



**THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON**

June 6, 2022

**The Honorable Henry Kerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036**

Re: Office of Special Counsel File No. DI-21-000033, DI-21-000470 and DI-21-000503

Dear Mr. Kerner:

I am responding to your November 17, 2020, letter to the Department of Veterans Affairs (VA), as well as the three additional addenda regarding whistleblower allegations that officials at the VA Central Texas Healthcare System (hereafter Temple) in Temple, Texas, engaged in conduct that may constitute gross mismanagement and a substantial and specific danger to public health.

The Deputy Under Secretary for Health, Performing the Delegable Duties of the Under Secretary for Health, directed Veterans Integrated Service Network 17, to assemble and lead a VA team to conduct an investigation. We conducted an investigation on this matter August 17, 2021 – December 17, 2021.

We do substantiate one allegation, partially substantiate one allegation and do not substantiate five allegations. We make four recommendations to Temple. The signed report will be sent to the respective offices with a request for an action plan.

Thank you for the opportunity to respond.

Sincerely,

A handwritten signature in black ink, appearing to read "DMcDonough", with a stylized flourish at the end.

Denis McDonough

Enclosure

DEPARTMENT OF VETERANS AFFAIRS

Washington, DC

Report to the

Office of Special Counsel

OSC File No. DI-21-000033, DI-21-000470 and

DI-21-000503

Central Texas VA Health Care System

Temple, Texas



Report Date: May 2022

Executive Summary

Background: Referral History

This case has a complex referral history. Pursuant to its authority in 5 U.S.C. § 1213(c), the Office of Special Counsel (OSC) referred to the Department of Veterans Affairs (VA) a whistleblower's allegations relating to practices in the Pain Management Clinic at the VA Central Texas Healthcare System, Temple, Texas (referred herein as Temple), that constitute gross mismanagement, an abuse of authority, or a substantial and specific danger to public health. OSC sent a letter dated November 17, 2020, referring the case OSC File No. DI-21-000033. The whistleblower is a Temple Pain Management Clinic physician. The whistleblower alleged that the Chief of Whole Health and Integrated Health Service (referred herein as Whole Health Service) instituted organization and policy changes that pose a danger to patients, namely, this official is alleged: (1) to have rescinded the facility's standard operating procedures (SOP) for prescribing buprenorphine, an opioid used to treat opioid use disorder (OUD), acute pain and chronic pain; (2) to have pressured providers to prescribe buprenorphine regardless of patient diagnosis and promoting incorrect guidance to providers that does not reflect the standard of care, placing patients at risk; and (3) to have engaged in improperly documented "self-consults" with Pain Management Team (PMT) patients, prior to their initial appointments, leading to potential billing irregularities and inequitable care. For a fuller context, we note that Temple's Pain Management Clinic is aligned under the Whole Health Service Line, and the clinic offers consultative and interventional pain management services, as discussed below. This report, required by 5 U.S.C. § 1213(c), is referred to herein as the "initial referral."

In response to an email request dated December 28, 2020, VA informed OSC that these allegations would be investigated by officials in VA's Veterans Integrated Service Network (VISN) 17, not the Veterans Health Administration's Office of the Medical Inspector (OMI).

By letter dated December 14, 2020, OSC referred additional related allegations to VA for investigation; these were lodged by the same whistleblower. They concern patient entry in the Temple Whole Health and Integrated Service or, more specifically, a reported change in process that will require all referrals to the Pain Management Clinic to be reviewed by Whole Health coaches, not physicians or pain management specialists. The whistleblower explains this would remove physicians and pain experts from the review process and prevent patients from receiving an initial clinical diagnosis. OSC referred to these additional allegations as an amendment to the initial referral.

By email dated January 14, 2021, OSC referred three additional allegations lodged by this same whistleblower all of which relate to operations in the Temple Pain Management Clinic. As a primary matter, OSC recommended that because the facility is already on notice of the investigation, VA should consider requesting the facility to place a moratorium on making or implementing significant changes within the Pain Management Clinic until VA's investigation is concluded, as these changes create the need to supplement the initial referral. This set of allegations concern: (1) the improper

limiting of referrals to VA's Community Care Program in violation of law and regulation; (2) a plan to replace the Pain Management Clinic's Registered Nurse (RN) with a Licensed Vocational Nurse (LVN) which is alleged to endanger patients; (3) improper oversight of the new Nurse Practitioner (NP) assigned to the Pain Management Clinic and assignment of duties which could create medical ethical challenges for certain providers and gaps in patient chart documentation. OSC referral DI-21-000503, Addendum to DI- 21-000033.

By email dated May 7, 2021, OSC referred three additional allegations for investigation that were lodged by a second whistleblower, the Chief, Temple Pain Management Clinic. In general, these concern allegations that certain facility staff: (1) violated the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018 (MISSION Act) by prohibiting pain management physicians from approving referrals to community care providers based on "improved continuity of care" criterion; (2) violated VA directives 6500 (VA Cybersecurity Program) and 1907.01 (Health Information Management) by ordering the redaction of portions of medical records containing disclaimers from clinicians advising patients that denial or termination of community care programs was based on specified physician direct orders; and (3) abused authority by manipulating clinical scheduling in VA's Computerized Patient Records System (CPRS). OSC underscored in this email that, consistent with the charge in the initial referral letter, any additional matter raised in the course of VA's investigation must be included in VA's report. In other words, these, like all of the additional allegations submitted after the initial referral, are to be included and addressed in the single VA report required by 5 U.S.C. § 1213(c) based on the initial referral.

As noted previously, VISN 17 was charged with this investigation. On April 13, 2021, a fact-finding was initiated and conducted by [REDACTED] Chief of Anesthesiology and Pain Management for the North Texas Healthcare System. A second fact-finding was requested because the first lacked clear conclusions relative to the allegations. The second fact-finding was initially assigned to [REDACTED] North Texas Healthcare System Ambulatory Care Physician who had some familiarity with the case, but because the allegations involved an official above his position, the VISN re-assigned this matter to [REDACTED] Deputy Chief of Staff for the West Texas Healthcare System, who began his work on December 17, 2021.

Caveats

We clarify that this report is independent of a report prepared by OMI, which investigated and reported to VA's Office of Accountability and Whistleblower Protection (OAWP) on a number of allegations submitted to OAWP by two different whistleblowers. OMI merged the two sets of allegations into one report, with the allegations organized into four general categories as they all related to alleged improper or inadequate care in Temple's Pain Management Clinic Service Line as placed under the Whole Health Service Line. OAWP ordered the four allegation-categories as follows: (1) Community Care and Referral management; (2) Opioid Use Disorder treatment; (3) Pain Management alignment and Resourcing; and (4) Consults and encounters. This report

is OAWP Case Nos. 15,931 and 16,455; OMI TRIM 2021-C-29, and was dispatched to OAWP on January 25, 2022, with copies sent to leadership of the U.S. House and Senate Veterans' Affairs Committees on April 6, 2022. See attached January 25, 2022, report.

It is also independent of the investigation and report that VA's Office of the Inspector General (OIG) tasked VISN 17 officials to conduct in response to a complaint submitted to its OIG HOTLINE, OIG Control Number: 2021-00936-HL-0322 (2021-02792) Temple, TX VAMC RP44. The hotline-reported allegations relate, in general, to the recent reorganization of clinical practice at the VA Central Texas Healthcare System, and the Director of Whole Health and, more specifically, alleged the Director violated agency rules and regulation, improperly conducted oversight and direction on members of the Pain Management team, coerced Veterans toward an alternative care pathway and treatment paradigms prior to a diagnosis and without the proper and complete informed consent of the patient; improper pain management.

These other whistleblower reports came into VA through other avenues, at different times, and intended for different ultimate VA end-users; thus, they were worked independently by different teams and not worked in coordination or collaboration with the VISN 17 staff working this OSC initial referral.

To help illustrate the timeline, OIG was offered first right to investigate this OSC initial referral (dated November 17, 2020), but OIG declined on November 23, 2020, because they had received a similar complaint through the OIG hotline, which they tasked to VISN 17 officials. (See OIG Hotline information in above paragraph). On November 24, 2020, OMI declined acceptance of this case. On the same date, it was tasked to VISN 17 for action, which again began on April 13, 2021 (with, presumably, the delay owing to the pandemic). On May 28, 2021, OAWP referred similar allegations it had received to OMI; OMI accepted the case for action on June 1, 2021. This became OAWP Case Nos. 15,931 and 16,455; OMI TRIM 2021-C-29. Teams were unaware of others' related work until much later, thus explaining the existence of the various reports and reasonably distinct conclusions on substantially similar allegations involving the same facility officials/staff and service lines.

OSC No. DI-21-000033, as amended by DI-21-000470 and DI-21-000503:

Specific Allegations of the Whistleblowers

1. [REDACTED] *has sought to rescind the facility's standard operating procedures (SOP) for prescribing buprenorphine, an opioid used to treat opioid use disorder (OUD), acute pain and chronic pain.*
2. [REDACTED] *pressured providers to prescribe buprenorphine regardless of patient diagnosis and promoted incorrect guidance to providers that does not reflect the standard of care, placing patients at risk.*

3. [REDACTED] has engaged in improperly documented "self-consults" with Pain Management Team (PMT) patients, prior to their initial appointments, leading to potential billing irregularities and inequitable care.
4. [REDACTED] initiated changes to the Pain Management referral process that imposed barriers to access to interventional pain care services.
5. Facility Chief of Staff [REDACTED] and Whole Health Director [REDACTED] violated the MISSION Act of 2018 (MISSION Act) and jeopardized patient health and safety by prohibiting pain management physicians from approving pain management community care programs for patients on the basis of the "improved continuity of care" criterion.
6. [REDACTED] violated VA directives 6500 (VA Cybersecurity Program) and 1907.01 (Health Information Management) by ordering the redaction of portions of medical records containing disclaimers from clinicians advising patients that denial or termination of community care programs was based on direct orders from [REDACTED] and [REDACTED].
7. Since coming to the agency in May 2020, [REDACTED] has abused his authority by manipulating his clinical scheduling in the CPRS system.

The fact-finding **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. Allegations were **unable to be substantiated** when the available evidence was insufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

Allegation 1 was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

Recommendations For Temple

1. No recommendations are made as the allegation was not substantiated. The fact-finding did support; however, that [REDACTED] did seek to rescind the facility's SOP for prescribing buprenorphine. It is noted that the SOP failed to conform with the current national standards of practice and required revision. The VA Central Texas Healthcare System in Temple, Texas, will review the currently local published SOP, revising it to conform with current national standards of practice.

Allegation 2 was **partially substantiated**. Investigation of this concern revealed a theoretical risk of undue influence upon individual clinical decision making that could potentially adversely impact a Veteran's health status. Investigation did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, or an abuse of authority. The Interventional Pain provider's training and

expertise lies in the procedurally based management of specific pain syndromes, they have no training or experience in Medication-Assisted Treatment (MAT) beyond that afforded by the minimal training required for obtaining the X waiver. Utilization of these providers in this fashion may not represent the best manner to provide MAT particularly given the high rate of community referral for interventional pain services for Temple.

Recommendations For Temple (Whole Health Department)

2. The VA Central Texas Healthcare System in Temple, Texas Whole Health Department will review the high rate of community referrals, as well as potential competency and training gaps that may explain the high percentage of referrals to the community, with the goal of providing the highest quality of care, while mitigating the percentage of community referral, where possible.

Allegation 3 was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. There is some concern about the adequacy of medical documentation by [REDACTED] that would most appropriately be addressed through the Ongoing Professional Practice Evaluation (OPPE) process.

Recommendations for Temple

No recommendations are made.

Allegation 4 was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

Recommendations For Temple (Whole Health Department)

3. The large number of referrals to the community indicates a need for additional evaluation to determine the root cause for the high percentage. The concerns brought forth regarding service agreements, will also be reviewed by the Department. The use of service agreements is a standard of practice that needs to continue. The Department will review the revised version to ensure adherence with all governing authorities, policies, and directives.

Allegation 5 was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safe.

Recommendations For Temple

4. Although the allegation was not substantiated, the question of consistency regarding the interpretation of best medical interest (BMI) criteria will be further investigated of the facility to ensure alignment with VA Directive and the MISSION Act.

Allegation 6 was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

Recommendations

No recommendations are made.

Allegation 7 was **substantiated**. Investigation of this concern did reveal evidence of a violation of rule and waste of funds.

Recommendations For Temple

5. Through consultation with Human Resources and the Office of General Counsel (OGC), it is recommended that the facility conduct further investigation into the allegation of [REDACTED] abuse of authority and follow up any findings of impropriety with appropriate action, that may include training, administrative action and discipline.

The results of this investigation were reviewed to determine final conclusions and actions the Agency intends to initiate, based on the conclusions. The conclusions and actions are outlined in the body of this report

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Introduction

By letter dated November 17, 2020, to the Department of Veterans Affairs (VA), the Office of Special Counsel (OSC) referred a whistleblower's allegations concerning staff/officials in the Pain Management Clinic at the VA Central Texas Healthcare System, Temple, Texas (referred herein as Temple) who were alleged to be engaged in actions that constitute gross mismanagement, an abuse of authority, or a substantial and specific danger to public health.

