pharmacists (ASHP) Statement on the P&T Committee (paragraph 15.a, page 9). The ASHP statement says:

“The P&T committee is composed of actively participating physicians, other prescribers, pharmacists, nurses, administrators, quality-improvement managers, and other health care professionals and staff who participate in the medication-use process. Customarily, P&T member appointments are based on guidance from the medical staff. The P&T committee should serve in an evaluative, educational, and advisory capacity to the medical staff and organizational administration in all matters that pertain to the use of medications (including investigational medications). The P&T committee is a policy-recommending body to the medical staff and the administration of the organization on matters related to the safe and therapeutic use of medications. The P&T committee is responsible to the medical staff as a whole, and its recommendations are subject to approval by the organized medical staff as well as the administrative approval process. The basic policies and procedures that govern the P&T committee’s administration of the formulary system should be incorporated, as appropriate, in the health system’s medical staff bylaws, medical staff rules and regulations, and other organizational policies.” (paragraph 4, page 164).

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” (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 VA medical center, when a patient transfers care to a second VA medical center...” (paragraph 17. t, page 14)

VHA Handbook 1108.05 *Outpatient Pharmacy Services*, May 30, 2006, outlines procedures for VA Medical Centers’ P&T Committees to restrict the quantity of selected medications dispensed, directing 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. For some prescriptions, a 30-day supply or less may be mandated. The Handbook directs that “In all instances, the P&T Committee must consider safety, patient care needs, and VISN resources when establishing such guidelines or restrictions,” (paragraph 5.d, page 3).

Aripiprazole and Ziprasidone

VA/DoD Clinical Practice Guidelines (CPG) are comprehensive statements about specific diseases; each provides diagnostic criteria and recommendations for pharmacologic management of its subject disease. VA and DoD clinicians developed these guidelines by systematically reviewing evidence of benefits and harms of alternative care options. VA medical centers use CPGs as examples of best prescribing practices and as guides in the development of prescribing policies. CPGs provide guidance and recommendations to prescribers but are not considered mandatory. The CPG for Major Depressive Disorder (MDD) recommends the prescription of antidepressants such as venlafaxine SA and antipsychotic drugs such as aripiprazole and ziprasidone for patients not previously treated with antipsychotic or antidepressant medication or who developed a clinical deterioration of their psychiatric disorder; however, the CPG does not address therapeutic adjustments for patients with MDD who are already stable on pharmacotherapy.

Findings

At the Medical Center, the Chief of Pharmacy, a non-physician, serves as the Chairman of the P&T Committee. On April 25, 2013, the Medical Center P&T Committee meeting minutes reflect a decision to restrict the continued prescription of aripiprazole and ziprasidone to patients already on these medications (see Attachment B). The minutes state that these restrictions are based on a Pharmacy cost-savings goal for FY 13 related to atypical antipsychotics. The minutes do not provide a clinical justification for the decision. According to VHA Handbook 1108.08, 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.

VA interviewed the MH representative to that Committee meeting and learned that she had objected to the blanket restriction on continued therapy with aripiprazole and ziprasidone for patients who are stable on such medications, including transferred patients who were prescribed such medications at another VA medical center, without a medical need for a change in the patient’s therapy. The minutes of the April 25, 2013,

P&T Committee meeting in which the local guidelines were approved do not reflect these objections. However, VA found documentation of the MH representative's objections in an earlier set of Committee minutes dating back to December 2012.

Other MH prescribers told VA that they had little or no input into the locally-developed clinical guidelines approved by the P&T Committee. However, we found emails from the Chief of Pharmacy to at least one MH provider asking him to provide input on this matter.

