VA | U.S. Department of Veterans Affairs

Office of the General Counsel
Washington DC 20420

MAR 19 2014

In Reply Refer To:

The Honorable Carolyn Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M. Street, NW, Suite 300
Washington, DC 20036-4505

RE: OSC File Nos. DI-13-4505

Dear Ms. Lerner:

Enclosed are the redacted and unredacted reports as described in the letter signed by VA Chief of Staff Jose D. Riojas. The Chief of Staff was delegated by Secretary Shinseki to sign the report. We hereby request that your office publish the enclosed redacted version. VA's unredacted response identifies the individuals who were interviewed during the investigation, or who conducted the investigation, by names and job titles.

If you have any questions about this request, please contact Jennifer Gray in the Office of General Counsel at 202-461-7634.

Sincerely,

Renee Szybala
Acting Assistant General Counsel

Enclosures

DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

March 12, 2014

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-13-4505

Dear Ms. Lerner:

I am responding to your letter regarding allegations made by (b) (6), M.D., a former Department of Veterans Affairs (VA) employee (hereafter, the whistleblower) at the Brockton Campus of the VA Boston Healthcare System, Brockton, Massachusetts, (hereafter, the Medical Center). The whistleblower alleged that the Community Living Center (CLC) rendered inappropriate medical and mental health care to three patients residing there, is not operating in accordance with agency-wide policies, and may have violated laws, rules, or regulations, engaged in gross mismanagement, and posed a specific danger to public health and safety. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as reported under 5 United States Code § 1213(d)(5).

The Secretary asked the Under Secretary for Health to review this matter and to take any actions deemed necessary under the above code. He, in turn, directed the Office of the Medical Inspector (OMI) to conduct an investigation. In its investigation, OMI substantiated the whistleblower's allegations regarding the first patient, partially substantiated the allegation regarding the second patient, but did not substantiate the allegation regarding the third patient. OMI substantiated that a Veteran, admitted to the CLC in (b) (6) 2003, with significant, chronic, mental health issues, did not have his first comprehensive psychiatric evaluation until (b) (6), 2011. OMI partially substantiated that a Veteran, resident in the CLC from (b) (6) 2005 to (b) (6) 2013, had only one psychiatric note written in his medical chart, on (b) (6), 2012, and might have benefited from more frequent evaluations. OMI did not substantiate that a Veteran had been on a psychotropic medication for more than 2 years without any attempt to decrease or discontinue its use. OMI's investigation found no violations of statutory laws, mandatory rules, or regulations. Findings from the investigation are contained in the report, which I am submitting for your review. I have reviewed these findings and agree with the recommendations in the report. We will send your office follow-up information describing actions that have been taken by the Medical Center to implement these recommendations.

Thank you for the opportunity to respond.

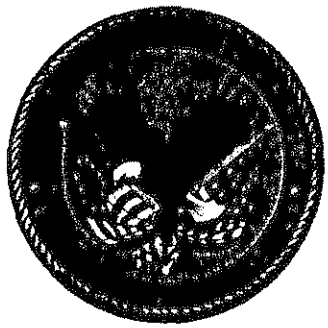
Sincerely,

Jose D. Riojas
Chief of Staff

Enclosure

OFFICE OF THE MEDICAL INSPECTOR
Report to the
Office of Special Counsel
OSC File Number DI-13-4505

Department of Veterans Affairs
VA Boston Healthcare System
Brockton, Massachusetts



Veterans Health Administration
Washington, DC

Report Date: January 2, 2014
TRIM 2013-D-1489

Executive Summary

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) investigate complaints lodged with the Office of Special Counsel (OSC) by (b) (6) M.D., a former Department of Veterans Affairs (VA) employee (hereafter, the whistleblower) from the Brockton Campus of the VA Boston Healthcare System (VABHS), Brockton, Massachusetts, (hereafter, the Medical Center). The whistleblower alleged that the Community Living Center (CLC) failed to provide appropriate medical and mental health care for specific individuals residing in the CLC and is not operating in accordance with agency-wide policies. The whistleblower alleged that the CLC may have violated laws, rules, or regulations, engaged in gross mismanagement and was a specific danger to public health and safety. OMI conducted a site visit to the Medical Center on December 12-13, 2013.