As noted in the Executive Summary, the Acting Under Secretary for Health directed Veterans Integrated Service Network (VISN) 17, VA Heart of Texas Health Care Network, to assemble and lead a VA team to conduct this investigation and prepare the report. As also noted in the Executive Summary, the initial referral of November 17, 2020, was amended several times to include additional related allegations, all of which are included in this report.

VISN 17 conducted a virtual investigation to Temple from August 17, 2021 – December 17, 2021.

Allegations of the Whistleblower

1. [REDACTED] has sought to rescind the facility's standard operating procedures (SOP) for prescribing buprenorphine, an opioid used to treat opioid use disorder (OUD), acute pain and chronic pain.
2. [REDACTED] pressured providers to prescribe buprenorphine regardless of patient diagnosis and promoted incorrect guidance to providers that does not reflect the standard of care, placing patients at risk.
3. [REDACTED] has engaged in improperly documented "self-consults" with Pain Management Team (PMT) patients prior to their initial appointments, leading to potential billing irregularities and inequitable care.
4. [REDACTED] initiated changes to the Pain Management referral process that imposed barriers to access to interventional pain care services.
5. Facility Chief of Staff [REDACTED] and Whole Health Director [REDACTED] violated the MISSION Act of 2018 (MISSION Act) and jeopardized patient health and safety by prohibiting pain management physicians from approving pain management community care programs for patients on the basis of the "improved continuity of care" criterion.
6. [REDACTED] violated VA directives 6500 (VA Cybersecurity Program) and 1907.01 (Health Information Management) by ordering the redaction of portions of medical records containing disclaimers from clinicians advising patients that denial or termination of community care programs was based on direct orders from [REDACTED] and [REDACTED]

7. Since coming to the agency in May 2020, [REDACTED] has abused his authority by manipulating his clinical scheduling in the CPRS system.

I. Facility Profile

VA Central Texas Healthcare System in Temple, Texas, is an integrated network of two VA medical centers and six community based outpatient clinics (CBOC), consisting of approximately 4300 employees. Temple is aligned under VISN 17. The Temple Pain Management is aligned under Whole Health and Integrated Health Service (Whole Health).

II. Conduct of Investigation

Pursuant to its authority in 5 U.S.C. § 1213(c), OSC referred to VA a whistleblower's allegations relating to practices in the Pain Management Clinic at Temple, that constitute gross mismanagement, an abuse of authority, or a substantial and specific danger to public health. OSC Letter dated November 17, 2020, referring case OSC File No. DI-21-000033. The whistleblower is a Temple Pain Management Clinic physician.

By letter dated December 14, 2020, OSC referred additional related allegations to VA for investigation; these were lodged by the same whistleblower. They concern patient entry in the Temple Whole Health and Integrated Service or, more specifically, a reported change in process that will require all referrals to the Pain Management Clinic to be reviewed by Whole Health coaches, not physicians or pain management specialists. OSC referred to these additional allegations as an amendment to the initial referral.

By email dated January 14, 2021, OSC referred three additional allegations lodged by this same whistleblower all of which relate to operations in the Temple Pain Management Clinic. As a primary matter, OSC recommended that because the facility is already on notice of the investigation, VA should consider requesting the facility to place a moratorium on making or implementing significant changes within the Pain Management Clinic until VA's investigation is concluded, as these changes create the need to supplement the initial referral. OSC referral DI-21-000503, Addendum to DI-21-000033. By email dated May 7, 2021, OSC referred three additional allegations for investigation that were lodged by a second whistleblower, the Chief, Temple Pain Management Clinic. OSC underscored in this email that, consistent with the charge in the initial referral letter, any additional matter raised in the course of VA's investigation, must be included in VA's report. In other words, these, like all of the additional allegations submitted after the initial referral, are to be included and addressed in the single VA report required by 5 U.S.C. § 1213(c) based on the initial referral.

As noted previously, VISN 17 was charged with this investigation. On April 13, 2021, a fact-finding was initiated and conducted by [REDACTED] Chief of Anesthesiology and Pain Management for the North Texas Healthcare System. A second fact-finding was requested because the first lacked clear conclusions relative to the allegations. The

second fact-finding was initially assigned to [REDACTED] North Texas Healthcare System Ambulatory Care Physician who had some familiarity with the case, but because the allegations involved an official above his position, the VISN re-assigned this matter to [REDACTED] Deputy Chief of Staff for the West Texas Healthcare System, who began his work on December 17, 2021.

III. Findings, Conclusions and Recommendations

Allegation 1

[REDACTED] has sought to rescind the facility's standard operating procedures (SOP) for prescribing buprenorphine, an opioid used to treat opioid use disorder (OUD), acute pain and chronic pain.

Background

The whistleblower explained that the Temple Pain Management Clinic was recently reorganized under Whole Health. Upon taking responsibility for the Pain Management Clinic, [REDACTED] has sought to rescind the facility's SOP for prescribing buprenorphine, which was issued by the Temple Pain Oversight Committee to address provider confusion about the proper use of buprenorphine for OUD and chronic pain. [REDACTED] asserted that rescission of the SOP is necessary to remove barriers to the use of buprenorphine products. The whistleblower alleged that this action denies providers essential information on the risks and acuity associated with OUD, threatens the clinical course for patients and may increase harm for patients with potential or diagnosed OUD, or those without OUD, by hindering the delivery of information on the use of opioids.

Findings

The fact-finding found that in June 2020, the Pain Oversight Committee at Temple was engaged in revising its existing policy and SOP regarding buprenorphine prescribing. [REDACTED] efforts appear to have been directed towards ensuring that the policies were consistent with VHA Notice 2019-18 which instructed VHA Healthcare Systems to remove barriers to treating OUD and prescribing buprenorphine/naloxone.

Both whistleblowers, expressed concerns that [REDACTED] efforts went beyond those goals of removing barriers. The expressed concerns where that the changes would promote the prescribing of buprenorphine with a lower threshold of clinical indication than was prudent. In addition, concerns were expressed that buprenorphine is not an innocuous medication and should be used as circumspectly as any other opiate.

Conclusions - Allegation 1

Allegation was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

Recommendations For Temple

1. No recommendations are made as the allegation was not substantiated. The fact-finding did support; however, that [REDACTED] did seek to rescind the facility's SOP for prescribing buprenorphine. It is noted that the SOP failed to conform with the current national standards of practice and required revision. The VA Central Texas Healthcare System in Temple, Texas, will review the currently local published SOP, revising it to conform with current national standards of practice.

Allegation 2

[REDACTED] pressured providers to prescribe buprenorphine regardless of patient diagnosis and promoted incorrect guidance to providers that does not reflect the standard of care, placing patients at risk.

Background

The whistleblower alleged that [REDACTED] direction of the Pain Management Clinic appears to be predicated on an inaccurate understanding of the evaluation and treatment of OUD and chronic pain. [REDACTED] has repeatedly informed physicians, including in emails to staff dated October 15 and October 17, 2020, that their performance can be tied to their willingness to prescribe buprenorphine. [REDACTED] directed that PMT physicians must obtain X-waivers—Drug Enforcement Administration (DEA)-issued waivers to prescribe buprenorphine—to treat patients manifesting criteria of OUD with buprenorphine. [REDACTED] also emphasized the financial incentives available to providers who prescribe buprenorphine, as described in VA's national buprenorphine guidance, which recommends providing incentive special pay for providers who obtain an X-waiver and prescribe buprenorphine to treat OUD. [REDACTED] has also repeatedly asserted to staff that a diagnosis of OUD or chronic pain is not required before prescribing buprenorphine. The whistleblower explained that [REDACTED] statements do not reflect the standard of care. He noted that buprenorphine is a potent opioid associated with all known risks of opioids, including hepatic injury; respiratory depression and death; abuse, misuse, or diversion; and opioid withdrawal. Thus, the risk of prescribing buprenorphine to patients who do not have OUD likely outweighs the benefit, according to the whistleblower's argument that placing professional and financial pressure on providers to prescribe buprenorphine while lowering the standard of care for prescribing it, creates a dangerous environment for patients, who may receive unnecessary opioid prescriptions that place their health at risk.

Findings

During the fact-finding, it was found that [REDACTED] did require Pain Management Section (PMS) providers to complete the DEA X-waiver training and apply for an X-waiver. Although not supportable by evidence, the fact-finding identified, what was described as apparent, that the motivation for the requirement of obtaining an X-waiver and promotion of prescribing of buprenorphine was due to a lack of other providers at the

facility willing to treat individuals with a dual diagnosis of chronic pain and opioid use disorder. The Interventional Pain provider's training and expertise lies in the procedurally based management of specific pain syndromes, with no training or experience in MAT beyond that afforded by the minimal training required for obtaining the X-waiver. A review of the whistleblower's Pay for Performance (P4P) plan for fiscal year (FY) 2021, identified the P4P goals did include a requirement to "manage 5 patients with concurrent chronic pain and complex persistent opiate dependence using appropriate medications." Per the whistleblower, the same performance measure was removed from his Performance Plan following an investigative visit conducted by DEA. The inclusion of the goal in [REDACTED] P4P, supports a financial incentive on the prescribing of a specific medication along with incentives to apply specific diagnoses is problematic and presents a specific and potentially substantial danger to patient safety.

Conclusions - Allegation 2

Allegation was **partially substantiated**. Investigation of this concern revealed a theoretical risk of undue influence upon individual clinical decision making that could potentially adversely impact a Veteran's health status i.e., establish a potential substantial and specific danger to public health or safety. The investigation did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, or an abuse of authority. The Interventional Pain provider's training and expertise lies in the procedurally based management of specific pain syndromes. No training or experience in MAT beyond that afforded by the minimal training required for obtaining the X-waiver has been provided to the Interventional Pain providers. Given the high rate of community referral for interventional pain services for Temple, the fact-finding determined the utilization of these providers in this fashion may not represent the best manner to provide MAT.

Recommendations For Temple (Whole Health Department)

2. The VA Central Texas Healthcare System in Temple, Texas Whole Health Department will review the high rate of community referrals, as well as potential competency and training gaps that may explain the high percentage of referrals to the community, with the goal of providing the highest quality of care, while mitigating the percentage of community referral, where possible.

Allegation 3

[REDACTED] has engaged in improperly documented "self-consults" with Pain Management Team (PMT) patients prior to their initial appointments, leading to potential billing irregularities and inequitable care.

Background

During the investigation, the whistleblower further alleged that [REDACTED] insists on conducting self-initiated patient contact with PMT patients prior to their initial PMT

appointments. The whistleblower alleged that during these encounters [REDACTED] is taking patient histories, making patient assessments, identifying risk levels for patient presentation and recommending the way to manage patients' treatment. It was stated that [REDACTED] previously coded these contacts as "historical" non-billable encounters, but recently stopped coding or charting them at all. According to the whistleblower, these encounters potentially bias to the PMT's patient assessments and the course of care for patients, while also being improperly billed or not billed at all. The whistleblower contended the established process under which patients are receiving inconsistent evaluations, impedes VA's mission to deliver appropriate, quality care to all Veterans.

Findings

The investigation identified that [REDACTED], the Director of Whole Health, was not performing self-consultation. As a member of the facility's Interdisciplinary Pain Management team, [REDACTED] would contact patients ahead of their scheduled team appointment. The patient encounters were reportedly inconsistently documented within the medical record. Per the whistleblower, at least one Veteran had medication dosage changes recommended by [REDACTED] without documentation in the medical record because of these pre-visits.

This occurred for a short period of time after [REDACTED] joined the team. When concerns were raised by members of the team about disruption of the interdisciplinary process, the consult process was modified to consist of individual appointments followed by an Interdisciplinary Team (IDT) meeting without the Veteran.

Conclusions - Allegation 3

Allegation was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. No evidence of inappropriate billing of care by the Director of Whole Health was identified. There is some concern about the adequacy of medical documentation by [REDACTED] which would most appropriately be addressed through the OPPE process.

Recommendations for Temple

No recommendations are made.

Allegation 4

[REDACTED] initiated changes to the Pain Management referral process that imposed barriers to access to interventional pain care services.

Background

The whistleblower disclosed that on November 30, 2020, Whole Health Chief

██████████ informed staff via email that all referrals to the Pain Management Clinic will now be reviewed solely by Whole Health “coaches,” who are not physicians or pain management providers. If the Whole Health coach approves the referral, the patient will be required to complete a Veterans Health Administration (VHA) course titled “Intro to Whole Health.” Patients will be directed to initiate a Personal Health Inventory and complete “individual coaching” or a second course, “Taking Charge of My Life and Health.” After these steps are completed, patients may select only one care “pathway:” acupuncture, chiropractic care, or pain clinic. They may not select more than one of these pathways at the same time.

