DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

April 2, 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-14-2175

Dear Ms. Lerner:

I am responding to your letter regarding an allegation made by a whistleblower at the Wilmington Department of Veterans Affairs (VA) Medical Center, (hereafter, the Medical Center) in Wilmington, Delaware. The whistleblower alleged that psychiatrists at the Medical Center were failing to follow local standard operating procedures (SOP) in the treatment of opioid use disorder. 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 that the Interim Under Secretary for Health refer the whistleblower's allegation to the Office of the Medical Inspector, who assembled and led a VA team on a site visit to the Medical Center on December 10–12, 2014. VA did not substantiate the whistleblower's allegation.

VA made three recommendations to the Medical Center. Findings from the investigation are contained in the enclosed 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-14-2175

Department of Veterans Affairs
Wilmington Veterans Affairs Medical Center
Wilmington, Delaware

Report Date: January 30, 2015

TRIM 2014-D-1258

## Executive Summary

The Interim Under Secretary for Health (I/USH) requested that the Office of the Medical Inspector (OMI) assemble and lead a team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Wilmington Department of Veterans Affairs (VA) Medical Center (hereafter, the Medical Center) located in Wilmington, Delaware. Olufemi Olatunji (hereafter, the whistleblower), who consented to the release of his name, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on December 10–12, 2014.

### Allegation

(b) (6), M.D., Interim Chief of Psychiatry, does not comply with agency policy regarding the treatment of patients with opioid use disorder (OUD).

VA **substantiated** allegations when the facts and findings supported that the alleged events or actions took place and **did not substantiate** allegations when the facts and findings showed the allegations were unfounded. VA was **not able to substantiate** allegations when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of findings, VA makes the following conclusions and recommendations.

### Conclusions

- VA **did not substantiate** the allegation that Dr. (b) (6), Interim Chief of Psychiatry, does not comply with agency policy regarding the treatment of patients with OUD. VA does not have a policy that dictates therapy for OUD, but relies instead on comprehensive guidelines for best current evaluation and therapeutic options based on VA/Department of Defense (DoD) Evidence Based Clinical Practice Guideline Management of Substance Use Disorders (SUD), August 2009 (VA/DoD Guideline), and the Substance Abuse and Mental Health Services Administration Treatment Improvement Protocol 40 (SubAbuse TIP). Dr. (b) (6) practice conforms to these guidelines.

- The Medical Center's standard operating procedure (SOP) BHS 7, "Buprenorphine/Naloxone (Suboxone®) Induction/Maintenance Treatment" (SOP Suboxone) does not conform to Veterans Health Administration (VHA) Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, which states, "pharmacotherapy with approved, appropriately-regulated opioid agonist must be available to **all** patients diagnosed with opioid dependence for whom there are no medical contraindications" and including those with disruptive behavior. SOP Suboxone lists disruptive behavior as a criterion for discharge from Suboxone treatment, which is not consistent with VHA Handbook 1160.01. That SOP does not

conform to VA's comprehensive guidelines in at least two areas: discharge from Suboxone treatment due to the patient's failure to maintain abstinence and treatment for continued cravings and use of opioids. The guidelines used by VA do not recommend discharge if a patient is not able to maintain abstinence and do recommend increasing the Suboxone dosage to treat continued craving.

- The SOP Suboxone's requirement to administratively discontinue treatment for disruptive behavior is not consistent with 38 Code of Federal Regulations (CFR) 17.107, which requires an assessment of the disruptive behavior in connection with VA's duty to provide good quality care, including care designed to reduce or otherwise clinically address the patient's behavior. Section 17.107 also provides specific procedures that must be followed for restrictions on a patient's care.

- All prescribing psychiatrists, including Dr. (b) (6) and Substance Abuse (SA) Clinic staff, ignore the erroneous sections of the SOP Suboxone. Since all providers are following VA's comprehensive guidelines and not SOP Suboxone, VA **did not substantiate** that Medical Center employees are engaging in conduct that may constitute violations of law, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health.