Summary of Allegations

The whistleblower's allegations are as follows:

1. A resident of the CLC admitted for a service-connected (b) (6) went more than five years without appropriate psychiatric consultation, treatment, or medication;

2. A resident of the CLC who was diagnosed with a service connected (b) (6) (b) (6) and (b) (6) went more than 11 years without any psychiatric treatment and specific lab monitoring required by VA regulations and policies for individuals taking anti-psychotic and psychotropic medications; and

3. Benzodiazepine, a psychotropic medication, was administered to a patient for more than two years without any attempt to decrease or discontinue use, when specific clinical directions and indications stated that this medication should not be given to this individual.

Conclusions:

OMI **substantiates** Allegation 1.

- Veteran 1 was admitted to the CLC in (b) (6) 2003, with significant, chronic, mental health issues. He had two brief contacts with psychiatrists in 2003 and 2008. However, his first comprehensive psychiatric evaluation did not occur until (b) (6), 2011. Medication assessments and modifications did not occur until the time of this consultation.

- The resident is currently engaged in treatment and is receiving individual counseling from the CLC psychologist; these visits have been occurring for the past several years.

OMI **partially substantiates** Allegation 2.

- Veteran 2 was a CLC resident from (b) (6) 2005 to (b) (6) 2013, and had one psychiatric note written in his medical chart on (b) (6) 2012, which addressed treatment recommendations. Given his extensive mental health issues, more frequent assessments by psychiatry service would have been beneficial.
- Veteran 2 was monitored for the potential side effects of the medications he was receiving.
- There was no evidence that the CLC tried to lower the doses or eliminate the psychotropic medications that Veteran 2 was receiving.

OMI **does not substantiate** Allegation 3.

- Between (b) (6) 2010, and (b) (6), 2012, Veteran 3's benzodiazepine (lorazepam) was reduced by 50 percent, from a maximum of 4 mg. in a 24-hour period to a maximum of 2 mg. in a 24-hour period.

Recommendations:

1. All CLC residents receiving antipsychotic/psychotropic medications should be assessed at least annually by the consultative liaison psychiatrist to ensure that the particular medication and dosage amount is consistent with the desired effects and with VA standards of care.
2. Current CLC residents on these drugs who have not been seen by psychiatry in the past 12 months should be seen as soon as possible.
3. Develop a process to minimize or eliminate the necessity for psychotropic medications by considering other methods such as behavioral techniques, counseling, etc., to try for the desired resident outcomes.

Summary Statement:

OMI's investigation did not find violation of statutory laws, rules, or regulations.

I. Introduction

The USH requested that OMI investigate complaints lodged with OSC by the whistleblower, who alleged that the CLC failed to provide appropriate medical and mental health care for specific individuals residing in the long-term care units, and was not operating in accordance with agency-wide policies. The whistleblower alleged that the CLC may have violated laws, rules, or regulations, engaged in gross mismanagement and was a specific danger to public health and safety. OMI conducted a site visit to the Medical Center on December 12-13, 2013.

II. Facility Profile

The Medical Center is part of the VABHS, Veterans Integrated Service Network (VISN) 1, which consists of three campuses, Brockton, Jamaica Plain, and West Roxbury, all are within a 40 mile radius of the greater Boston area. The Medical Center offers long-term care, a chronic spinal cord injury unit, mental health services (inpatient and outpatient), comprehensive primary care, and a domiciliary for homeless Veterans. An inpatient psychiatric unit for women and a residential rehabilitative unit for women with both posttraumatic stress disorder (PTSD) and substance abuse are also available. Both the homeless Veterans program and the women's program are regional referral centers for Veterans throughout New England. The chronic spinal cord injury unit offers specialized programs and respite care for Veterans with spinal cord injuries and disabilities. The 110-bed CLC also offers respite care to Veterans throughout New England. The Medical Center's chronic and acute inpatient psychiatric programs and substance abuse programs were recently honored with an award as a Center of Excellence for Seriously Mentally Ill Veterans.