The whistleblower explained that previously, if a primary care or other physician referred a patient to the Pain Management Clinic, a pain physician reviewed the patient’s chart information and determined what next steps would be taken to provide appropriate care. Under ██████████ new directive, physicians and pain experts are removed from the review process and patients do not receive an initial clinical diagnosis. As a result, patients may receive inappropriate care without the oversight of a pain physician. In addition, patients are required to complete coursework before being permitted access to the Pain Management Clinic, potentially delaying the delivery of appropriate physician based clinical care. The whistleblower alleged that it is VHA policy that complementary and integrative health may not be used as an alternative to conventional medicine, and ██████████ directive appears to violate this national policy by permitting the replacement of conventional pain care with complementary care, such as acupuncture. Additionally, in VA regulation 38 C.F.R. § 17.33(a)(2) and (3), respectively, a VA patient has the right to the extent of eligibility, under the law, to receive prompt and appropriate treatment for any physical or emotional disability and the right to the least restrictive conditions necessary to achieve treatment purposes. The whistleblower alleged that ██████████ actions, which are a direct consequence of the problematic reorganization of the Pain Management Clinic that we highlighted in Footnote 1 of our November 17, 2020, letter violate both of these patient’s rights and have a significant negative impact on the delivery of patient care.

Findings

During the fact-finding, the whistleblower indicates that the requirement for provider completion of the “Intro to Whole Health” VHA course was only implemented for consult referrals to Complimentary and Integrative Health Services and not for consult referral to interventional pain management. This is reflected in the template for Pain Management consultation, as well as in the service agreement for Pain Management Services at Temple. The service agreement additionally indicates that patients may receive interventional pain concurrently with acupuncture or chiropractic care.

Conclusions - Allegation 4

Allegation was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

Recommendations For Temple (Whole Health Department)

3. The large number of referrals to the community indicates a need for additional evaluation to determine the root cause for the high percentage. The concerns brought forth regarding service agreements, will also be reviewed by the Department. The use of service agreements is a standard of practice that needs to continue. The Department will review the revised version to ensure adherence with all governing authorities, policies, and directives.

Allegation 5

Facility Chief of Staff [REDACTED] and Whole Health Director [REDACTED] violated the VA Mission Act of 2018 (Mission Act) and jeopardized patient health and safety by prohibiting pain management physicians from approving pain management community care programs for patients on the basis of the "improved continuity of care" criterion.

Background

Specifically, it was alleged that beginning in January 2021, [REDACTED] ordered the whistleblower and his staff to disapprove all referrals for community care plans made by primary care physicians if the referral cited "improved continuity of care" as the sole criterion for the referral. The whistleblower further alleged that these patients were compelled to continue their pain programs at the VA facility. The whistleblower asserted that this policy disrupts established pain programs for Veterans, causes undue delay in treatment, and violates the MISSION Act, which provides that a Veteran may be referred to a community health care provider if the patient and referring doctor agree that it is in the "patient's best interest."

Findings

A patient may qualify for referral to Community Care with a variety of criteria. These include drive time, wait time and situations in which the referring clinician and the Veteran determined that Community Care is in the patient's best medical interest. The fact-finding did not provide detailed analysis of individual patient referrals, only noting that many appeared to be referred to Community Care by request of the patient. During the fact-finding discussions with one of the whistleblowers, the factfinder noted an appearance that many of the Community Care requests are not referred due to drive time, wait time, or other criteria that are easily quantifiable. Rather, many referrals followed requests from Veterans to continue seeing outside Pain Management providers who prescribe chronic opiates, a service that can also be provided by VA Patient-aligned Care Team (PACT) providers or Mental Health. Veterans may request Community Care and may receive it if they satisfy any of the criteria, including best medical interest due to improved continuity of care. The factfinder did not discover an instance in which a patient was denied Community Care despite being qualified for such care.

Conclusions - Allegation 5

This allegation was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

Recommendations For Temple

4. Although the allegation was not substantiated, the question of consistency regarding the interpretation of best medical interest (BMI) criteria will be further investigated of the facility to ensure alignment with VA Directive and the MISSION Act.

Allegation 6

██████ violated VA directives 6500 (VA Cybersecurity Program) and 1907.01 (Health Information Management) by ordering the redaction of portions of medical records containing disclaimers from clinicians advising patients that denial or termination of community care programs was based on direct orders from ██████ and ██████

Background

The whistleblower and other members of the Interventional Pain Management team were tasked with receiving interventional pain consults and redirecting to the internal service those that were referred to the community for continuation of care using a BMI rationale. When primary care providers persisted in placing these referrals, the whistleblower began the practice of identifying ██████ and ██████ by name in the consult comments as being the source of instructions to redirect these consults to the in-house interventional pain management team.

Findings

██████ required the Interventional Pain Management team to compile the list of consults in which ██████ and himself had been so identified with the intent of having the comments redacted. The whistleblowers were not aware of any consults having entries redacted as a result of these efforts and in fact, it is not possible to redact consult entries in CPRS. Although, ██████ did seek to have entries redacted in which he was inappropriately directly named; no entries were in fact redacted.

Conclusions - Allegation 6

Allegation was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

Recommendations

No recommendations are made.

Allegation 7

Since coming to the agency in May 2020, [REDACTED] has abused his authority by manipulating his clinical scheduling in the CPRS system.

Background

Rather than establishing the proper consultation process in CPRS, [REDACTED] instructs to inappropriately control the type and the number of patients that he admits to his clinical practice, jeopardizing patient care and violating multiple VA directives related to Complementary and Integrative Health (CIH) services and outpatient scheduling processes and procedures.

Findings

The whistleblower provides clinic scheduling grids and total patient counts indicating available clinic slots for 2 half days weekly with a total of 41 patient encounters during FY 2021 that did not begin until June 2021. Based upon guidance for VA physician staff and availability for clinical care, [REDACTED] should be engaged in clinical care on a .7 full-time employee equivalent (FTEE) basis.

Conclusions - Allegation 7

Allegation was **substantiated**. Investigation of this concern did reveal evidence of a violation of rule and waste of funds. The fact-finding supported that since coming to the agency in May 2020, [REDACTED] did abuse his authority by manipulating his clinical scheduling in the CPRS system.

Recommendations For Temple

5. Through consultation with Human Resources and the Office of General Counsel (OGC), it is recommended that the facility conduct further investigation into the allegation of [REDACTED] abuse of authority and follow up any findings of impropriety with appropriate action, that may include training, administrative action and discipline.

Note: The facility's recommended follow-up action plan for this report is found in Attachment 3 - Network Fact-Finding Evaluation.

VI. Summary Statement

The Department developed this report in consultation with other VHA and VA offices to address the allegations raised above. We reviewed the allegations and determined the merits of each. We found that the majority of the allegations did not have merit, while

also finding a partial substantiation and one full substantiation of the allegations raised.

A detailed review was conducted into all allegations, and subsequent fact-finding results. Although the fact-finding result may have returned a not substantiated determination, determination, the review identified additional actionable findings requiring attention.

To the allegation that [REDACTED] has sought to rescind the facility's SOP for prescribing buprenorphine, an opioid used to treat OUD, acute pain and chronic pain, the allegation was **not substantiated**. Although the fact-finding did support that [REDACTED] did seek to rescind the facility's SOP for prescribing buprenorphine, an opioid used to treat OUD, acute pain and chronic pain, the SOP failed to conform with the current national standards of practice and required revision.

To the second allegation, that [REDACTED] pressured providers to prescribe buprenorphine regardless of patient diagnosis and promoted incorrect guidance to providers that does not reflect the standard of care, placing patients at risk, the allegation is **partially substantiated**. The fact that [REDACTED] ordered the providers to become X-waivered by the DEA and begin treating patients with OUD using Suboxone (Buprenorphine and Naloxone), supports that the allegation to be more fact and likely support substantiation.

The allegation that [REDACTED] has engaged in improperly documented "self-consults" with PMT patients prior to their initial appointments, leading to potential billing irregularities and inequitable care was **not substantiated**. There is a concern that [REDACTED] did alter the agenda for the PMT meetings to more of an administrative focus, which is a clear violation of the facility Charter of the Comprehensive Addiction and Recovery Act Mandated Pain Management Team.

The fact-finding did **not substantiate** that [REDACTED] initiated changes to the Pain Management referral process that imposed barriers to access to interventional pain care services. The percentage of consults referred to the community is extremely high, with 90% of the new consults referred to community care. The large number of referrals to the community indicates a need for additional evaluation to determine the root cause for the high percentage.

The fact-finding did **not substantiate** the allegation that the facility Chief of Staff, [REDACTED] and Whole Health Director, [REDACTED] violated the MISSION Act and jeopardized patient health and safety by prohibiting pain management physicians from approving pain management community care programs for patients on the basis of the "improved continuity of care" criterion. However, the question of consistency regarding the interpretation of BMI criteria requires additional investigation to ensure alignment with VA Directive and the MISSION Act.

The allegation that [REDACTED] violated VA Directives 6500 (VA Cybersecurity Program) and 1907.01 (Health Information Management) by ordering the redaction of portions of medical records containing disclaimers from clinicians advising patients that denial or termination of community care programs was based on direct orders from [REDACTED]

and [REDACTED] was **not substantiated**, with no further investigation required at this time.

The final allegation that was investigated, of whether, since coming to the Department in May 2020, [REDACTED] has abused his authority by manipulating his clinical scheduling in the CPRS system was **substantiated** during the fact-finding(s). The facility will conduct further investigation into the allegation of [REDACTED] abuse of authority and follow up any findings of impropriety with appropriate action, that may include training, administrative action and discipline.

In consideration of the review of the allegations, and subsequent fact-finding results, the Department intends to institute all corrective actions relating to the delivery of patient care, in accordance with all governing authorities, policies and directives.

Note: The facility's recommended follow-up action plan for this report is found in Attachment 3 - Network Fact-Finding Evaluation.

Attachments

- Attachment 1 - Network Fact-Finding Evaluation
- Attachment 2 - Fact-Finding Report dated December 17, 2021
- Attachment 3- Pain Management Team Operations and Scheduling SOP 2021-002
- Attachment 4 - Draft Pain Management Service Agreement
- Attachment 5 - Consult Template
- Attachment 6 - OMI Temple TX OAWP 15931_16455 Report

Attachment

1



U.S. Department of Veterans Affairs

Veterans Health Administration

In Reply Refer To: 10N/17

FOR OFFICIAL USE ONLY

March 18, 2022

U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

SUBJECT: Agency Fact Finding - OSC File No. DI-21-000033 Referral for Investigation, OSC File Nos. DI-21-000470 and DI-21-000503-Addendum to OSC File No. DI-20-000033.

On November 17, 2020, Henry J. Kerner, Special Counsel, reported a whistleblower disclosure to Secretary Robert J. Wilkie, that the Department of Veterans Affairs (VA), Central Texas Veterans Health Care System (CTVHCS), Temple, Texas, engaged in actions that constitute gross mismanagement, an abuse of authority, and a substantial and specific danger to public health. The whistleblower alleged that [REDACTED] CTVHCS Chief of Whole Health and Integrated Health Service (Whole Health), instituted organizational and policy changes that are detrimental to the delivery of patient care in the Pain Management Clinic.

In response, on April 13, 2021, a fact-finding was initiated, conducted by [REDACTED] Chief of Anesthesiology and Pain Management for the North Texas Healthcare System, which concluded on May 11, 2021. The results of the fact-finding to the initial allegations uncovered additional concerns, with a lack of clear conclusions to all allegations, resulting in the need for an additional more focused fact-finding.

A second, more focused fact-finding was arranged, with [REDACTED] North Texas Health Care System Ambulatory Care Physician, assigned to conduct the investigation. Considering the allegations involve questions relating to an individual of a higher rank, the assignment of [REDACTED] was reconsidered. While [REDACTED] was utilized because of familiarity with the case, we had to move in a different direction in order to comply with the requirement that the issues be looked at by someone of higher rank than that of the personnel being investigated, with an alternate fact-finding investigator assignment. On approximately August 12, 2021, after an exhaustive search, the new investigator was assigned.

The additional fact-finding was conducted by [REDACTED] Deputy Chief of Staff for the West Texas Healthcare System, which concluded on December

17, 2021. The fact-finding involved seven (7) specific whistleblower allegations, with varying determination of sustainment.

To the allegation that [REDACTED] has sought to rescind the facility's standard operating procedures (SOP) for prescribing buprenorphine, an opioid used to treat opioid use disorder (OUD), acute pain, and chronic pain, the allegation was **not substantiated**. Although the fact-finding did not substantiate the allegation, [REDACTED] did seek to rescind the facility's SOP for prescribing buprenorphine. However, the SOP failed to conform with the current National standards of practice and required revision.

To the second allegation, that [REDACTED] pressured providers to prescribe buprenorphine regardless of patient diagnosis and promoted incorrect guidance to providers that does not reflect the standard of care, placing patients at risk, the allegation is **partially substantiated**. The fact that [REDACTED] ordered the providers to become X-waivered by the DEA and begin treating patients with Opioid Use Disorder (OUD) using Suboxone (Buprenorphine and Naloxone), supports that the allegation to be more fact and likely support substantiation.