Prescribing providers in the MH Service Line told us that the Pharmacy Service was asking MH providers to discontinue aripiprazole or ziprasidone prescribed for Veterans as psychiatric inpatients at other VA medical centers, usually Hunter Holmes McGuire VA Medical Center, Richmond, Virginia or Salem VA Medical Center, Salem, Virginia. The COS told VA that the MH providers had been asked to review their patients on aripiprazole and to consider other medications that were less expensive. The COS also related that some of the providers did choose to use other medications for patients. The COS said that when providers felt aripiprazole was the most appropriate medication for particular patients, they documented the justification. If the pharmacy disapproved the request, the provider could appeal this decision to the COS. The COS assured us that only when the provider had asked for an alternative antipsychotic medication was it offered to the patients, emphasizing that there were no automatic changes from aripiprazole to another atypical antipsychotic. MH providers told us that they prescribed the less expensive medications, even though they were concerned about the side effects of weight gain and sedation. These providers also indicated that they were aware of an appeal process but were under the impression that appealing a pharmacy decision to deny a request would not result in the COS overturning that decision. Providers told us that they did not submit appeal requests because of what they felt was a forgone conclusion.

Conclusions to Allegation 1

- VA substantiated that the Medical Center's P&T Committee encouraged providers to switch Veterans from aripiprazole or ziprasidone prescribed by other VHA providers, based on a Pharmacy cost-savings goal for Fiscal Year 2013 related to atypical antipsychotics. VA's evidence is derived primarily from interviews with mental health prescribing providers, and perceptions were consistent from one provider to the next. On the basis of these interviews, we believe the preponderance of evidence leads to our substantiating the allegation. Therefore, VA concludes that the P&T Committees' decision was not in compliance with VHA's policy on VA National Formulary (VANF) management process, which prohibits restrictions of VANF medications at the local level based solely on economics and/or without legitimate need for a change in therapy, and thus may have constituted a substantial and specific danger to public health and safety. Although each Veteran had his or her medications reviewed by their MH provider before any adjustment took place, many providers felt that they had no option other than to prescribe some other medication in place of the originally prescribed aripiprazole or ziprasidone. They followed this guidance, despite their

disagreement with the change in treatment, citing concerns about the side effects of weight gain and sedation.

- VA substantiated that the MH representative to the P&T Committee voiced concerns to the Committee about the blanket restriction on continued therapy with aripiprazole or ziprasidone for patients who are stable on such medications, including transferred patients who were prescribed these medications at another VA Medical Center, without a clinical determination of the need to change the patient's therapy. VA is concerned that the P&T Committee did not follow the procedures in the VHA Handbook.
- Although there is no local policy that requires a physician to serve as Chairperson of the Medical Center P&T Committee, or that prohibits the Chief of Pharmacy from serving in that capacity, the Medical Center could improve its policy making and medication oversight with a physician as chairperson or the Chief of Pharmacy as secretary, as is the practice in other VHA medical centers.

Recommendations to the Medical Center

1. Immediately stop the practice of automatically removing patients from VANF medications (without a legitimate clinical need) initiated by an authorized provider at another VA medical facility, when a patient transfers their care to the Medical Center.
2. Immediately stop the practice of automatically removing Medical Center patients from VANF medications (specifically, aripiprazole or ziprasidone) without a legitimate clinical need.
3. Conduct 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 P&T Committee on April 25, 2013, to restrict use of these medications, to ascertain whether any adverse patient outcomes occurred as a result of discontinuance of the medication.
4. Upon completion of above review, if adverse events are identified related to a patient's clinical care, appropriate disclosures should be made, consistent with the requirements of VHA Handbook 1004.08.
5. Where warranted, appropriate action should be taken against Medical Center leadership and the P&T Committee for approving actions that were not consistent with VHA policy on VANF management and may constitute a substantial and specific risk to public health.
6. Educate Medical Center leadership and the P&T Committee on the policy and procedure requirements outlined in VHA Handbook 1108.05, and VHA Handbook 1108.08.

7. Improve local policy making and medication oversight by designating a physician as chairperson of the P&T Committee and the Chief of Pharmacy as secretary.