- One of the four psychiatrists (not Dr. (b) (6) ) prescribing Suboxone is unfamiliar with OUD comprehensive guidelines. VA, however, found no evidence that this physician inappropriately discharged any Veteran from the Medical Center OUD treatment program.

- Although SOP Suboxone did not conform to VHA policy and comprehensive guidelines for best current evaluation and therapeutic options based on the VA/DoD Guideline and the SubAbuse TIP, it was not implemented in the treatment of Veterans. VA **did not substantiate** that the Medical Center's opioid use treatment program, as implemented, violated law, rule, VHA directive or policy, or was a substantial and specific danger to public health.

**Recommendations to the Medical Center**

1. Complete the revision of the Suboxone SOP so that it is consistent with the comprehensive guidelines and with VHA Handbook 1160.01.

2. If care agreements are included in the new SOP Suboxone, they should avoid language that threatens automatic discharge from therapy for illicit drug use; the care agreement could inform the patient that failure to abstain from illicit drug use may result in a clinical reassessment of their therapeutic options.

3. Through record reviews, peer reviews, or similar strategies, assess the practice of the one psychiatrist who was not familiar with the comprehensive guidelines and provide training or patient follow up, if indicated.

**Summary Statement**

OMI has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement, or created a substantial and specific danger to public health. 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 to establish accountability, when appropriate, for improper practices. VA found no violations of VA and VHA policy, as implemented, gross mismanagement, or a substantial and specific danger to public health.

## Table of Contents

## I. Introduction

The I/USH requested that OMI assemble and lead a VA team to investigate allegations lodged with OSC concerning the Medical Center. The whistleblower, who consented to the release of his name, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health.

## II. Facility Profile

A member of the Veterans Integrated Service Network (VISN) 4, the Medical Center has a capacity of 60 acute care beds and 60 Community Living Center beds for extended care. It operates Community-Based Outpatient Clinics (CBOC) in three counties of Delaware and four counties of southern New Jersey. A teaching hospital, the Medical Center provides a full range of patient care services with state-of-the-art technology in primary care and long-term care in areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, geriatrics, and extended care. It is also a certified community cancer center.

## III. Specific Allegation of the Whistleblower

(b) (6), M.D., Interim Chief of Psychiatry, does not comply with agency policy regarding the treatment of patients with OUD.

## IV. Conduct of Investigation

The VA team conducting the investigation consisted of (b) (6), M.D., Deputy Medical Inspector, and (b) (6), RN, Clinical Program Manager, both of OMI; (b) (6), M.D., Deputy National Mental Health Program Director, Addictive Disorders, Mental Health Services, Office of Patient Care Services, VA Central Office; and (b) (6), HR Specialist, OAR. The VA team reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A.

The VA team interviewed the whistleblower via teleconference on December 1, 2014.

The VA team conducted a site visit to the Medical Center on December 10–12, 2014, holding an entrance briefing with Medical Center leadership including the following individuals: the Director, Assistant Director, Chief of Staff (CoS), Nurse Executive, and members of the VISN 4 staff. The team toured the Medical Center's SUD Clinic.

We interviewed the following employees during the site visit:

- (b) (6), M.D., Medical Center Interim Chief of Psychiatry
- (b) (6), M.D., Medical Center Psychiatrist
- (b) (6), Social Worker

- (b) (6), Social Worker
- (b) (6) M.D., CoS
- (b) (6), Risk Manager

Interviewed by telephone:

- (b) (6), M.D., former Medical Center CoS, currently assigned to the Philadelphia VA Medical Center
- (b) (6) RN, Assistant CoS for Behavioral Health, former Nurse Manager of the SA Clinic
- (b) (6), M.D., Behavior Health Physician and Addiction Psychiatrist, Philadelphia VA Medical Center
- (b) (6), RN, Clinical Nurse Specialist, Addiction Services, Philadelphia VA Medical Center
- (b) (6) M.D., Psychiatrist, Vineland, New Jersey CBOC
- (b) (6), M.D., Psychiatrist, Cape May, New Jersey CBOC

The team held an exit briefing with the same Medical Center and VISN leadership in attendance at the entrance briefing.