The allegation that [REDACTED] has engaged in improperly documented "self-consults" with Pain Management Team (PMT) patients, prior to their initial appointments, leading to potential billing irregularities and inequitable care was **not substantiated**. There is, however, a concern that [REDACTED] did alter the agenda for the PMT meetings, to more of an administrative focus, a clear violation of the facility Charter of the Comprehensive Addiction and Recovery Act Mandated Pain Management Team.

The fact-finding did **not substantiate** that [REDACTED] initiated changes to the Pain Management referral process that imposed barriers to access to interventional pain care services. The percentage of consults referred to the community is extremely high, with 90% of the new consults referred to community care. The large number of referrals to the community indicates a need for additional evaluation to determine the root cause for the high percentage.

The fact-finding did **not substantiate** the allegation the facility Chief of Staff [REDACTED] and Whole Health Director [REDACTED] violated the Mission Act of 2018 ("Mission Act") and jeopardized patient health and safety. Specifically, by prohibiting pain management physicians from approving pain management community care programs for patients on the basis of the "improved continuity of care" criterion. The question of consistency regarding the interpretation of BMI criteria requires additional investigation to ensure alignment with VA Directive and the MISSION Act.

The allegation that [REDACTED] violated VA directives 6500 ("VA Cybersecurity Program") and 1907.01 ("Health Information Management") by ordering the redaction of portions of medical records containing disclaimers from clinicians advising patients that denial or termination of community care programs was based on direct orders from [REDACTED] and [REDACTED] was **not substantiated**, with no further investigation required at this time.

The final allegation that was investigated, of whether, since coming to the agency in May 2020, [REDACTED] has abused his authority by manipulating his clinical scheduling in the CPRS system was **substantiated** during the fact-finding. This substantiated allegation will be considered in determining the appropriate corrective action(s).

In consideration of my review of the allegations, and subsequent fact-finding results, the Agency intends to institute all corrective actions relating to the delivery of patient care in accordance with all governing authorities, policies, and directives. To those substantiated allegations that extend outside of the delivery of patient care, the Agency, through consultation with Human Resources and the Office of General Counsel (OGC), will initiate the appropriate administrative action.

This concludes my evaluation of the current fact-finding results into the whistleblower allegations addressed through the date of this document.

[REDACTED]
[REDACTED]
VISN 17 Network Director

Enclosure:

Fact-Finding Report dated May 11, 2021
Fact-Finding Report dated December 17, 2021

Attachment 2

Investigative Team Members (Fact-Finding December 17, 2021)

[REDACTED], Deputy Chief of Staff, West Texas VAHCS

Interviewees

[REDACTED]

Department of Veterans Affairs

Memorandum

Date: December 17, 2021

From: Deputy Chief of Staff / Specialty Care, West Texas VA Health Care System (WTVHCS)

Subj: OSC File No. DI-21-000033 Referral for Investigation, OSC File Nos. DI-21-000470 and DI-21-000503--
Addendum to OSC File No. DI-20-000033

To: US Office of Special Counsel, 1730 M Street, N.W., Suite 300, Washington, D.C. 20036-4505

Thru: Human Resources ER/LR, VISN 17; Office of Network Director, VISN 17

On November 17, 2020, Henry J. Kerner, Special Counsel reported a whistleblower disclosure to Secretary Robert J. Wilkie that the Department of Veterans Affairs (VA), Central Texas VA Healthcare System (CTVHCS), Temple, Texas engaged in actions that constitute gross mismanagement, an abuse of authority, and a substantial and specific danger to public health. The whistleblower alleged that the [REDACTED] CTVHCS Chief of Whole Health and Integrated Health Service (Whole Health), instituted organizational and policy changes that are detrimental to the delivery of patient care in the Pain Management Clinic. Specifically,

- a. [REDACTED] has sought to rescind the facility's standard operating procedures (SOP) for prescribing buprenorphine, an opioid used to treat opioid use disorder (OUD), acute pain, and chronic pain.
- b. [REDACTED] pressured providers to prescribe buprenorphine regardless of patient diagnosis and promoted incorrect guidance to providers that does not reflect the standard of care, placing patients at risk; and
- c. [REDACTED] has engaged in improperly documented "self-consults" with Pain Management Team (PMT) patients, prior to their initial appointments, leading to potential billing irregularities and inequitable care.

Subsequently, an additional allegation was made by the whistleblower and communicated in an addendum dated December 14, 2020. The allegation specified that the Chief of Whole Health, CTVAHCS had:

- d. [REDACTED] initiated changes to the Pain Management referral process that imposed barriers to access to interventional pain care services.

On May 7, 2021, and additional whistleblower. Dr. Raja [REDACTED] Chief, CTVAHCS Pain Management Section, forwarded three additional allegations., detailed below, which meet OSC's statutory substantial likelihood threshold. The additional allegations disclosed by Dr. Shahadi and transmitted for investigation are:

- e. Facility Chief of Staff [REDACTED] and Whole Health Director [REDACTED] violated the VA Mission Act of 2018 ("Mission Act") and jeopardized patient health and safety by prohibiting pain

management physicians from approving pain management community care programs for patients on the basis of the "improved continuity of care" criterion.

- f. [REDACTED] violated VA directives 6500 ("VA Cybersecurity Program") and 1907.01 ("Health Information Management") by ordering the redaction of portions of medical records containing disclaimers from clinicians advising patients that denial or termination of community care programs was based on direct orders from [REDACTED] and [REDACTED]
- g. Since coming to the agency in May 2020, [REDACTED] has abused his authority by manipulating his clinical scheduling in the CPRS system.

The whistleblower, [REDACTED] [REDACTED] was contacted and interviewed by this investigator via video conference on September 10, 2021. Subsequently, Dr. [REDACTED] forwarded over 100 emails containing multiple email chains between himself and CTVAHCS leadership along with other members of the healthcare team at CTVA as well as multiple publications from VHA. After review of the above documents, a second interview with Dr. [REDACTED] was conducted on December 9, 2021. Dr. [REDACTED] Chief, Pain Management Service was also interviewed via telephone on December 12, 2021.

Findings:

- a. [REDACTED] has sought to rescind the facility's standard operating procedures (SOP) for prescribing buprenorphine, an opioid used to treat opioid use disorder (OUD), acute pain, and chronic pain.

Dr. [REDACTED] explained that the CTVHCS Pain Management Clinic was recently reorganized under Whole Health. Upon taking responsibility for the Pain Management Clinic, [REDACTED] has sought to rescind the facility's SOP for prescribing buprenorphine, which was issued by the CTVHCS Pain Oversight Committee to address provider confusion about the proper use of buprenorphine for OUD and chronic pain. [REDACTED] asserted that rescission of the SOP is necessary to remove barriers to the use of buprenorphine products. Dr. [REDACTED] alleged that this action denies providers essential information on the risks and acuity associated with OUD, threatens the clinical course for patients, and may increase harm for patients with potential or diagnosed OUD, or those without OUD, by hindering the delivery of information on the use of opioids. Dr. [REDACTED] is prepared to provide specific examples to investigators to illustrate this allegation.

In June 2020, the Pain Oversight Committee at CTVAHCS was engaged in revising its existing policy and SOP regarding buprenorphine prescribing. [REDACTED] efforts appear to have been directed towards ensuring that the policies were consistent with VHA Notice 2019-18 which instructed VHA healthcare systems to remove barriers to treating OUD. and prescribing buprenorphine/ naloxone. Drs. [REDACTED] and [REDACTED] both expressed concerns that the [REDACTED] efforts went beyond those goals of removing barriers. They expressed concern that the changes would promote the prescribing of buprenorphine with a lower threshold of clinical indication than was prudent. They express concerns that buprenorphine is not an innocuous medication and should be used as circumspectly as any other opiate.

Allegation was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

- b. [REDACTED] **pressured providers to prescribe buprenorphine regardless of patient diagnosis and promoted incorrect guidance to providers that does not reflect the standard of care, placing patients at risk.**

Dr. [REDACTED] alleged that [REDACTED] direction of the Pain Management Clinic appears to be predicated on an inaccurate understanding of the evaluation and treatment of OUD and chronic pain. [REDACTED] has repeatedly informed physicians, including in e-mails to staff dated October 15 and October 17, 2020, that their performance can be tied to their willingness to prescribe buprenorphine. [REDACTED] directed that PMT physicians must obtain X-waivers—Drug Enforcement Administration-issued waivers to prescribe buprenorphine—to treat patients manifesting criteria of OUD with buprenorphine. [REDACTED]

[REDACTED] also emphasized the financial incentives available to providers who prescribe buprenorphine, as described in VA's national buprenorphine guidance, which recommends providing incentive special pay for providers who obtain an X-waiver and prescribe buprenorphine to treat OUD.

[REDACTED] has also repeatedly asserted to staff that a diagnosis of OUD or chronic pain is not required before prescribing buprenorphine. Dr. [REDACTED] explained that [REDACTED] statements do not reflect the standard of care.^{3,4} He noted that buprenorphine is a potent opioid associated with all known risks of opioids, including hepatic injury; respiratory depression and death; abuse, misuse, or diversion; and opioid withdrawal. Thus, the risk of prescribing buprenorphine to patients who do not have OUD likely outweighs the benefit, according to Dr. [REDACTED]. Dr. [REDACTED] argues that placing professional and financial pressure on providers to prescribe buprenorphine while lowering the standard of care for prescribing it, creates a dangerous environment for patients, who may receive unnecessary opioid prescriptions that place their health at risk.

The Whole Health Director did require Pain Management Section (PMS) providers to complete the Drug Enforcement Administration (DEA) X-waiver training and apply for an X-waiver. It is apparent that the motivation for the requirement of obtaining x-waiver and promotion of prescribing of buprenorphine stems from a lack of other providers at the facility willing to treat individuals with a dual diagnosis of chronic pain and opioid use disorder. The Interventional Pain provider's training and expertise lies in the procedurally based management of specific pain syndromes, they have no training or experience in MAT beyond that afforded by the minimal training required for obtaining the X waiver. Dr. [REDACTED] Pay for Performance (P4P) plan for FY21 did include a requirement to "manage 5 patients with concurrent chronic pain and complex persistent opiate dependence using appropriate medications." This performance measure was removed from Dr. [REDACTED] Performance Plan following an investigative visit conducted by DEA per Dr. [REDACTED]. Certainly, placing a financial incentive on the prescribing of a specific medication along with incentives to apply specific diagnoses is problematic and presents a specific and potentially substantial danger to patient safety. Again, the measure was removed from Dr. [REDACTED] performance part way through FY21.

Allegation was **partially substantiated**. Investigation of this concern revealed a theoretical risk of undue influence upon individual clinical decision making that could potentially

adversely impact a veteran's health status. Investigation did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, or an abuse of authority. The Interventional Pain provider's training and expertise lies in the procedurally based management of specific pain syndromes, they have no training or experience in MAT beyond that afforded by the minimal training required for obtaining the X waiver. Utilization of these providers in this fashion may not represent the best manner to provide MAT particularly given the high rate of community referral for interventional pain services for CTVAHCS.

- c. [REDACTED] has engaged in improperly documented "self-consults" with Pain Management Team (PMT) patients, prior to their initial appointments, leading to potential billing irregularities and inequitable care.

Dr. [REDACTED] further alleged that [REDACTED] insists on conducting self-initiated patient contact with PMT patients prior to their initial PMT appointments. Dr. [REDACTED] alleged that during these encounters [REDACTED] is taking patient histories, making patient assessments, identifying risk levels for patient presentation, and recommending the way to manage patients' treatment. [REDACTED] previously coded these contacts as "historical" non-billable encounters, but recently stopped coding or charting them at all. According to Dr. [REDACTED], these encounters potentially bias the PMT's patient assessments and the course of care for patients, while also being improperly billed or not billed at all. They also establish a process under which patients are receiving inconsistent evaluations, which, Dr. [REDACTED] contends, impedes the VA's mission to deliver appropriate, quality care to all veterans.

The Director of Whole Health was not found to be performing self-consultation. The Director of Whole Health as a member of the facility's Interdisciplinary Pain Management team would contact patients ahead of their scheduled team appointment. These patient encounters were reportedly inconsistently documented within the medical record. Per Dr. [REDACTED], at least one veteran had medication dosage changes recommended by [REDACTED] without documentation in the medical record because of these pre-visits.

This occurred for a short period of time after [REDACTED] joined the team. When concerns were raised by members of the team about disruption of the interdisciplinary process, the consult process was modified to consist of individual appointments followed by an IDT meeting without the veteran. No evidence of inappropriate billing by the Director of Whole Health was identified.

Allegation was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. There is some concern about the adequacy of medical documentation by [REDACTED] which would most appropriately be addressed through the Ongoing Professional Practice Evaluation (OPPE) process.

- d. [REDACTED] initiated changes to the Pain Management referral process that imposed barriers to access to interventional pain care services.