Recommendations for VHA

8. Remind and reinforce other Medical Centers on the policy and procedure requirements outlined in VHA Handbook 1108.05 and VHA Handbook 1108.08 for the processing of formulary medications.

Alprazolam

At the May 2014 P&T Committee meeting, members addressed prescribing restrictions for the benzodiazepine, alprazolam. Alprazolam is a controlled substance with a known potential for addiction and risk of respiratory depression or death, if combined with alcohol or other opioids. Alprazolam is the most commonly misused benzodiazepine and contributes to an increasing number of drug-related deaths in West Virginia.^{1,2} In addition, the USH established a goal of achieving a 10 percent decrease in the combined use of opioids and benzodiazepines by September 15, 2014.³ Based on these concerns, the Medical Center P&T Committee determined that new prescriptions for alprazolam should be reviewed by a psychiatrist for patient safety before dispensing, and the current 422 patients with an active order for alprazolam should be grandfathered in and not reviewed.

Conclusion

- VA did not substantiate that the Medical Center restricted the prescribing of alprazolam for cost containment reasons, and that the restriction requiring psychiatric review was motivated by safety concerns and therefore was allowable according to VHA Handbook 1108.05.

Recommendation for the Medical Center

None

Prescription Quantities

The December 13, 2012, minutes of the P&T Committee document their discussion on restricting quantities of several medications, including venlafaxine SA,⁴ ziprasidone, lamotrigine, and duloxetine to a 30-day supply (with refills, when the provider thought refills were appropriate). VA found medical staff and the members of the Pharmacy

¹ Shah NA, Abate MA, Smith MJ, et al. Characteristics of alprazolam-related deaths compiled by a centralized state medical examiner. *AM J Addict* 2012;21 Supplement 1:S27-34.

² Trust for America's Health (TFAH). Prescription drug abuse 2013: Strategies to stop the epidemic. [Issue Report]. 2013;408045 (October). Accessed May 6, 2014.

³ Memorandum from the Under Secretary for Health, "Opioid Safety Initiative Requirements," April 2, 2014.

⁴ SA refers to sustained action.

Service in agreement that this restriction was based on safety considerations as well as Medical Center resource concerns. The providers did not indicate that the resources of primary care clinics were strained because of the 30-day supply limitation per prescription. Providers did not identify any Veteran who had their medication interrupted by this restriction.

Conclusion

- VA did not substantiate that the Medical Center restricted the quantity of medication dispensed solely for cost. The restriction limiting the prescription quantity was motivated by safety concerns as well as cost concerns and therefore allowable under VHA Handbook 1108.05.

Recommendation to the Medical Center

None

Opiate prescriptions linked to performance ratings

VA Handbook 5007, *Pay Administration*, Part IX, Paragraph 12 (d.) March 24, 2013, states, "Physicians and dentists must be advised of the specific goals and objectives that will be measured in determining their eligibility for performance pay and the maximum monetary value associated with those goals and objectives. These goals and objectives and the maximum amount of performance pay available in connection with achieving the specified goals and objectives [must] be communicated by an appropriate management official to the individual physician or dentist within 90 days of the beginning of each fiscal year. For newly hired physicians and dentists, goals and objectives [must] be communicated within 30 days of their entrance on duty."

The COS and the Chief, PCSL reported that they did include a measure on opioid reduction in the FY 2014 Physician Performance Plan for PC physicians. They added this measure to the Plan in January 2014 rather than at the beginning of FY 2014. They added this measure based on their assessment of the need for coordinated measures to reduce the prescription reductions in a clinically appropriate manner which was apparent to many VHA clinical leaders before the beginning of FY 2014. The USH issued a memorandum in April 2014 directing VHA to reduce opioid and benzodiazepine prescriptions in a clinically appropriate way. The COS and Chief, PCSL felt that their decision to add this performance measure to the FY2014 Physician Performance Plan for PC physicians was confirmed by the guidance found in the USH's memorandum.