III. Allegations

The whistleblower's allegations are as follows:

1. A resident of the CLC admitted for a service-connected (b) (6) went more than five years without appropriate psychiatric consultation, treatment, or medication;

2. A resident of the CLC who was diagnosed with a service connected (b) (6) (b) (6) and (b) (6) went more than 11 years without any psychiatric treatment and specific lab monitoring required by VA regulations and policies for individuals taking anti-psychotic and psychotropic medications; and

3. Benzodiazepine, a psychotropic medication, was administered to a patient for more than two years without any attempt to decrease or discontinue use, when specific clinical directions and indications stated that this medication should not be given to this individual.

IV. Conduct of Investigation

An OMI team consisting of (b) (6), M.D., Medical Inspector, OMI; (b) (6) (b) (6), Ed.D., Clinical Psychologist, OMI; (b) (6), M.D., board certified in geriatric psychiatry; and (b) (6), Registered Nurse (R.N.), Chief, Facility Based CLC Programs, Veterans Health Administration (VHA), conducted the site visit. OMI reviewed relevant policies, procedures, reports, memorandums, electronic health records (EHR), and other documents, a complete list of which is in Attachment A. OMI held an entrance and an exit briefing with Medical Center leadership including: (b) (6), Medical Center Director; (b) (6), M.D., Chief of Staff; and (b) (6), Quality Management Service.

OMI interviewed the following CLC personnel:

(b) (6), Ph.D., Psychologist

(b) (6), M.D.

(b) (6), Physician Assistant (b) (6), Ph.R., Clinical Pharmacist

(b) (6), M.D., Psychiatry Liaison to CLC

(b) (6), Ph.R., Clinical Pharmacist

(b) (6), R.N., Nurse Manager for 4-1B

(b) (6), R.N., Nurse Manager for 4-2b

(b) (6), R.N., Minimum Data Set Coordinator for 4-2b

On December 11, 2013, before the site visit, OMI interviewed the whistleblower via telephone. He provided additional information regarding his clinical experiences as the consultative liaison psychiatrist to the CLC.

The Office of General Counsel reviewed OMI's findings to determine whether there was any violation of law, rule, or regulation.

OMI **substantiated** allegations when the facts and findings supported that the alleged events or actions took place. OMI **did not substantiate** allegations when the facts showed the allegations were unfounded. OMI **could not substantiate** allegations when we found no conclusive evidence either to sustain or refute the allegations.

V. Background

VA has made a transition from an institutional medical model (nursing home) to a person-centered care model (CLC) in its long-term care facilities. The heart of person-centered care is the relationship between the resident and the frontline staff who care

for the resident daily. The life of the resident is enriched when his or her desires are honored each and every day.

The CLC at Brockton consists of four units: 4-1c, 4-2c, 4-1b, and 4-2b. The first two units are dedicated to short stay skilled nursing/rehabilitation and hospice/palliative care services. Unit 4-1b is dedicated to short-term care (less than 90 days) and rehabilitation. There are a few long-term residents on 4-1b who will eventually be transferred to 4-2b, which provides long-term care. Many of the residents on 4-2b also have dementia-related diagnoses. Current CLC strategy is to phase out existing long-term residents and increase the utilization of home and community-based care programs when appropriate. OMI learned that the CLC has not admitted a new long-term care resident in over 3 years. CLC's changing focus is on short term stays and rehabilitative services.

The whistleblower disclosed that Brockton management has failed to provide appropriate medical and mental health care for specific individuals residing in the long-term care units (4-1b and 4-2b) of the CLC. He was especially concerned that long-term residents who were receiving antipsychotic and psychotropic medications, were not monitored as they should have been, and that these medications were not being reduced or eliminated.