Dr. [REDACTED] disclosed that on November 30, 2020, Whole Health Chief [REDACTED] informed staff via e-mail that all referrals to the Pain Management Clinic will now be reviewed solely by Whole Health "coaches," who are not physicians or pain management providers. If the Whole Health coach approves the referral, the patient will be required to complete a Veterans Health Administration (VHA) course titled "Intro to Whole Health." Patients will be directed to initiate a Personal Health Inventory and complete "individual coaching" or a second course, "Taking Charge of My Life and Health." After these steps are completed, patients may select only one care "pathway": acupuncture, chiropractic care, or pain clinic. They may not select more than one of these pathways at the same time.

Dr. [REDACTED] explained that previously, if a primary care or other physician referred a patient to the Pain Management Clinic, a pain physician reviewed the patient's chart information and determined what next steps would be taken to provide appropriate care. Under [REDACTED] new directive, physicians and pain experts are removed from the review process and patients do not receive an initial clinical diagnosis. As a result, patients may receive inappropriate care without the oversight of a pain physician. In addition, patients are required to complete coursework before being permitted access to the Pain Management Clinic, potentially delaying the delivery of appropriate physician-based clinical care.

Dr. [REDACTED] noted that it is VHA policy that complementary and integrative health may not be used as an alternative to conventional medicine. [REDACTED] directive appears to violate this national policy by permitting the replacement of conventional pain care with complementary care, such as acupuncture. Additionally, federal regulations state that VA patients are entitled to receive prompt and appropriate treatment and have the right to the least restrictive conditions necessary to achieve treatment purposes. Dr. [REDACTED] alleged that [REDACTED] actions—which are a direct consequence of the problematic reorganization of the Pain Management Clinic that we highlighted in Footnote 1 of our November 17, 2020, letter—violate both of these patient rights and have a significant negative impact on the delivery of patient care.

Dr. [REDACTED] indicates that the requirement for enrollment and completion of the "Intro to Whole Health" VHA course was only implemented for referrals to CIH services and not for referral to interventional pain management. This is reflected in the template for Pain Management consultation as well as in the service agreement for Pain Management services at CTVAHCS. The service agreement additionally indicates that patients may receive interventional pain concurrently with acupuncture or chiropractic care.

Allegation was **not substantiated**. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

- e. **Facility Chief of Staff [REDACTED] and Whole Health Director [REDACTED] violated the VA Mission Act of 2018 ("Mission Act") and jeopardized patient health and safety by prohibiting pain management physicians from approving pain management community care programs for patients on the basis of the "improved continuity of care" criterion.**

Specifically, beginning in January 2021, [REDACTED] ordered Dr. [REDACTED] and his staff to disapprove all referrals from primary care physicians for community care plans citing

"improved continuity of care" as the sole criterion for the referral, and instead, compel these patients to continue their pain programs at the VA facility. Dr. [REDACTED] asserted that this policy disrupts established pain programs for veterans, causes undue delay in treatment, and violates the Mission Act, which provides that a veteran may be referred to a community healthcare provider if the patient and referring doctor agree that it is in the "patient's best interest."

In my discussions with Dr. [REDACTED] the chief of Pain Management, it appears that many of the Community Care (CC) requests that do not qualify by drive time or wait time are requests by veterans to continue seeing outside Pain Management providers who prescribe chronic opiates for the veterans. Services that can and should be provided by VA PACT providers or Mental Health. The limitation of Community Referrals for BMI when veteran does not qualify on basis of wait time or distance or lack of available services is fully consistent with Mission Act and prudent resource management. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

- f. [REDACTED] violated VA directives 6500 ("VA Cybersecurity Program") and 1907.01 ("Health Information Management") by ordering the redaction of portions of medical records containing disclaimers from clinicians advising patients that denial or termination of community care programs was based on direct orders from [REDACTED] and [REDACTED]

Dr. [REDACTED] and other members of the Interventional Pain Management team were tasked with receiving interventional pain consults and redirecting to the internal service those that were referred to the community for continuation of care using a Best Medical Interest rationale. When Primary care providers persisted in placing these referrals, Dr. [REDACTED] began the practice of identifying [REDACTED] and [REDACTED] by name in the consult comments as being the source of instructions to redirect these consults to the in-house interventional pain management team.

[REDACTED] required the Interventional Pain Management team to compile the list of consults in which [REDACTED] and himself had been so identified with the intent of having the comments redacted. Drs. [REDACTED] and [REDACTED] were not aware of any consults having entries redacted as a result of these efforts and in fact, it is not possible to redact consult entries in CPRS. Although, [REDACTED] did seek to have entries redacted in which he was inappropriately directly named, no entries were in fact, redacted.

Allegation was not substantiated. Investigation of this concern did not reveal evidence of a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

- g. Since coming to the agency in May 2020, [REDACTED] has abused his authority by manipulating his clinical scheduling in the CPRS system.

Rather than establishing the proper consultation process in CPRS, [REDACTED] instructs Lee to inappropriately control the type and the number of patients that he admits to his clinical

practice, jeopardizing patient care and violating multiple VA directives related to complimentary and integrative health services and outpatient scheduling processes and procedures.

Dr. [REDACTED] provides clinic scheduling grids and total patient counts indicating available clinic slots for two half days weekly with a total of 41 patient encounters during FY21 that did not begin until June 2021. Based upon guidance for VA physician staff and availability for clinical care, [REDACTED] should be engaged in clinical care on a .7 FTEE basis.

Allegation was substantiated. Investigation of this concern did reveal evidence of a violation of rule and waste of funds.

Respectfully,

[REDACTED]

Attachment

3

PAIN MANAGEMENT TEAM OPERATIONS AND SCHEDULING

SOP 2021-001

Dr. E. Tangle, Veterans Medical
Center
Service Line(s)

Service Line(s)

Signatory Authority

Whole Health Services Pain Clinic

Edward S. Lee, MD
Clinical Director, Whole Health Services

Effective Date

September 1, 2021

Responsible Owner

Reaffirmation Date

Rita E. Smith, MD
Clinical Supervisor, Pain Clinic

September 1, 2024

1. PURPOSE AND AUTHORITY

a. The purpose of this Standard Operating Procedure (SOP) is to establish guidelines for scheduling Veterans within the Pain Management Team (PMT), procedures within the PMT, and to ensure appropriate assessment, management and monitoring of patients who have been deemed to be of higher risk and complexity due to their comorbidities and polypharmacy needs. This SOP must be followed by clinicians within the PMT, who will present, discuss, and monitor appropriate patients.

b. The PMT includes, but is not limited to the following members:

- (1) PMT Chair
- (2) Pain Management Specialist
- (3) Whole Health Coordinator
- (4) Behavioral Health Specialist
- (5) Rehabilitation Specialist
- (6) Addiction Specialist
- (7) Clinical Pharmacy Specialist
- (8) Social Worker
- (9) Whole Health Coach
- (10) Primary Care Pain Champion
- (11) Pain Management, Opioid Safety, and PMDP (PMOP) Coordinator

c. This SOP sets forth mandatory processes and procedures to ensure compliance with DVA Memorandum 011-001, PAIN MANAGEMENT AND ASSESSMENT, April 24, 2018; VHA Directive 2009-053, PAIN MANAGEMENT, October 28, 2009; and VHA Directive 1137, PROVISIONS OF COMPLIMENTARY AND INTEGRATIVE HEALTH (CIH), May 18, 2017, and Public Law 114-198. Sec 911, July 22, 2016

2. PROCEDURES

a. A member of the PMT will place a consult for a patient to be seen by the PMT in the monthly Medical Specialty Shared Appointment.

b. The consults will be reviewed by the PMOP coordinator and the PMT Chairperson (if necessary). The PMT will be notified of the patients to be presented prior to the scheduled Medical Specialty Shared Appointment. Individual providers may work up and review patients scheduled for the Medical Specialty Shared Appointment in preparation for an individualized discussion.

c. Patients will be scheduled via face to face, telephone, or VVC for the Medical Specialty Shared Appointment. If the patient is not available at the time of the meeting, the patient shall be rescheduled or a patient evaluation shall be completed via chart review and discussion solely amongst the PMT.

d. Following the initial patient discussion at the Medical Specialty Shared Appointment, the PMT may decide to follow the patient as a team or may recommend a treatment plan that can be implemented by specific team members or the Primary Care Provider (PCP).

(1) In cases that require longitudinal or ongoing coordinated care, the Veteran will be seen by all appropriate members of the PMT for individual assessments with subsequent PMT discussion within 60 days.

(2) Criteria for longitudinal or ongoing coordinated care are as follows:

- i. History of chronic pain with comorbid substance use disorders or complex persistent opioid dependence due to long-term opioid therapy.
- ii. High risk of suicide
- iii. Frequent hospitalization due to uncontrolled pain
- iv. History of multiple interventions, including surgical management, with persistent pain.
- v. High risk as determined by Stratification Tool for Opioid Risk Mitigation (STORM) and Care Assessment Needs (CAN) scores.

e. Following the individual appointments, the patient will be rescheduled for a follow-up Medical Specialty Shared Appointment discussion to determine any further longitudinal needs or discharge. If the patient has longitudinal needs and needs to continue follow-up with members of the PMT, a subsequent review date will be determined for another Medical Specialty Shared Appointment.

3. ASSIGNMENT OF RESPONSIBILITIES

a. **Medical support assistant/Advanced medical support assistant (MSA/AMSA)**. The Whole Health Clinic MSA/AMSA will make 2 attempts to contact the Veteran by phone for scheduling and then send notification letter indicating that consult will be discontinued if they fail to respond to scheduling effort within 2 weeks. The

MSA/AMSA will call to remind new and returning patients of their upcoming scheduled appointment. Restricted scheduling keys and privileges will be granted to the PMT MSA/AMSA to protect PMT shared and individual appointments. They will be responsible for obtaining the PMT clinic availability report. The MSA/AMSA will assist the PCPs in blocking clinic time to attend PMT, if desired. The MSA/AMSA will serve as the scribe during all Medical Specialty Shared Appointments, assisting with the patient's care plan for the PMT Chairperson's review and entrance into the EMR.

b. **PMT Chairperson.** The Chairperson will lead a monthly Medical Specialty Shared Appointment and oversee implementation of Personalized, Proactive, Patient-Driven Care for each Veteran by the Pain Management Team. Overseeing care coordination will include: active medication management, functional restoration strategies, complementary and integrative approaches, behavioral health approaches, and interventional approaches. The chairperson will finalize all documentation to be entered into the patient's Electronic Medical Record (EMR).

c. **Pain Management Specialist.** The Pain Management Specialist will assist with evaluation of patient specific pain generators to help determine appropriateness of care to include: active medication management (non-opioid, and opioid management, including buprenorphine), functional restoration strategies, complementary and integrative approaches, behavioral health approaches, and interventional approaches. Patients can be scheduled into the provider's specific clinic for further evaluation and patient centered care as deemed appropriate.

d. **Whole Health Coordinator.** The Whole Health Coordinator will also assist with evaluation of patient specific pain generators to help determine appropriateness of care to include: active medication management (non-opioid, and opioid management, including buprenorphine), functional restoration strategies, complementary and integrative approaches, behavioral health approaches, and interventional approaches. The Whole Health Coordinator will have additional expertise in empowering and equipping patients to take charge of their health and well-being through self-management approaches, based on the Veteran's mission, aspiration, and purpose. Patients can be scheduled into the provider's specific clinic for further evaluation and patient centered care as deemed appropriate.

e. **Behavioral Health Specialist.** The Behavioral Health Specialist, with expertise in Pain Management, will assist appropriate patients in engaging in psychological, behavioral, and cognitive approaches to pain. This specialist will evaluate the motivation of interest and facilitate the engagement of Veterans in patient focused mental health approaches to pain. Patients can be scheduled into the provider's specific clinic for further evaluation and patient centered care as deemed appropriate.

f. **Rehabilitation Specialist.** The Rehabilitation Specialist will assist in the evaluation of appropriate active and functional restorative modalities and approaches to pain within the patient's specific pain care plan. Veterans can be scheduled into the

provider's specific clinic for further evaluation and patient centered care as deemed appropriate.

g. **Addiction Specialist.** The Addiction Specialist will assist in the evaluation, diagnosis, and treatment of patients with opioid use disorder. If the patient has opioid use disorder, the addiction specialist will help facilitate patient enrollment in SATP inpatient or outpatient programs as indicated and also facilitate enrollment into the BUP/SUD clinic as deemed appropriate.

h. **Clinical Pharmacy Specialist.** The Clinical Pharmacy Specialist will assist with the patient specific opioid and non-opioid medication plan of care and will assist with longitudinal medication management as necessary. Patients can be scheduled into the provider's specific clinic for further evaluation and patient centered care as deemed appropriate.

i. **Social Worker.** The Social Worker will assist with planning, coordinating, and implementing support services related to the patient's individualized pain care plan. The Social Worker will call patients in advance to explain the purposes and goals of the PMT.

j. **Whole Health Coach.** The Whole Health Coach will assist, support, and partner with the Veteran to develop a personalized health plan based on the Veteran's own goals, values, preferences, and lifestyle. The Coach will assist the patient in evaluating and exploring options of care available through the Whole Health Service.

k. **Primary Care Pain Champion.** The Primary Care Pain Champion will serve as a subject matter expert in the area of Primary Care Pain within the PMT. This provider will act as liaison between the PMT and the Primary Care Provider, assisting with pain education and longitudinal pain care management for patients seen within the PMT.

l. **PMOP Coordinator.** The PMOP Coordinator will also act as a liaison between the PMT and the Primary Care Provider, assisting with selection and scheduling of patients to be seen by the PMT and oversee completion of Opioid Safety Initiative (OSI) reviews and data-based risk reviews for opioid-exposed patients. The PMOP coordinator will serve as the point of contact for business and patient focused care related to the PMT.

m. **Primary Care Provider.** The Primary Care Provider will be encouraged to attend appropriate IDT meetings and participate in the development of a patient-centered plan of care for their Veteran that can be executed longitudinally with the support of the PMT. Should the Primary Care Provider not be able to attend the Medical Specialty Shared Appointment, recommendations from the PMT will be discussed with the provider by the Primary Care Pain Champion.