The COS and the Chief, PCSL told VA that they had monitored the physician-level prescribing data on such prescriptions throughout the fiscal year and found that the data did not take into account the opioid prescriptions written by mid-level providers for which

the primary care physicians were responsible.⁵ In the absence of accurate monthly physician prescribing data, they removed this measure from the Plan in August 2014. VA reviewed all the relevant Plans, and confirmed that the measure had been removed.

VA also found that the Chief, PCSL had implemented a performance measure aimed at reducing opioid prescriptions. This measure was in line with the clinical goal of reducing opioid prescriptions when clinically appropriate and in line with the Opioid Safety Initiative Requirements set forth by the USH in a Memorandum of April 2, 2014. The measure was removed from all of the Physician Performance Plans before the end of the fiscal year.

Conclusion

- VA substantiated that management did not communicate the opioid performance measure to all PC physicians within 90 days of the beginning of the FY, as required by VHA policy.

Recommendation to the Medical Center

9. In accordance with VHA policy, ensure performance measures are communicated to physicians in a timely manner.

Allegation 2

Findings

Clinical pharmacy specialists (CPS) are registered pharmacists who have had an additional year of training beyond education and training clinical pharmacists receive. This additional training familiarizes the pharmacist with patients who are usually treated for a chronic medical condition that requires close medication monitoring. CPSs are especially suited to initiate, adjust and terminate medications for patients requiring chronic anticoagulation, anti-hypertensive therapy, or cholesterol reduction treatment.

VHA Directive 2008-043, August 7, 2008, *Scope of Practice for Pharmacists with Direct Patient Care*, provides that VA CPSs are assigned to work in clinical settings and to function as providers of medication management services, including initiating, adjusting or canceling medications. In addition, CPSs order monitoring tests, order consultations, and conduct comprehensive reviews of a patient's health and drug history. The CPS' clinical roles and limitations are outlined in a written scope of practice and must include the individual's prescriptive authority. VHA Directive 2009-14, March 12, 2009, *Establishing Medication Prescribing Authority for Clinical Pharmacy Specialists*, states that CPSs may prescribe controlled substances only if the state of licensure or

⁵ Mid-level providers including advanced practice nurses (APN) and physician assistants (PA) may only prescribe opioid medications in VHA medical facilities if their state of licensure permits them to do so. If APN or PA does not have opioid prescription privileges, the physician assigned as the mid-level provider's collaborating or supervising physician signs and is responsible for the prescription.

registration permits. Each such scope of practice also identifies the supervising physician and must be approved by the COS.

The VA Center for Medication Safety, the VHA Pharmacy Benefits Management Services, the VA Medical Advisory Panel and the VISN Pharmacy Executives jointly published the guidance, "Pharmaceutical Use Outside of Approved Indications: Guidance on 'Off-Label' Prescribing," in August 2013. This provides general principles and recommendations when considering pharmaceutical use outside of approved dosing, chronology, disease or disease state, or populations. Under this policy guidance, "off label" prescribing at VHA medical facilities is permissible.

The Medical Center had assigned a single CPS to work closely with a pain management physician in the Pain Management Clinic. In this capacity, the CPS initiated, adjusted, and terminated medications.

On April 8, 2014, the CPS wrote an initial prescription for lamotrigine for a Veteran with chronic back pain, consistent with the practice of the pain management physician.⁶ Lamotrigine is a medication that is FDA indicated for the treatment of epilepsy but is used "off label" for the treatment of chronic pain unresponsive to medications approved for pain management. Lamotrigine is not a controlled substance. On May 7, 2014, the CPS increased the lamotrigine dose consistent with the recommendation to start that medication with a low dose and increase the dose slowly.