Antipsychotic medications, such as olanzapine, risperidone, clozapine, etc., are used primarily to manage psychosis including delusions, hallucinations, and disordered thought. Psychotropic medications, such as lorazepam, alprazolam, hydroxyzine, etc., are capable of affecting mental activity, emotions, perception, and behavior, and are prescribed accordingly.

VA expects providers to meet community standards of medical practice and to comply with the Center for Medicaid/Medicare Services' expectations as described in the State Operations Manual Guidance to Surveyors for Long-Term Care facilities.[1]

Specifically:

1. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used: (i) In excessive dose (including duplicate therapy); (ii) For excessive duration; (iii) Without adequate monitoring; (iv) Without adequate indications for its use; (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or (vi) Any combinations of the reasons above.

2. Antipsychotic drugs – Based on a comprehensive assessment of a resident, the facility must ensure that: (i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and (ii) Residents who use antipsychotic drugs receive gradual dose reductions, and

[1]Center for Medicaid/Medicare Services, *State Operations Manual Guidance to Surveyors for Long Term Care Facilities*, January 7, 2011.

behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

The Long Term Care Institute (LTCI) is a leading organization focused on quality and performance improvement, compliance with community standards of care, and new program development. It routinely surveys long-term care, hospice, and other residential care facilities. One item LTCI assesses when surveying facilities is verification that each resident's drug regimen is free from unnecessary drugs as defined above.

The American Psychiatric Association has also established professional practice guidelines recommending that individuals taking antipsychotic and psychotropic medications have specific laboratory tests, including complete blood counts and liver function tests on a routine basis. This helps ensure that medication is not producing unsafe side effects. These guidelines further state that efforts should be made to reduce or eliminate the use of these medications.

VI. Findings

The whistleblower presented three Veterans who received long-term care on unit 4-1b and 4-2b, alleging that they did not get the appropriate care for their medical and mental health issues.

Allegation 1: A resident of the CLC admitted for a service-connected (b) (6) (b) (6) went more than five years without appropriate psychiatric consultation, treatment, or medication.

Veteran 1 is a (b) (6) year-old male, Army combat (b) (6) who is 100 percent service-connected for (b) (6) He has a history of multiple suicide attempts, including stabbing himself in the (b) (6) and overdosing on medications. He was first admitted to the CLC in (b) (6) 2003 due to suicidal ideation, and has been a resident there since (b) (6) Prior to admission to the CLC, he had approximately eight admissions for medical and/or psychiatric reasons.

His first contact with a psychiatrist in the CLC was on (b) (6) 2003, whose note in the EHR refers to an extensive assessment by a psychology intern on (b) (6) 2003. The Veteran was referred for testing by the unit physician who wanted to assess the resident's mental capacities. It is unclear as to whether the resident was actually seen by the psychiatrist. His EHR indicates that on (b) (6) 2008, he briefly saw an emergency room psychiatrist, who had been called by unit staff, due to the resident's crying and disruptive behavior. The psychiatrist indicated in the EHR that the resident was in good control and that he told staff there was no reason for any intervention or change at that time.

On (b) (6) 2011, due to the resident's pain and depressive features, a psychiatric consultation was initiated by the unit psychologist. On (b) (6), the resident was seen by the consultative liaison psychiatrist (the whistleblower) who recommended changes

to his antidepressant medication. Another psychiatrist made a follow-up visit to assess the resident after these medication changes. He indicated that there had been an improvement in the resident's condition and that current antidepressant doses should remain unchanged. On (b) (6) , 2012, the whistleblower returned to see the resident and noted that the resident had regressed and that his depressive symptoms had become more severe. As the resident refused to take any medication, the whistleblower encouraged the CLC team to convince him to change his mind. On (b) (6) , 2013, the resident was seen by the psychiatry service to evaluate his ability to make decisions regarding his health, such as the right to refuse medications; the assessment determined that the resident had the ability to retain decisional authority for his care.