4. SCHEDULING

a. **CONSULTS:** Any member of the PMT can request professional consultation for high risk and/or complex medical cases. The PMOP coordinator and PMT chairperson

(if necessary) will review and schedule patients for the upcoming PMT monthly Medical Specialty Shared Appointment. A new individual consult will be needed if a patient is to be seen by a specific provider within PMT as determined by the patient's individual pain care plan during the Medical Specialty Shared Appointment. This consult will be entered by the PMOP Coordinator within the parameters of the specific provider's specialty. Consults will be reviewed by the designated provider within 72-hours of being received. Should the provider be on leave or unavailable for an extended period of time, the PMOP Coordinator will work with the specific provider for consult disposition. The patient is to be seen within 60 days of the original consult date.

b. **COMMUNICATION:** Members of the PMT will be notified via encrypted email one week prior to the scheduled Medical Specialty Shared Appointment of patients that are scheduled. Individual providers may work up and review patients scheduled for the Medical Specialty Shared Appointment in preparation for an individualized discussion.

c. **MEDICAL SPECIALTY SHARED APPOINTMENT TIME ALLOCATION:**

(1) 60 minute- new patient discussion, 30 minute- follow-up discussion

- i. Team discussion
- ii. Development of patient-centered pain care plan

(2) Options for case review periods

- i. PMT review only with pain care plan to be discussed with the patient's Primary Care Provider by Primary Care Pain Champion
- ii. PMT review with Primary Care Provider present
- iii. PMT review with patient present
- iv. PMT review with patient and Primary Care Provider Present

(3) Primary Care Attendance: The patient's PCP will be invited to attend the follow-up, Medical Specialty Shared Appointment. Clinical time for the PCP will be blocked in the appropriate manner if the PCP elects to attend the Medical Specialty Shared Appointment. If the PCP elects not to attend the meeting, the recommendations/plan will be discussed with the PCP via the Primary Care Pain Champion and/or PMOP coordinator (if necessary).

5. DISCHARGING PATIENTS FROM PMT

a. **LONGITUDINAL CARE:** Patients will be followed in the pain clinic longitudinally as long as clinically indicated, in collaboration with the PMT.

b. **CRITERIA FOR DISCHARGE:**

- (1) Sustained improvement in pain and function.
- (2) Adherence to treatment plan, including:
 - i. Receiving prescribed medications only from VA providers.
 - ii. Taking medications strictly as directed
 - iii. Urine drug testing results that are consistent with prescribed medications.
- (3) Engagement and/or completion of self-management approaches.
- (4) No complications or hospitalizations for 3 months.

c. **TRANSITION OF CARE:** Care of patients will transition from the Pain Management Clinic to Primary Care when the meets all discharge criteria. Primary Care would then be responsible for prescription of medications.

(1) If the Primary Care Provider does not agree with the recommend medication regimen, they **MUST** provide an alternative treatment plan that is equally safe, effective, and acceptable to the patient.

(2) Risk Mitigation: PACT providers will implement risk mitigation strategies in collaboration with PACT nurses, Clinical Pharmacists, and Intensive Case Management or other Care Coordinators, when indicated, including:

- i. Keeping informed consent for long-term opioid therapy current
- ii. Querying the Prescription Drug Monitoring Program
- iii. Checking urine drug screen
- iv. Educating patients and care givers or family members on overdose and prescribing naloxone.

d. **ONGOING COLLABORATION:** Referring provider may re-consult any member of the Pain Management Team at any time for a change in status or risk.

6. REFERENCES

a. VHA Directive 1137, Provision of Complementary and Integrative Health (CIH), May 18, 2017, [CIH Directive 1137 D 2017-05-18 Link](#).

b. VHA Directive 2009-053, Pain Management, October 28, 2009, [Pain Management Directive 2009-053 Link](#).

c. DVA Memorandum 011-001, Pain Management and Assessment, April 24, 2018, [Pain Management and Assessment Link](#).

d. Comprehensive Addiction Recovery ACT (CARA), PL 114-198, Sec. 911. July 22, 2016

7.

[List frequency of required review, at minimum at recertification, when there are changes to the governing document (for example, national policy or a health care accreditation body mandate), and any regulatory requirement for more frequent review. If applicable, cite the location where the review is documented.]

8. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of [September 2026 – 5 years from effective date]. In the event of contradiction with national policy, the national policy supersedes and controls.

9. SIGNATORY AUTHORITY

[Redacted] Physician
Clinical Director, Whole Health and Integrated Health Services
Date Approved: Month Day, Year

[Name] (if applicable) [Delete this if not needed]
Additional title, as appropriate
[Title of Service Line Chief]
Date Approved: Month Day, Year "wasn't sure if we needed another signing authority"

NOTE: The signature remains valid until rescinded by an appropriate administrative action.

DISTRIBUTION: [Insert distribution practices here, such as, Emailed to the [Name] Distribution List on [DATE]. SOPs are available at: LINK.]

Attachment

4

***Integrated Pain Management Service Agreement
Central Texas VA Healthcare System***

I. Preamble:

- A. The Whole Health and Integrated Health Service offers comprehensive pain management consultative services that deliver interventional pain management procedures as well as pharmacotherapy, including opioid management, and integrative pain management modalities to include acupuncture and chiropractic treatments, as part of a Biopsychosocial approach to pain management. This service agreement is in alignment with a paradigm shift that is occurring throughout the entire VA healthcare system from one of simply managing pain to providing a comprehensive pain rehabilitation plan, empowering veterans to take control of their lives and health to promote a healthier lifestyle and improve their quality of life.
- B. Some degree of functional restoration is always possible. Nonpharmacologic and non-interventional measures should be provided for any pain conditions prior to referral for specialty pain management services.
- C. According to the Medical Center Memorandum on Patient Rights (004VES-002, October 2, 2019):

Patients have the right to have their pain assessed and to receive treatment to manage their pain. Patients and their treatment team will develop a pain management plan together. Patients are expected to guide the treatment process by communicating their pain, needs, preferences and the effectiveness of treatment received and by working in collaboration with the team to optimize their treatment.

- D. This Service Agreement is based on the Stepped Care Model of Pain Management as described in VHA Directive 2009-053 from October 28, 2009, and the Central Texas VHCS Pain Management Policy, MCP 011-001. Any future revisions of this directive will serve as a basis for implementation of this Service Agreement.
- E. Consultation is available for both inpatient and outpatient pain management. This includes consultation for patients in palliative care.

II. Services Included:

The following services are a party to this agreement:

- Ambulatory Care Service
- Medicine Service
- Surgical Service
- Anesthesia Service

- Mental Health and Behavioral Medicine Service
- Physical Medicine and Rehabilitation Service
- Pharmacy Service
- Nursing Service
- Whole Health and Integrated Health Service
- Community Care Service
- Geriatrics and Extended Care

III. Objectives:

- A. To integrate the consultation process for comprehensive, interdisciplinary pain management to Veterans.
- B. To implement the VHA stepped-care approach to pain management, involving teaching Veterans self-management skills and providing pain management in all appropriate settings, including primary care and specialty care.
- C. To transition Veterans with chronic pain from a pain management strategy to a Recovery Model of care, focusing on functional restoration and improvement in quality of life.

IV. Expected Response Time:

Response to consults will be within VA guidelines.

V. Requirements:

A. Consult process:

1. Primary Care providers and Specialty Clinic providers will enter a consult order for the Integrated Pain Management Clinic
 - a. Providers must document a focused evaluation pertinent to the pain site within 6 months of the consult in any VA or community setting to rule out emergent and urgent conditions based on focalizing neurologic findings. Referrals from Community Care may refer to the Non-VA documentation of such.
 - b. All requests for acupuncture, chiropractic care, interventional pain management, and consultation for medication management for chronic pain will be submitted to this clinic for consultation.
 - c. Acupuncture and Chiropractic care will not be authorized concurrently – Veterans will need to complete a course of one treatment before being authorized for the other. Veterans may be referred to Pain Management concurrently with the other services.
 - d. While patients will be encouraged to participate in Whole Health Coaching, this is not a requirement.

2. Patients will be referred to Community Care if they meet MISSION Act criteria for drive time and wait time, or if they require a service that is not available at CTVHCS.

- B. Pharmacotherapy: Consultations to the Pain Clinic to optimize pharmacotherapy can be requested if conservative measures and initial pharmacotherapy are ineffective, or if referring providers have concerns about opioid safety that Clinical Pharmacy Pain Management is unable to address.

Referring providers must be mindful of the fact that abruptly weaning or stopping opioids increases the risk of overdose and suicide.

1. The Pain Management service will assist with tapering or rotation of medications, with the goal of stabilizing patients on safe and effective analgesic regimens that improve function and quality of life. In some cases, long-term full- or partial-agonist opioid therapy may be recommended, based on careful consideration of the risks and benefits, as well as an understanding of the patient's goals of care. This is based on the Interagency Taskforce on Best Practices for Pain Management recommendations that:
 - a. Weaning or stopping opioids should be done on the basis of a shared decision with the patient on the goals of treatment and the risks and benefits of continuing opioids vs. weaning them.
 - b. Consultation with pain management and behavioral health can be incorporated as part of treatment planning and implementation.
2. Buprenorphine (with or without naloxone) should be considered, as this is the first-line treatment for OUD or Complex Persistent Opioid Dependence due to Long-Term Opioid Therapy. Buprenorphine is effective for both analgesia and for OUD treatment and can be managed in both Specialty and Primary Care.
3. Naloxone: This medication is a critical opioid risk-mitigation tool and should be prescribed for any patients who are prescribed opioids, or have a history of OUD, unless there is a true contraindication. Naloxone may be ordered through Naloxone Education and Use Note template.
4. Inpatient consultation: Providers may request bedside consultation for acute pain management of hospitalized patients due to acute, evolving processes, such as in the perioperative setting. An Inpatient Pain Management consult order must be entered and the Pain Management section must be contacted by telephone. For hospitalized patients who are stable and with a history of chronic pain, an outpatient Integrated Pain Management consultation may be placed prior to

discharge.

- C. Pain Management outside of Whole Health and Integrated Health Service. Separate consults can be entered for the following:
 - 1. Physical Medicine and Rehabilitation Service
 - a. Physiatry (Rehab MD Physician) which will determine if Skilled Therapy Services are needed (PT, OT and KT).
 - b. TENS unit through Physical Therapy Section
 - 2. Whole Health Service
 - a. Introduction to Whole Health
 - b. Yoga
 - 3. Mental Health and Behavioral Medicine
 - a. Cognitive Behavioral Therapy for Chronic Pain
- D. Coordination of care:
 - 1. The providers in the Integrative Pain Clinic will assess patients and collaborate with the Veteran to develop an Individualized Treatment Plan based on the patient's Personal Health Inventory and Personal Health Plan. This plan may include:
 - a. Health Coaching
 - b. Complementary and Integrative Health approaches, including Mind-Body approaches, Acupuncture, Chiropractic care, Tai Chi, Yoga, and others.
 - c. Interventional pain management procedures.
 - d. Pharmacotherapy.
 - e. Rehabilitative approaches, including Physical, Occupational and Kinesiotherapy Services.
 - f. Behavioral approaches, including Cognitive Behavioral Therapy for Chronic Pain.
 - g. Nutritional approaches
 - 2. Pain Clinic providers may present cases they believe constitute higher risks and complexity due to the Veteran's comorbidities and polypharmacy with the members of the Interdisciplinary Pain

Management Team (PMT) at an Interdisciplinary Team (IDT) meeting, which occurs no less than once monthly.