VA reviewed the scope of practice for all Medical Center CPSs and found them to be compliant with VHA Directive 2008-043. Our review of the scope of practice for the CPS in the Pain Management Clinic indicated that she was authorized to initiate and adjust lamotrigine. As required by the Directive, the COS authorized her scope of practice, and her supervising provider reviewed performance quarterly. We also learned from Pharmacy Services management that the pain management physician often used this medication as an analgesic. The CPS holds pharmacy licenses in North Carolina and South Carolina, neither of which permits CPSs to prescribe scheduled medications. Her scope of practice at the Medical Center does not include prescribing scheduled medication, so the Medical Center does not permit her to prescribe these medications.

We reviewed the Veteran's medical record and found the care and medications prescribed to be appropriate.

Conclusion for Allegation 2

- VA did not substantiate that pharmacists improperly prescribe medications to patients in clinics, and essentially function as psychiatrists.

⁶ In May 2014, the CPS was assigned to the pain management clinic. However, she was re-assigned to the Mental Health Service Line in June 2014.

Recommendation to the Medical Center

None

VI. Summary Statement

The VA team has developed this report in consultation with other VA and VHA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement, an abuse of authority, or risked public health or safety. In particular, OGC has provided a legal review and OAR has examined the issues from an human resources perspective, establishing individual accountability, when appropriate, for improper personnel practices. VA found actions that constitute a violation of VA and VHA policy and pose a substantial and specific danger to public health and safety.

Attachment A

Documents Reviewed by VA

Department of Veterans Affairs, VA Handbook 1108.08, *VHA Formulary Management Process*, February 26, 2009.

Department of Veterans Affairs, VHA Handbook 1108.05 *Outpatient Pharmacy Services*, May 30, 2006.

CPG for Management of Major Depressive Disorder (MDD) and Management of Bipolar Disorder in Adults.

Veterans Health Administration, Directive 2008-043, *Scope of Practice for Pharmacists and Direct Patient Care*, August 7, 2008.

Veterans Health Administration, Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

Veterans Health Administration, Directive 2009-014, *Establishing Medication Prescribing Authority for Clinical Pharmacy Specialists*, March 2, 2009.

Veterans Integrated Service Network, *Pharmacy Executive Recommendations for Antipsychotic Section in Schizophrenia and Schizoaffective Disorders*, June 2012.

VA Center for Medication Safety, VHA Pharmacy Benefits Management Services VA Medical Advisory Panel and VISN Pharmacy Executives, *Pharmaceutical Use Outside of Approved Indications Guidance on "Off-label" Prescribing*, August 2013

Under Secretary for Health memorandum: "Opioid Safety Initiative Requirements," April 02, 2014.

Acting Deputy Under Secretary for Health for Operations and Management (10N) Memorandum, January 24, 2014.

Veterans Administration, Handbook 5007 titled *Pay Administration, Part IX, Paragraph 12 (d.)*,

Medical Center, Pharmacy & Therapeutics committee meeting minutes, FY2013 and FY2014.

Medical Center, Mental Health Special Drug Request (SDR) Consults FY2013 and FY2014.

Medical Center, Pharmacy Staff meeting minutes FY2013 and FY2014.

Medical Center, By-Laws, Rules and Regulations of the Medical Staff.

Medical Center, Pharmacist's Scope of Practice.

Medical Center, Pharmacist's Performance Appraisals

Attachment B:

See Minutes of April 25, 2014 C&P Committee Meeting

(separate document)

Attachment B

PHARMACY AND THERAPEUTICS COMMITTEE

Thursday, April 25, 2013 - 2 p.m. - 3C-115b

AGENDA

APPROVAL OF MINUTES: The February and March 2013 minutes were approved as written.