OMI learned that visits and consultations from the psychiatry service have to be initiated by the unit psychologist, and recommendations for treatment are passed on to the medical team. The team can then decide whether or not to follow the psychiatric recommendations. It did not appear that the psychiatry service makes routine or consistent attempts to follow residents after an initial consultation to assess response to recommendations; there was no consistency or policy related to when or under what circumstances they would visit CLC residents after consultation.

In 2011, Veteran 1 expressed an interest in individual psychotherapy and began receiving weekly visits by the CLC psychologist. Since that time, these visits have occurred on a regular basis. The EHR contains numerous "behavioral" notes describing his issues and difficulties. Occasionally, the resident refuses to see his psychologist, but often reconsiders and ends up attending most of his sessions. He tends to reject his psychiatric medications, despite the psychologist's efforts to convince him of medication benefits.

As the resident has been on antidepressants and other medications that can cause toxicity and other physical symptoms, laboratory tests, including vitamin B12 and thyroid stimulating hormone (TSH) levels, were ordered in 2009, 2010, and 2011. His first testosterone level was drawn on (b) (6) , 2011, upon the recommendation of the consultative liaison psychiatrist (the whistleblower), who also recommended that vitamin B12 and TSH levels be repeated, since they had not been drawn since (b) (6) of that year.

Conclusion: OMI **substantiates** Allegation 1.

- Veteran 1 was admitted to the CLC in (b) (6) 2003, with significant, chronic, mental health issues, and while he had two brief contacts with psychiatrists in 2003 and 2008, his first significant psychiatric consultation did not occur until (b) (6) , 2011. Medication assessments and modifications did not occur until the time of this consultation.

- The resident is currently engaged in treatment and is receiving individual counseling from the CLC psychologist; these visits have been occurring for the past several years.

Recommendations:

The Medical Center should:

1. Ensure all CLC residents receiving antipsychotic/psychotropic medications are assessed at least annually by the consultative liaison psychiatrist to verify that the particular medication and dosage amount is consistent with desired effects and VA standards of care.

2. Arrange for current CLC residents who are taking antipsychotic/psychotropic medications, and who have not been seen by psychiatry in the past 12 months, to be seen as soon as possible.

Allegation 2: A resident of the CLC who was diagnosed with a service connected (b) (6) and (b) (6) went more than 11 years without any psychiatric treatment and specific lab monitoring required by VA regulations and policies for individuals taking anti-psychotic and psychotropic medications.

Veteran 2 was a (b) (6) year-old (b) (6), 100 percent service-connected for (b) (6), who died on (b) (6), 2013, while a resident in the CLC. His death was due to (b) (6). He was diagnosed with (b) (6) in 1993, but also had a number of psychiatric issues, which led to psychiatric inpatient admissions in 1998, 1999, and 2002. Reasons for admissions included (b) (6), (b) (6), (b) (6), (b) (6), (b) (6), (b) (6) and (b) (6).

On (b) (6), 2002, due to his (b) (6) the Veteran was transferred to the CLC from inpatient psychiatry for rehabilitation. In reviewing the EHR, there was no indication that his (b) (6). On (b) (6), he was discharged to a foster home, where he received his care on an outpatient basis. During this time, he was seen by several clinical care providers, including psychiatrists who determined that he needed more intensive care than could be provided in an outpatient setting. He was experiencing problems with falling, walking, and moving his left arm. On (b) (6), 2005, he was readmitted to the CLC with a diagnosis of (b) (6) (b) (6).

Due to the nature of his symptoms, the Veteran was placed on a number of medications including several antidepressants and other psychotropics. OMI reviewed his EHR and found only one psychiatric note during his stay in the CLC, which spanned (b) (6) 2005 to (b) (6) 2013. The note was written by the whistleblower on (b) (6), 2012.

OMI's review also found that, while in the CLC, the Veteran had approximately two liver function tests per year and approximately three complete blood count tests per year. These tests were done to monitor the resident for potential deleterious effects from his medications. There was no evidence in the Veteran's EHR of a systematic process or effort to reduce and/or eliminate the use of his antidepressant and psychotropic medications.

Conclusions: OMI **partially substantiates** Allegation 2.