## V. Findings

*Background*

OUD is a medical diagnosis of opioid addiction and is characterized by an individual's compulsive use of opioids, prescribed or illicitly obtained. Morphine, heroin, oxycodone, and hydrocodone are common opioids involved with OUD. This disorder exhibits a maladaptive pattern of opioid use leading to significant patient impairment or distress.

Opioids stimulate specialized opioid receptors to cause the well-known opioid effects of pleasure, euphoria, and pain relief, as well as drowsiness and respiratory depression. Continued use of opioids renders their receptors less responsive, requiring a greater opioid dose to achieve the same therapeutic or euphoric effect. A reduction or cessation of opioid use may cause signs and symptoms of withdrawal, such as jitters, agitation, anxiety, muscle cramps, and diarrhea.[1]

Buprenorphine is a synthetic opioid used in the treatment of OUD. It reacts with the same receptors as those stimulated by the opioids underlying OUD but to a lesser extent, and is therefore, classified as an opioid partial agonist. It does not produce the euphoria and sedation to the extent of other opioids. It alleviates the withdrawal symptoms that reduction or cessation of these other opioids can cause. However, when combined with sedatives like alcohol or benzodiazepines, buprenorphine can cause

[1] "The Neurobiology of Opioid Dependence: Implications for Treatment." *Science Practice Perspectives*. July 2002. 1(1): 13-20. (http://www.ncbi.nlm.nih.gov).

respiratory depression.[2] Because buprenorphine reacts more tightly with opioid receptors than other opioids do, it displaces those opioids from the receptors, rendering them ineffective. This blocking effect of buprenorphine is therefore protective against overdose by other opioids.

Naloxone is an opioid receptor blocker or antagonist that is combined with buprenorphine for the treatment of OUD. If injected, buprenorphine alone has some potential for abuse, and therefore, diversion. Naloxone blocks the effects of all opioids including buprenorphine if the naloxone is injected. However, naloxone is not effective if taken orally while buprenorphine is, so the combination of buprenorphine and naloxone (Suboxone) is as effective as buprenorphine alone for the treatment of OUD without the abuse or diversion concern that buprenorphine alone has, making Suboxone a commonly-used formulation of buprenorphine for OUD treatment.

Suboxone treatment occurs in three stages: induction, stabilization, and maintenance. At induction, the patient is switched from the opioid to Suboxone, usually in an outpatient clinic setting. Stabilization has occurred when all withdrawal signs and symptoms have resolved. Maintenance therapy may continue for months or years. Urine tests for opioids and other illicit drugs are recommended and usually performed during treatment with Suboxone to monitor the patient's adherence to abstinence from these drugs.

*OUD Treatment at the Medical Center*

VHA Handbook 1160.04, *VHA Programs for Veterans with Substance Use Disorders*, describes the different specialized programs for treatment of eligible Veterans with substance use disorder. VA does not have a policy regarding the prescription of opioid agonists. Instead, VA relies on comprehensive clinical reviews with therapeutic recommendations to ensure best medical practice. In the case of opioid agonist therapy, the VA/DoD Guideline, the SubAbuse TIP, and the Pharmacy Benefits Management criteria provide evidence-based guidelines for the evaluation and treatment of OUD.

The SOP Suboxone outlines the Medical Center's approach to OUD treatment including Suboxone use. VA learned from SA Clinic staff that the whistleblower had drafted this SOP and the Medical Center CoS and Chief of Psychiatry had approved it in 2012. It includes a treatment agreement that a Veteran being considered for treatment of OUD with Suboxone is to sign. The agreement describes the goals and processes for treatment, as well as the Veteran's responsibilities during treatment, and includes criteria for discharge from the Suboxone treatment program.

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[2] Benzodiazepines are a class of psychoactive drugs used in treatment of conditions like anxiety, agitation, and acute seizures. This class of drugs has potential for abuse and overdose symptoms may include drowsiness, respiratory depression and cardiorespiratory arrest. Benzodiazepines are not opioids and do not react with the opioid receptor.