QUALITY ASSURANCE: Results from Monitoring and Evaluation

1. Adverse Drug Reactions (ADRs) (Dec Jan)
(Follow-ups) Documents attached
2. Medication Errors – Pharmacy (1 errors reported) Document attached
3. Medication Errors –Consolidated Mail Outpatient Pharmacy (CMOP) 16
See text box
4. Medication Errors –Nursing 1st Qtr Document attached
5. CLC DUE (Dec, Jan, Feb, Mar) Document attached
6. Narcotic Inspection (Jan, Feb), also follow-up Apr 2012 Report—
Documents attached
7. High Alert Medications (Monthly Ward Inspections) No issues
8. Ethics (Recurring Item) No issues
9. Allergy Ingredient Report (Feb, Mar) No issues
10. Anticoagulation Referrals from 4th Qtr, FY 12 from December Meeting—
Nothing referred

4- Delayed or Lost in Transit
5-Missing from Order
2-Wrong Quantity
2-Damaged
1-Defective, poor quality
2-Miscellaneous reasons

OLD BUSINESS:

1. Chief of Staff Recommendations Regarding Pharmacy Initiatives

Month	Monthly Assigned Goal	Monthly Savings Achieved	% Target Achieved
Oct	\$80,824	\$81,256	101%
Nov	\$72,387	\$108,541	150%
Dec	\$72,246	\$117,509	163%
Jan	\$72,246	\$119,461	165%
Feb	\$72,246	\$110,488	153%
Mar	\$72,246	\$139,046	184%

2. Aripiprazole – Mental Health Provider Plan to meet Pharmacy Cost Saving Goal for FY13 related to Atypical Antipsychotics—plan attached
3. VA Medical Center Non-Formulary Management Process—MCM written and being routed for concurrence and signature
4. Switch High Dose Hydrocodone/APAP 500mg to 325mg—Complete
5. Lantus/Levemir—Complete
6. MUE on Zolpidem—Complete
7. MUE on Modafinil—Complete

8. MUE on Mometasone Nasal--Complete
9. Lansoprazole 30mg Dose--Complete
8. Potassium Chloride (KCL) 8 mEq Dose--Complete
9. Use of GI Cocktail for Outpatients--Complete
10. Combivent Respimat--Complete, one change approved out of committee
11. TDAP for Employees--Complete
12. Sugar Free Metamucil--Complete

NEW BUSINESS:

1. "Value of the Month" March-Advocacy and April-Respect
2. MCM on Standing Order Protocols for the Community Living Center (CLC)—document attached
3. Ezetimibe - Cost Savings—document attached
4. National Contract Announcement - Fish Oil—document attached
5. Request for Renal Dialysis Medications to have different timeframe Limits—document attached
6. Rosuvastatin to Atorvastatin Conversion—document attached

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
BECKLEY, WEST VIRGINIA

PHARMACY AND THERAPEUTICS (P&T) COMMITTEE
April 25, 2013
Room 3C-115b

PRESENT:

(b)(6)	05/05	Chief, Pharmacy/Chairperson
	03/05	Chief of Staff
	05/05	Chief, Dental Service
	04/05	Surgeon, Acute Care Service Line (ACSL)
	05/05	Associate Chief, Pharmacy
	04/05	Clinical Pharmacy Specialist
	03/05	Chief, Primary Care Service Line (PCSL)
	01/05	Clinical Pharmacy Specialist
	03/05	Clinical Pharmacy Specialist
	03/05	Quality Management (QM) Coordinator
	04/05	Clinical Pharmacy Specialist
	03/05	Clinical Care Coordinator (CCC), Critical Care Team
	05/05	Secretary, Pharmacy/Recorder

EXCUSED:

(b)(6)	03/05	Medical Director, PCSL
	01/05	Medical Director, Geriatrics and Extended Care Service Line (G&ECSL)
	03/05	Physician's Assistant, Mental Health Service Line (MHSL)
	00/05	Infection Control Coordinator
	01/05	Bar Code Medication Administration (BCMA) Coordinator
	03/05	Physician, PCSL

CALL TO ORDER: The meeting was called to order by the chairperson at 2 p.m., in Room 3C-115b. There were 12 voting members in attendance at this meeting which represents a quorum (at least 51 percent of committee members).