- Veteran 2 was a CLC resident from (b) (6) 2005 to (b) (6) 2013, and had one psychiatric note written in his medical chart on (b) (6), 2012, which addressed treatment recommendations. Given his extensive mental health issues, more frequent assessments by psychiatry service would have been beneficial.
- Veteran 2 was monitored for the potential side effects of the medications he was receiving.
- There was no evidence that the CLC tried to lower the doses or eliminate the psychotropic medications that Veteran 2 was receiving.

Recommendation:

The Medical Center should:

3. Develop a process to minimize or eliminate the necessity for psychotropic medications by considering other methods such as behavioral techniques, counseling, etc., to achieve the desired resident outcomes.

Allegation 3: Benzodiazepine, a psychotropic medication, was administered to a patient for more than two years without any attempt to decrease or discontinue use, when specific clinical directions and indications stated that this medication should not be given to this individual.

Veteran 3 was an (b) (6)-year-old single male, 100 percent service-connected for (b) (6), (b) (6), who died in the CLC on (b) (6), 2013. The cause of death was (b) (6) (b) (6) He had a long history of medical and psychiatric difficulties such as (b) (6), (b) (6), (b) (6), (b) (6), and (b) (6). Medical notes in his EHR begin in 1993 and indicate that he had chronic medical difficulties resulting in frequent transfers from community hospitals, to foster homes, to community nursing homes, to medical/psychiatric units in both the Medical Center and the West Roxbury VA Medical Center. He would often become agitated and belligerent, necessitating admission to inpatient psychiatry for stabilization. His longest admission to inpatient psychiatry took place at the Medical Center between (b) (6) and (b) (6). Upon discharge, he was immediately transferred to the CLC for long-term care to treat his medical and psychiatric problems. He remained in the CLC until the time of his death.

On (b) (6), 2010, the Veteran received his first psychiatric consultation, which was conducted by the whistleblower. Upon reviewing his EHR, the whistleblower learned that the resident had standing orders to take as needed up to 4 mg. of lorazepam in a 24-hour period, a benzodiazepine for anxiety, and up to 35 mg. of olanzapine for agitation. The whistleblower recommended a trial decrease in the dose of olanzapine because he believed it was likely worsening the resident's mental status. He recommended no changes to the doses for lorazepam. OMI did not find evidence in the

EHR of clinical direction or indication that benzodiazepine should not be given to this Veteran.
On (b) (6), 2012, the whistleblower was again consulted by the CLC on the care of this Veteran. The whistleblower noted in the EHR that since his 2010 consultation, the maximum dosage of olanzapine had been reduced by 64 percent to 12.5 mg. Despite the fact that the whistleblower, in his consultation of 2010, had not commented on lowering the lorazepam dose, the maximum dose of lorazepam had been reduced by 50 percent to 2 mg.

Evidence-based recommendations of the American Geriatrics Society (2012) updated the criteria for potentially inappropriate medication use in older adults. It stated that older adults have increased sensitivity to benzodiazepines, which increases the risk of cognitive impairment, delirium, falls, fractures, and motor vehicle accidents, and should be avoided in the treatment of insomnia, agitation, or delirium. As with all drugs, doses should be reduced or eliminated if clinically appropriate. A decision to give benzodiazepines or any drug to any resident is based on clinical indications and the physician's judgment.

Conclusion: OMI **does not substantiate** Allegation 3.

Between (b) (6), 2010, and (b) (6), 2012, Veteran 3's benzodiazepine (lorazepam) was reduced by 50 percent, from a maximum of 4 mg. to a maximum of 2 mg. in a 24-hour period.

Recommendation: None

Attachment A

Documents Reviewed by OMI

1. VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008.

2. American Psychiatric Association, *Practice Guideline for the Treatment of Patients with Alzheimer's Disease and Other Dementias*, 2013.

3. Center for Medicaid/Medicare Services, *State Operations Manual Guidance to Surveyors for Long Term Care Facilities*, January 7, 2011.

4. American Geriatrics Society, *American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*, 2012.