- a. The PMT consists of the following members:
 - i. Pain Specialist
 - ii. Behavioral Health Specialist with expertise in Pain Management.
 - iii. Rehabilitation Specialist
 - iv. Addiction Specialist
 - v. Clinical Pharmacy Specialist
 - vi. Social Worker
 - b. After discussing these cases at the IDT meeting, the PMT may decide to follow the patient as a team or may recommend a treatment plan that can be implemented by specific members of the team or the referring provider.
 - c. Criteria for longitudinal care are as follows:
 - i. History of chronic pain with comorbid substance use disorders or complex persistent opioid dependence due to long-term opioid therapy.
 - ii. High risk of suicide
 - iii. Frequent hospitalization due to uncontrolled pain
 - iv. History of multiple interventions, including surgical management, with persistent pain.
 - v. High risk as determined by STORM and CAN scores.
 - d. In cases that require longitudinal care, the Veteran will be seen by all appropriate members of the PMT for individual assessments and discussed at another IDT meeting within 60 days.
 - e. Referring providers will be invited to participate in the IDT meetings to be involved in treatment planning for their patient and afforded the opportunity to ask questions and have concerns addressed.
3. Patients will be followed in the pain clinic longitudinally as long as clinically indicated, in collaboration with the PMT. Criteria for discharge include:
- a. Sustained improvement in pain and function.
 - b. Adherence to treatment plan, including:
 - i. Receiving prescribed medications only from VA providers.

- ii. Taking medications strictly as directed
 - iii. Urine drug testing results that are consistent with prescribed medications.
 - c. Engagement in self-management approaches.
 - d. No complications or hospitalizations for 3 months.
4. Transition of Care: Care of patients will transition from the Pain Management Clinic to Primary Care when the meets all discharge criteria. Primary Care would then be responsible for prescription of medications.
- a. If the Primary Care Provider does not agree with the recommend medication regimen, they must provide an alternative treatment plan that is equally safe, effective, and acceptable to the patient.
 - b. Risk Mitigation: PACT providers will implement risk mitigation strategies in collaboration with PACT nurses, Clinical Pharmacists, and Intensive Case Management or other Care Coordinators, when indicated, including:
 - i. Keeping informed consent for long-term opioid therapy current.
 - ii. Querying the Prescription Drug Monitoring Program
 - iii. Checking urine drug screen
 - iv. Educating patients and care givers or family members on overdose and prescribing naloxone.
 - c. Ongoing Collaboration: Referring provider may re-consult any member of the Pain Management Team at any time for a change in status or risk.

E. Communication:

- 1. The consult result note will be utilized to communicate recommendations and treatment plan back to the referring clinician. Involvement of the PACT RN Case Manager and daily PACT team huddles are highly recommended in order to improve communication and continuity of care for these complex patients.
- 2. Other channels of communication can be used for urgent concerns, including e-mail, telephone, and instant messaging.
- 3. Intensive Case Management and other Care Coordination may be indicated for some Veterans. The Care Coordinators will facilitate

communication between the different specialty clinics and the Veteran's PACT teamlet.

VI. Monitor & Evaluation of this agreement

- A. All stakeholders will remain in open communication regarding the effectiveness of this agreement.
- B. This agreement will be renewed within three years of date of final signature or sooner as deemed necessary by all stakeholders.

VII. Attachments:

Pain Management Policy July 2021 Final Draft

X

Chief of Staff
Central Texas VA Healthcare System

X

Associate Director
Patient Care Services

X

Associate Chief of Staff
Mental Health and Behavioral Medicine

X

Associate Chief of Staff
Physical Medicine and Rehabilitation

X

Associate Chief of Staff
Anesthesiology

X

Associate Chief of Staff
Surgery

X

Associate Chief of Staff
Medicine

X

Associate Chief of Staff
Community Care

Associate Chief of Staff Pharmacy



Associate Chief of Staff Geriatrics and Extended Care

Attachment

5

MEDICAL RECORD

CONSULTATION SHEET

ZZAEARP, WYATT TEST

XXX-XX-0001 07/04/1948 (Age: 73) NSC VETERAN

17 NAUSET BEACH AVENUE

HARLINGEN TEXAS 78550 Phone: (915) 555-4444

Consult Request: Consult | Consult No.: 6245014

To: TEM WHS OUTPT PAIN MANAGEMENT

From: A MED NEURO PHY ESTPT2 T EX

(Requested: 12/15/2021 12:02 pm)

Requesting Facility: OLIN E. TEAGUE VET CEN

REASON FOR REQUEST: (Complaints and findings)
PAIN MANAGEMENT CONSULTATION GUIDELINES:

This consultation request is for Pain Management Procedures.

1. Reason for Request: Where is the primary location of the patient's worst pain for the consultant to address?

- Back Pain Yes
- Neck Pain Yes
- Other No (please specify):

2. Interventional Pain Management Procedures:

- Does the patient desire to receive interventional pain management injections for the management of Chronic Pain? Yes

3. Imaging:

- The patient needs to have advanced imaging of the area involved within the last two years. MRI is usually the preferred advanced imaging for the spine.

If MRI is contraindicated then obtain CT scan of the involved area. If the patient had prior surgery to the spine, then please request MRI with and without contrast if the renal function allows it. The official imaging report must be reviewed by pain management before the consultation can be accepted. Please specify where the official imaging report is found:

(Choice of only one is accepted; may not choose more than one)
CPRS

4. Blood Thinners:

- Is the patient receiving any blood thinners such as Coumadin, aspirin, clopidogrel, TSOACs (apixaban, dabigatran, or rivaroxaban) etc. Yes

- If the patient is on blood thinners, can the patient discontinue that medication for about 7 days WITHOUT ANY BRIDGING medication and without significant risk of developing stroke, cardiovascular insult, or any other problem for which the patient is receiving

that medication to prevent. Yes

=====

AUTHOR & TITLE:

| DATE:

ID #: _____ | ORGANIZATION: OLIN E. TEAGUE VE | REG #: _____ | LOC: A MED NEURO

Page 1 of 3

Standard Form 513 (Rev 9-77)

MEDICAL RECORD

CONSULTATION SHEET

ZZAEARP, WYATT TEST

XXX-XX-0001

07/04/1948 (Age: 73)

NSC VETERAN

Reason For Request continued.

5. Laboratory investigations:

- Is the patient Diabetic? Yes
- If YES, then the HGB A1C within the last three months of the date of the consultation needs to be less than 8 for intervention.
- Please indicate the VALUE and the DATE of the last HGB A1C:
No data available for: GLYCOHEMOGLOBIN

6. The Interventional Pain Management Clinic requires responses to the following questions regarding various modalities that may have been used in the management of pain in this patient's pain:

- a) Has the patient tried Physical Therapy or exercise within the last year? Yes
- b) Has the patient tried Acetaminophen and/or NSAIDs within the last year? Yes
- c) Has the patient tried Gabapentin and /or Duloxetine if neuropathic pain was suspected? Yes
- d) Has the patient tried the TENS Unit be tried within the last year? Yes
- e) Has the patient tried Cognitive Behavioral Therapy (CBT) or Pain Psychology within the last year? Yes

7. Comments:

*****NOTES*****

ALL FIELDS MUST BE FILLED OUT for the consultation to go through, just like the MRI template. The consultation will not go through if one field is not answered.

REASON FOR REQUEST (STAT CONSULT GUIDANCE):

Pertinent History/Physical/Diagnostic Information:
back pain

Existing Treatment Plan:
none

PROVISIONAL DIAG: Other low back pain(ICD-10-CM M54.59)

REQUESTED BY:	PLACE:	URGENCY:
Chief of Whole Health Service	Consultant's choice	Routine
(Pager:)	SERVICE RENDERED AS:	CLINICALLY IND. DATE:

(Phone: 57878)

|Outpatient

|Dec 15, 2021

MEDICAL RECORD

CONSULTATION SHEET

ZZAEARP, WYATT TEST

XXX-XX-0001

07/04/1948 (Age: 73)

NSC VETERAN
=====

C H A R T C O P Y

No Consultation Results available.

Attachment

6

DEPARTMENT OF VETERANS AFFAIRS

Washington, DC

Report to the

Office of Accountability and Whistleblower Protection

Case Number 15-001 and 15-155

Central Texas Veterans Health Care System

Temple, Texas



Report Date: January 25, 2022

TRIM 2021-C-29

Executive Summary

The Acting Under Secretary for Health directed the Office of the Medical Inspector (OMI) to assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations submitted to the Office of Accountability and Whistleblower Protection (OAWP) concerning the Central Texas Veterans Health Care System (hereafter, Temple) located in Temple, Texas. The two known whistleblowers made allegations related to improper or inadequate care in the Pain Management Section (PMS) of the Whole Health Service (WHS) which may have put Veteran patients' safety at risk. We conducted a site visit to Temple on August 3-5, 2021, with virtual participation by some team members.

Specific Allegations of the Whistleblowers

We combined the two different whistleblower allegations into four categories to facilitate the investigative process.

1. Community Care and Referral management

- a. [REDACTED] Clinical Director of Whole Health, violated the Mission Act by refusing to allow Community Care Referrals for pain management.¹ This includes referrals determined by a physician to be in the best interest of the Veteran and those for improved continuity of care.

2. Opioid Use Disorder treatment

- a. [REDACTED] ordered PMS to become X-waivered by the Drug Enforcement Agency (DEA) and start treating patients with Opioid Use Disorder (OUD) using Suboxone (Buprenorphine + Naloxone).² The Central Texas Veterans Health Care System has a Mental Health/ Substance Abuse Treatment Program that can professionally manage these medical problems and provide psychosocial support.
- b. Dr. Lee is circumventing Standard Operating Procedures (SOP) and professional standards of care for use of Buprenorphine and Suboxone.
- c. [REDACTED] requested a subordinate to delegate prescription of controlled substances to a Nurse Practitioner, Ms. Williamson, who works under his supervision and his orders.

¹ The John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018 was signed into law on June 6, 2018. It requires VA to implement a Veterans Community Care Program to furnish required care and services to covered Veterans through eligible entities and providers: <https://www.regulations.gov/document/VA-2019-VHA-0008-23586>.

² An X waiver refers to the Drug Addiction Treatment Act (DATA2000) "waiver" legislation that authorized the outpatient use of buprenorphine for the treatment of opioid use disorder. Any clinician can administer buprenorphine to a patient with opioid withdrawal symptoms in the hospital, but in order to write prescriptions for buprenorphine, clinicians must have an X-Waiver: <https://penncamp.org/education/what-is-an-x-waiver-and-who-needs-one/>.

- d. *Whole Health is not tracking Buprenorphine as part of the VA's long-term opioids monitoring.*

3. *Pain Management alignment and Resourcing:*

- a. *Aligning Pain Management under Whole Health places Veteran patients at risk.*
- b. [REDACTED] *is planning to diminish Interventional Pain resources and reallocate them to Whole Health.*
- c. [REDACTED] *planned to exchange Pain Management's long-term Registered Nurse (RN) in the pain procedure room by a licensed vocational nurse (LVN).*

4. *Consults and encounters:*

- a. [REDACTED] *is performing self consults outside the VA's clinical screening and treatment procedures.*
- b. [REDACTED] *has been performing encounters without billing or engaging physician utilization.*
- c. [REDACTED] *has implemented centralized control over consults in Whole Health and the Pain Management Team that interferes with Veteran access to physician care.*

We 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. We were unable to substantiate allegations when the available evidence was insufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After a careful review of the evidence, we make the following conclusions and recommendations:

Conclusions for Allegation 1

- We **do not substantiate** the WHS Clinical Director refused to allow community care referrals for pain management.
- We **partially substantiate** that the WHS Clinical Director violated the MISSION Act by refusing to allow community care referrals for pain management based on best medical interest (BMI) criteria. There is confusion regarding multiple interpretations of BMI criteria and instructions given by the WHS Clinical Director regarding BMI approval which are not fully in alignment with MISSION Act.
- There are a large number of consults that are referred to the community (90% of which are new consults).

- The WHS Clinical Director identified concerns regarding community care referrals for pain management lacking comprehensive provision of care as described in the referrals' associated Standardized Episodes of Care (SEOC).
- Temple Memorandum 011-001, *Pain Management and Assessment* dated April 24, 2018, notes the Pain Management Clinic is a resource for interventional pain management modalities, primarily pain management interventions for pain relief only; however, the new draft of the policy (currently in the concurrence process) establishes policy for the assessment and management of Veterans' pain using the stepped-model of pain care in alignment with Veterans Health Administration (VHA) guidelines.
- The draft PMS service agreement lacks collaboration of pain medicine and palliative care teams, as described in VHA Directive 2009-053, *Pain Management's* stepped care model and includes verbiage regarding the MISSION Act for community care referrals that is not inclusive of all criteria; however, it does expand PMS services and discusses collaboration in the provision of pain management in appropriate settings, including primary care and specialty care, in alignment with VHA guidelines regarding the stepped-care model of pain care.
- Large numbers of pain management consults are referred to the community; however, the facility has not thoroughly analyzed the reasons behind the large number or implemented actions to address all causes of the large referral numbers. Additionally, there are many discontinued consults to the community due to the inability to contact the patient.

Recommendations to Temple

1. Consult with VHA Office of Community Care to assist in determining the parameters of BMI criteria to include continuity of care. Once BMI criteria parameters are determined, provide education to all PMS and WHS staff.
2. Monitor 10% of pain management consults referred to the community for 6 months to determine if SEOC guidelines for bundled services such as physical and occupational therapy are followed, if appropriate. Compare with consults within Temple PMS for similar levels of compliance with SEOC guidelines as done for community referrals. Develop actions to address nonconformities.
3. Complete and implement draft Temple MCP 011-001, *Pain Management* to replace the existing policy dated April 24, 2018.
4. Revise the Integrated Pain Management Service Agreement to include collaboration of pain medicine and palliative care teams, as described in VHA Directive 2009-053's stepped care model and address the inaccurate MISSION Act criteria verbiage. Once revised, finalize and implement the service agreement and pain management consult referral template and process as soon as possible.