VA found three instances in which either SOP Suboxone or the treatment agreement was not in conformance with evidenced-based recommendations for treatment with Suboxone. The SOP states, "patients who are not making progress in their treatment of addiction using Buprenorphine evidenced by positive urines for opioids, benzodiazepines, cocaine, or other illicit drugs will be discharged from Buprenorphine treatment and referred to an abstinence-based program." This practice is not consistent with the VA/DoD Guideline, which recommends that the provider gradually increase the dose of Suboxone in this situation to address continued opioid cravings.

The treatment agreement outlines two criteria for discharge from Suboxone therapy. The first stipulates, "I agree to conduct myself in a courteous manner in the physician's office of treatment setting and understand that any threatening or disruptive behavior will result in a 2-year suspension from Suboxone treatment." This stipulation is not consistent with VHA Handbook 1160.01, which states, "pharmacotherapy with approved, appropriately-regulated opioid agonist must be available to all patients diagnosed with opioid dependence for whom there are no medical contraindications." If the Veteran's behavior becomes disruptive, the behavior itself must be addressed (e.g., police escort while in the facility, assistance with psychosocial issues, etc.) without withholding necessary medications. See 38 CFR § 17.107, VA response to disruptive behavior of patients. In addition, the language used in the treatment agreement is threatening and could undermine patient provider trust and the potential for recovery.

The second criterion for discharge states, "I agree to periodic witnessed drug testing each time I am in the clinic for refill; and urine must be clean of all illicit substances within 28 days. If not, treatment will be discontinued and any alteration in urine specimen will lead to a 1-year suspension from Suboxone treatment." This practice is not consistent with current, recommended, evidence-based treatment guidelines described in the VA/DoD Guideline and the SubAbuse TIP. Further, PBM criteria states specifically, "failure to obtain negative urine drug screens or abstinence should not be used as criteria for discontinuation of buprenorphine."[3] Both the treatment guidelines and PBM criteria recommend that the provider consider gradually increasing the dose to address continued opioid cravings in the case of the patient's failure to achieve abstinence during the first 4 weeks of treatment.

The VA team interviewed all four psychiatrists who prescribe Suboxone in the Medical Center's outpatient setting. All but one were able to articulate the comprehensive guidelines regarding the prescription of Suboxone for OUD. These providers also stated that they do not discharge a patient from Suboxone treatment if he or she is unable to achieve abstinence in 28 days, but they rather increase the Suboxone dosage to diminish or eliminate cravings consistent with current treatment guidelines. All providers stated that they do not discontinue Suboxone because of a patient's disruptive behavior. Although their practice is not consistent with the Medical Center's current SOP Suboxone and treatment agreement, it is consistent with the comprehensive guidelines. The three providers aware of the guidelines maintained that the practice of

[3] VA Pharmacy Benefits Management Service Buprenorphine/Naloxone and Buprenorphine for Opioid Dependence Criteria for Use for Office-Based Opioid Treatment (OBOT). Updated September, 2014. (http://www.pbm.va.gov).

administratively discontinuing Suboxone for lack of total abstinence or disruptive behavior, as described by the whistleblower, is not the standard in their practice, and as far as they knew, not the standard of practice throughout the VA system. During the interview, no SA Clinic staff member claimed that the psychiatrist unfamiliar with the guidelines had ever discharged any Veterans from the treatment program based on the Medical Center's SOP Suboxone.

The whistleblower alleged that in the case of Veteran 1, Dr. (b) (6) continued treatment with Suboxone while the Veteran continued to use illicit opioids may have contributed to the Veteran's admission to the Intensive Care Unit (ICU). The whistleblower provided VA with three additional names (Veterans 2–4, below) who, he claimed, had been continued on Suboxone despite evidence of continued illicit opioid use, contrary to VHA policy.

*Veteran 1*

The whistleblower alleged that during the week of (b) (6), 2014, this patient with a history of heroin and oxycodone use had been admitted to the ICU for treatment; his condition could have been precipitated or complicated by his continued intake of Suboxone and illicit drugs. VA's review of the medical record revealed that Veteran 1 has a long history of alcohol, stimulant, and cannabis use disorders. He became addicted to prescription opioids after treatment for multiple injuries and chronic pain. His multiple medical and psychiatric conditions include chronic pulmonary disease, heart disease, and multiple suicide attempts.