APPROVAL OF MINUTES: The minutes of the February and March 2013 meetings were approved as written, with a correction to the February minutes to include the need for follow-up on the patient who reported an ADR with tamsulosin. The need for follow-up on this ADR was not included in the follow-up actions from the ADR discussion in the February 2013 meeting.

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P&T Committee, April 25, 2013

Recommendation/Action: None

Follow-up: June 2013

2. TOPIC: Aripiprazole—Special Drug Request (SDR)

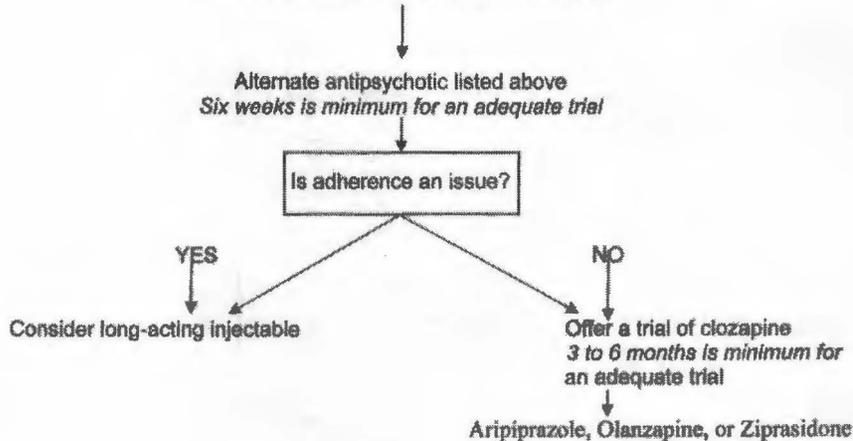
Discussion: The Associate Chief, Pharmacy worked with the MH providers to develop a more definitive plan regarding the use of atypical antipsychotics as she had agreed to do in the February 2013 meeting.

The Associate Chief, Pharmacy met with MH prescribers. They agreed upon the algorithms listed below. They have several new prescribers coming on board that will help them follow up quicker after they make changes. We are being lenient in approving those on atypicals for psychosis/schizophrenia/history of SI/Homicidal Ideation (HI), etc. Aripiprazole and ziprasidone are both being targeted (turned off from filling at the Consolidated Mail Outpatient Pharmacy [CMOP], no 90 day supplies are being issued, addressing them as they request their refills). SDRs are required to continue or to initiate these two antipsychotics. The Associate Chief, Pharmacy is personally addressing the SDRs.

ANTIPSYCHOTIC ALGORITHMS BASED ON INDICATION

Psychosis

Shown in alphabetical order and does not imply preference
Haloperidol, Loxapine, Perphenazine, Quetiapine, or Risperidone
Six weeks is minimum for an adequate trial



P&T Committee, April 25, 2013

The committee members reviewed the document proposing the conversion from rosuvastatin to atorvastatin and the recommended changes to the SDR for rosuvastatin. The committee members were in agreement to make the conversion and to make the changes to the SDR for rosuvastatin.

Conclusion: The committee members were in agreement to make the conversion from rosuvastatin to atorvastatin and to make the changes to the SDR for rosuvastatin.

Recommendation/action: Patients will be converted from rosuvastatin to atorvastatin as refills are requested on rosuvastatin according to the conversion table below:

Rosuvastatin Daily Dose	Atorvastatin Daily Dose Conversion
5 mg	20 mg
10 mg	40 mg
20 mg	40 mg
40 mg	80 mg

These conversions will be accomplished by the pharmacy staff. Patients will be sent an informational letter by the pharmacy when the conversion is made.

Follow-up: June 2013

Around the room:

No topics for discussion.

There being no further items for discussion, the meeting adjourned at 3:15 p.m.

(b)(6)

Chairperson

Date: 5-20-2013

~~CONCUR~~ NON-CONCUR:

(b)(6)

Chief of Staff

Date: 5/20/13

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