The Veteran started Suboxone treatment and intensive outpatient rehabilitation for his OUD in (b) (6) 2014. Although able to abstain from illicit drugs other than opiates, he continued to use illicit opiates while engaged in outpatient rehabilitation. Between (b) (6) 2014, his psychiatrist increased his Suboxone dose, but the illicit opioid use continued intermittently, despite engagement in intensive outpatient psychotherapy.

On (b) (6) 2014, while on Suboxone, the Veteran reported using four bags of heroin after witnessing a friend commit suicide by shooting himself. The Veteran did not overdose on heroin that night and kept his appointment with his psychiatrist the next day, when he discussed the drug use candidly.

During the week of (b) (6), 2014, Veteran 1 was admitted to the ICU for treatment of pneumonia and exacerbation of his chronic pulmonary disease. At the time of admission, the medical record reflects that he was conscious and extremely short of breath, neither of which are symptoms of heroin use or overdose. However, during his hospitalization, he became confused, a symptom consistent with his pneumonia-related hypoxia. In the ICU, he was sedated to reduce his agitation.

After his pneumonia treatment and discharge from the Medical Center, Veteran 1 continued to engage in outpatient therapy for his OUD. His urine tests were frequently negative for illicit opiates and consistently negative for other illicit drugs until (b) (6) 2014, when his urine test was positive for cocaine. In (b) (6) 2014, he was discharged from the intensive outpatient program for treatment of OUD and from Suboxone treatment for failure to abstain from illicit drug use and failure to consistently attend intensive outpatient groups, but he remained in individual outpatient psychiatric treatment and counseling. He failed to keep outpatient appointments in October and November and individual psychiatry appointments as late as (b) (6), 2014. Since then, multiple outreach attempts by phone have been unsuccessful.

Although Veteran 1 continued to use illicit drugs while receiving treatment with Suboxone, we conclude that his therapy with that medication was not only appropriate but likely life-saving. A potentially life-threatening overdose of four bags of heroin was likely prevented by the blocking effect of the Suboxone on his opioid receptors. Further, we conclude that his hospital admission and treatment in (b) (6) 2014, was for treatment of pneumonia, not for an overdose of Suboxone or for an adverse interaction between that and another medication. The obtundation Veteran 1 exhibited during that hospitalization was due either to pneumonia-related hypoxia or therapeutically-induced sedation and not to an overdose of Suboxone.

*Veteran 2*

Veteran 2 has been treated intermittently with Suboxone since (b) (6) 2011. Due to use of illicit drugs, he was discharged from therapy with Suboxone in (b) (6) 2011 and again in (b) (6) 2012, prior to the arrival of Dr. (b) (6). He was restarted on Suboxone in (b) (6) 2013, and has remained engaged in outpatient rehabilitation throughout 2014 despite occasional use of alcohol and marijuana. According to his medical record, Veteran 2 has not suffered any complications related to his use of alcohol or illicit drugs during his treatment with Suboxone.

Although Veteran 2 used alcohol and illicit drugs during his OUD therapy with Suboxone, we conclude that this therapy, consistent with the comprehensive guidelines, was without complication.

*Veteran 3*

Veteran 3 was started on Suboxone in (b) (6) 2013. In (b) (6) he reported marijuana and alcohol use. However, by (b) (6) 2013, urine tests did not show illicit drug use and he remained engaged in outpatient treatment until he relapsed and was lost to follow up in (b) (6) 2013.

In (b) (6) 2014, the Veteran was again treated with Suboxone. However, he was unable to abstain completely from opioids. He reported increased pain and in response to that pain, his Suboxone was increased. The Veteran reported improvement in pain control, and despite encouragement to continue intensive outpatient group therapy, he

continued illicit opioid use. In (b) (6) 2014, his urine tests for opiates, cocaine, and cannabis were positive and SA Clinic staff informed him that if he could not abstain from illicit drugs, they would discharge him from the Suboxone program. In (b) (6) 2014, the Veteran was tapered off Suboxone. According to his medical record, he has not suffered a complication related to his use of alcohol or illicit drugs during his treatment with Suboxone.

Although Veteran 3 used alcohol and illicit drugs during his OUD therapy with Suboxone, we conclude that his therapy was consistent with the comprehensive guidelines; we conclude that the therapy was without complication.

*Veteran 4*

Veteran 4 began Suboxone therapy in (b) (6) 2013. Throughout (b) (6) 2013 and (b) (6) 2014, the Veteran kept weekly clinic appointments and was able to abstain from opiates about half of the time. He also continued to drink alcohol. He was able to achieve abstinence from opiates by (b) (6) 2014. However, he continued to use stimulant medication illicitly obtained from friends due to extreme daytime sleepiness. In early (b) (6), the SA Clinic nurse confronted the Veteran with his failure to comply with the treatment agreement. After that confrontation, the Veteran chose not to return for counseling or Suboxone therapy despite attempts by SA Clinic personnel to contact him.

Although Veteran 4 used alcohol and illicit drugs including stimulants during his OUD therapy with Suboxone, his therapy was consistent with the comprehensive guidelines; we conclude that the therapy was without complication.

Of the four Veterans reviewed, two were discharged for illicit drug use, and two were advised of potential discharge if they could not abstain from illicit drug use. In each of these four instances, the investigative team concludes the OUD therapy was appropriate. Withdrawal of Veterans 1 and 2 from therapy was consistent with VHA policy and with national guidelines because in each instance, the decision was based on an evaluation of the risks and benefits of continued therapy by the provider who was prescribing the Suboxone to the individual Veteran. In both of these instances the decisions were not based on a non-clinical application of the Medical Center policy. Although the nursing personnel may have informed Veteran 3 that he would be discharged from Suboxone therapy if he could not abstain, ultimately the Veteran was tapered off the medication after individual evaluation by his Suboxone provider, consistent with VHA policy and national guidelines. Similar to Veteran 3, SA Clinic personnel informed Veteran 4 of the possibility of withdrawal from Suboxone therapy because of continued illicit drug use. However, before the provider could make an assessment, the Veteran withdrew from the program himself despite attempts by SA Clinic personnel to evaluate him and make appropriate therapy recommendations.

VA confirmed that the whistleblower reported his concerns to management via the electronic incident reporting system. The Risk Manager who received the concerns

forwarded them to the CoS at the time (the former Medical Center CoS), who stated to the VA team that he reviewed the concerns, spoke with Dr. (b) (6) and determined that Dr. (b) (6) practice for prescribing Suboxone was evidence-based and supported by the addiction treatment community. He felt no further action was indicated.

The whistleblower alleged that The Joint Commission had found that Dr. (b) (6) was not prescribing Suboxone according to facility policy. In May 2014, The Joint Commission did perform an unannounced survey of the Medical Center that included the mental health and addiction treatment areas. The VA team reviewed the report of that survey and found no reference to such a finding.

The whistleblower also alleged that Dr. (b) (6) patients appear to have a lower success rate in the program; thus, it appears his practice may render the Medical Center's treatment program for OUD less effective. As a measure of the success of addiction programs treating OUD, VA's Mental Health Information System reports the percentage of patients receiving opioid agonist therapy such as Suboxone. The more successful programs have a greater percentage of patients receiving such therapy; the Medical Center's rate for the 3rd quarter of fiscal year 2014 was 35.5 percent; this significantly exceeds the average of 29.2 percent for all VA addiction treatment programs.

## VI. Conclusions

- VA **did not substantiate** the allegation that Dr. (b) (6), Interim Chief of Psychiatry, does not comply with agency policy regarding the treatment of patients with OUD. VA does not have a policy that dictates therapy for OUD but relies instead on comprehensive guidelines for best current evaluation and therapeutic options based on the VA/DoD Guideline and the SubAbuse TIP. Dr. (b) (6) practice conforms to these guidelines.

- The Medical Center's SOP Suboxone does not conform to VHA Handbook 1160.01, which states, "pharmacotherapy with approved, appropriately-regulated opioid agonist must be available to **all** patients diagnosed with opioid dependence for whom there are no medical contraindications" and including those with disruptive behavior. SOP Suboxone lists disruptive behavior as a criterion for discharge from Suboxone treatment, which is not consistent with VHA Handbook 1160.01. That SOP does not conform to VA's comprehensive guidelines in at least two areas: discharge from Suboxone treatment due to the patient's failure to maintain abstinence and treatment for continued cravings and use of opioids. The guidelines used by VA do not recommend discharge if a patient is not able to maintain abstinence and do recommend increasing the Suboxone dosage to treat continued craving.

- The SOP Suboxone's requirement to administratively discontinue treatment for disruptive behavior is not consistent with 38 CFR § 17.107, which requires an

assessment of the disruptive behavior in connection with VA's duty to provide good quality care, including care designed to reduce or otherwise clinically address the patient's behavior. Section 17.107 also provides specific procedures that must be followed for restrictions on a patient's care.

- All prescribing psychiatrists, including Dr. (b) (6) and SA Clinic staff, ignore the erroneous sections of the SOP Suboxone. Since all providers are following VA's comprehensive guidelines and not SOP Suboxone, VA **did not substantiate** that Medical Center employees are engaging in conduct that may constitute violations of law, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health.

- One of the four psychiatrists (not Dr. (b) (6) ) prescribing Suboxone is unfamiliar with OUD comprehensive guidelines. VA, however, found no evidence that this physician inappropriately discharged any Veteran from the Medical Center OUD treatment program.

- Although SOP Suboxone did not conform to VHA policy and comprehensive guidelines for best current evaluation and therapeutic options based on the VA/DoD Guideline and the SubAbuse TIP, it was not implemented in the treatment of Veterans. VA **did not substantiate** that the Medical Center's opioid use treatment program, as implemented, violated law, rule, VHA directive or policy, or was a substantial and specific danger to public health

**Recommendations to the Medical Center**

1. Complete the revision of the Suboxone SOP so that it is consistent with the comprehensive guidelines and with VHA Handbook 1160.01.

2. If care agreements are included in the new SOP Suboxone, they should avoid language that threatens automatic discharge from therapy for illicit drug use; the care agreement could inform the patient that failure to abstain from illicit drug use may result in a clinical reassessment of their therapeutic options.

3. Through record reviews, peer reviews, or similar strategies, assess the practice of the one psychiatrist who was not familiar with the comprehensive guidelines and provide training or patient follow up, if indicated.

**Summary Statement**

OMI has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement, or created a substantial and specific danger to public health. In particular, OGC has provided a legal review, and OAR has examined the issues from a human resources perspective to establish accountability, when appropriate, for improper personnel practices. VA found no violations of VA and VHA

policy, as implemented, gross mismanagement, or a substantial and specific danger to public health.

## Attachment A

Documents reviewed in addition to the electronic medical records:

Medical Center Standard Operating Procedure BHS 7, Buprenorphine/Naloxone (Suboxone) Induction/Maintenance Treatment.

Medical Center Suboxone Treatment Agreement.

Medical Center, Organizational Chart.

The Joint Commission, Official Accreditation Report for the Unannounced Visit on May 20–23, 2014.

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

VHA Handbook 1160.04, *VHA Programs for Veterans with Substance Use Disorders (SUD).* March 7, 2012.

VA/DoD Evidence Based Clinical Practice Guideline Management of Substance Use Disorders (SUD), August, 2009.

VA Pharmacy Benefits Management Service Buprenorphine/Naloxone and Buprenorphine for Opioid Dependence Criteria for Use for Office-Based Opioid Treatment (OBOT). Updated September, 2014.

Substance Abuse and Mental Health Services Administration Treatment Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, A Treatment Improvement Protocol (TIP) 40.

Electronic Patient Event Reports submitted by the whistleblower.