5. Perform an in-depth analysis of pain management consults referred to the community and develop actions to improve quality, efficiency and if possible, decrease the numbers of consults to the community while maintaining alignment with VHA community care guidelines.
6. Implement a communication plan to proactively inform Veterans receiving pain management care of the possible change in care location (from the community to VA) if their care will be impacted.
7. Review the large number of discontinued pain management consults and develop mitigating strategies to ensure patients receive pain management care.

Conclusions for Allegation 2

- We **substantiate** that the WHS Clinical Director ordered PMS providers to become X-waivered by the DEA and start treating patients with OUD using Suboxone (Buprenorphine and Naloxone); however, he chose not to enforce the providers' getting the X-waiver and none currently have the waiver.
- We **do not substantiate** the WHS Clinical Director is circumventing SOPs and Professional Standards of Care for use of Buprenorphine and Suboxone.
- We **substantiate** the WHS Clinical Director requested a subordinate be the collaborating physician to the WHS Nurse Practitioner (NP), who works under his supervision and his orders; however, the subordinate declined and no further requests were made.
- As a result of not having a collaborating physician with a Texas license, the WHS NP cannot prescribe controlled substances which limits her care of patients in the PMS.
- Memorandum 116A-009, *Buprenorphine/Naloxone Therapy for Opioid Use Disorder*, dated June 25, 2019, does not list the WHS as one of the services affected by the policy related to Buprenorphine/Naloxone therapy for opiate use disorders.
- PMS clinicians failed to manage Veterans with complex pain beyond offering interventional pain management services.
- Veteran 1's case illustrates the potentially serious consequences of opioid tapers and the impact of poorly managed chronic pain.
- Pharmacy clinicians are the central point pain management care for patients with complex pain; however, they have difficulty obtaining opioid prescriptions from providers.
- Although the Integrated Pain Management Service Agreement draft integrates the consultation process for comprehensive, interdisciplinary pain management, it has not yet been approved for publication.

Recommendations to Temple

8. Assign a collaborating physician licensed in Texas to the WHS NP and ensure the WHS NP's privileges are updated to permit prescribing controlled substances once complete.
9. Revise the facility Memorandum 116A-009 and add WHS under "Affected Services" to address Buprenorphine/Naloxone therapy for opiate use disorders.
10. Modify the existing Memorandum or create a new document/SOP that outlines responsibilities for care of patients with complex pain.
11. Expand the PMS scope beyond interventional pain management services and include pain medication management.
12. Provide education to all facility providers regarding the Integrated Pain Management Service Agreement and new consult template once approved.

Conclusions for Allegation 3

- We **do not substantiate** aligning PMS under the WHS places patients at risk. However, the realignment was poorly communicated to sections directly impacted by the decision.
- There are no reporting structure requirements or recommendations in the Executive Decision Memo *Engaging Veterans in Lifelong Health, Well-being and Resilience Integrated Project Team* dated March 4, 2020, thus leaving the reporting structure to the facility's discretion.
- There is a potential risk to patients due to the lack of direct involvement by PMS clinicians in the management of patients with complex pain.
- We **do not substantiate** the WHS Clinical Director plans to reduce PMS resources and reallocate them to the WHS. We found a plan to increase resources including RN and LVN nurse staffing for PMS.
- The PMS clinic is underutilized due to inefficient use of space, clinic appointment length, a focus on interventional procedures, underutilization of the WHS NP and a lack of permanently assigned nursing staff.
- The WHS Clinical Director made plans to change the utilization of space in the Pain Clinic area to accommodate WHS providers which may impact the need for a larger computer monitor to accommodate a provider's vision needs.
- Temple's implementation of the Stepped Care Model of Pain Management is problematic. The primary clinicians involved in managing opioids at Temple are the pain pharmacists who do not have the ability to prescribe controlled substances.

- We found no evidence of interdisciplinary planning or consultation regarding pain management patients, and the focus of both the Pain Management Team (PMT) and Pain Oversight Committee meetings have changed to policy discussions and not patient care discussions.
- Although the components for an interdisciplinary pain management team are present at Temple, there is limited evidence of interdisciplinary team interaction.
- The Comprehensive Addiction and Recovery Act (CARA) mandated PMT charters as written discourages use of PMS physicians except in the event of an interventional pain procedure. Guidance in the charter conflicts from the "Function" section to the "Elements" section.
- The review requested by Temple for a comprehensive review of the PMS by the National Program Office for Pain Management, Opioid Safety, and the Prescription Drug Monitoring Programs has not yet occurred at the time of our investigation.

Recommendations to Temple

13. Implement a change management plan in coordination with the Quality Management Department/High Reliability Organization (HRO) Department for the alignment of PMS under the WHS using HRO implementation activities.
14. Immediately increase PMS involvement in the care of patients with complex pain in modalities other than interventional pain procedures. Audit PMS consults monthly to ensure compliance.
15. Complete resource requests process for PMS. Once additional resources are obtained, analyze clinic grids and pain management flow, ensure appropriate time allocation for procedures, appropriate procedures and maximize productivity of PMS.
16. If the WHS Clinical Director's plan regarding changing the utilization of space in the Pain Clinic area proceeds, such plans must provide for reasonable accommodations such as dual monitors and/or large monitors for staff.
17. Review the WHS NP's assigned duties and adjust to ensure the role is fully utilized to manage PMS patients and provide care within the NP's scope of practice.
18. Fill current vacant PMS clinic slots with appropriate PMS patients as outlined in Step 2 of VHA Directive 2009-053 Pain Management.
19. Review Clinical Practice Guidelines and other VHA evidence-based sources with PMS clinicians to clarify appropriate use of List I and II recommendations in VHA Directive 1137(2) *Provision of Complementary and Integrative Health*, dated May 18, 2017.

20. Implement pain care across the Temple health care system using the Stepped Care Model of Pain Management and provide education to pertinent staff. Ensure best ethics practices described in VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, dated May 13, 2020, are incorporated.
21. Fully comply with VHA PMT Memorandum, VHA Directive 1137(2) and VHA Directive 2009-053 sections identified in this report. Discontinue efforts to develop specific local policies. Until compliance with these national policies are reached, further develop guidelines to comply with national policies based on local need.
22. Appropriately utilize the interdisciplinary PMT in caring for patients with pain conditions as described in both CARA and Temple's charter for this team.
23. Revise the CARA mandated PMT charter to include broadening the scope of services PMS physicians may provide and resolve the conflicting guidance in the "Function" and "Elements" section.
24. Ensure there is an interdisciplinary pain management team.

Recommendation to VHA

1. Complete the external review requested from the National Program Office for Pain Management, Opioid Safety and the Prescription Drug Monitoring Programs as soon as possible.

Conclusions for Allegation 4

- We **do not substantiate** that the WHS Clinical Director is performing self-consults outside the VA's clinical screening and treatment procedures or has been performing encounters without billing or engaging physician utilization.
- We **substantiate** that the WHS Clinical Director ceased the review of patients during the PMT meeting in December 2020 and instead is utilizing this meeting for administrative purposes in violation of the Temple *Charter of the Comprehensive Addiction and Recovery Act Mandated Pain Management Team*, the facility-designated body responsible for coordinating and overseeing pain management therapy for patients experiencing acute and chronic pain (non-cancer related) as required by the CARA Act.
- The use of the consultative visit Current Procedural Terminology (CPT) code 99243 for the PMT meeting is inappropriate.
- The informal weekly meeting outside of the PMT implemented by the WHS Clinical Director has resulted in patient care discussions and decisions regarding patients with pain diagnoses which has not included all members of the PMT, and which have not been documented in the electronic health record (EHR). The lack of presence of the entire PMT interdisciplinary team may have resulted in a less

thorough review of each patient's case. The lack of recording these discussions in the patient's EHR may impact communication related to that patient's plan of care.

Recommendations to Temple

25. Immediately resume the review and oversight of pain management therapy for patients experiencing acute and chronic pain (non-cancer related) during the PMT meeting as described in the Temple *Charter of the Comprehensive Addiction and Recovery Act Mandated Pain Management Team*. The chair of the PMT will ensure the review completed in the PMT meeting is documented in the patients' EHR.
26. Consult with HIMS and determine the appropriate CPT coding for the PMT meeting and what criteria is required of the CPT code.
27. Determine if the weekly informal meeting reviewing patients with pain diagnoses should continue and if so, ensure the discussion and/or relevant information is documented in the patients' EHR.

Summary Statement

We have developed this report in consultation with other VHA and VA offices to address OAWP's concerns that improper or inadequate care in the Temple PMS have put Veteran patients' safety at risk. We reviewed the allegations and determined the merits of each. VHA Human Resources has examined personnel issues to establish accountability, and the National Center for Ethics in Health Care has provided a health care ethics review. We found that leadership have implemented changes in the types of pain management services offered and have attempted to address the large number of pain management consults sent to the community; however, we found no resulting risks to patient safety as a result of the changes. We identified inefficiencies in pain clinic utilization, the lack of health care system wide pain management practices which do not use the Stepped Care Model of Pain Management and weak interdisciplinary PMT processes.

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I. Introduction

The Acting Under Secretary for Health directed the Office of the Medical Inspector (OMI) to assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations submitted to the Office of Accountability and Whistleblower Protection (OAWP) concerning the Central Texas Veterans Health Care System (hereafter, Temple) located in Temple, Texas. The two known whistleblowers made allegations related to improper or inadequate care in the Pain Management Section (PMS) of the Whole Health Service (WHS) which may have put Veteran patients' safety at risk. We conducted a site visit to Temple on August 3-5, 2021, with virtual participation by some team members.

II. Facility Profile

Temple is a complexity level 1a facility serving Veterans in 39 counties in Central Texas.^{3,4} Temple has two medical centers located in Temple and Waco, a stand-alone multispecialty clinic in Austin, five community-based outpatient clinics (CBOC) in Brownwood, Cedar Park, College Station, Palestine and La Grange, and two Vet Centers in Austin and Harker Heights/Killeen. The PMS is aligned under the WHS and offers consultative and interventional pain management services at the Temple and Austin locations. The PMS completed 903 consults in fiscal year (FY) 2020 and 1,044 consults in FY 2021 through August 18, 2021.⁵

III. Specific Allegations of the Whistleblowers

We combined the two different whistleblower allegations into four categories to facilitate the investigative process.

1. Community Care and Referral management:

- d. *Dr. Edward Lee, Clinical Director of Whole Health, violated the Mission Act by refusing to allow Community Care Referrals for pain management.⁶ This includes referrals determined by a physician to be in the best interest of the Veteran and those for improved continuity of care.*

2. Opioid Use Disorder treatment:

³ Complexity 1a facilities have high volume, high risk patients, most complex clinical programs, and large research and teaching programs. VHA Office of Productivity, Efficiency, and Staffing, Facility Complexity Level Model Fact Sheet (2017).

⁴ <https://reports.vssc.med.va.gov/ReportServer/Pages/ReportViewer.aspx?%2fOPES%2fFacilityComplexity%2fVariableData&rs:Command=Render&rc:Parameters=True&FYParam=FY20&StationParam=674>.

⁵ VHA Support Service Center (VSSC) Consult – Patient Details Report: <https://reports.vssc.med.va.gov/ReportServer/Pages/ReportViewer.aspx?/Access/Consults/Consult+-+Patient+Details&rs:Command=Render>.

⁶ The John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018 was signed into law on June 6, 2018. It requires VA to implement a Veterans Community Care Program to furnish required care and services to covered Veterans through eligible entities and providers: <https://www.regulations.gov/document/VA-2019-VHA-0008-23586>.

- a. [REDACTED] ordered PMS to become X-waivered by the Drug Enforcement Agency (DEA) and start treating patients with Opioid Use Disorder (OUD) using Suboxone (Buprenorphine + Naloxone).⁷ The Central Texas Veterans Health Care System has a Mental Health/ Substance Abuse Treatment Program that can professionally manage these medical problems and provide psychosocial support.
- b. [REDACTED] is circumventing Standard Operating Procedures (SOP) and professional standards of care for use of Buprenorphine and Suboxone.
- c. [REDACTED] requested a subordinate to delegate prescription of controlled substances to a Nurse Practitioner, Ms. Williamson, who works under his supervision and his orders.
- d. Whole Health is not tracking Buprenorphine as part of the VA's long-term opioids monitoring.

3. Pain Management alignment and Resourcing:

- a. Aligning Pain Management under Whole Health places Veteran patients at risk.
- b. [REDACTED] is planning to diminish Interventional Pain resources and reallocate them to Whole Health.
- c. [REDACTED] planned to exchange Pain Management's long-term Registered Nurse (RN) in the pain procedure room by a licensed vocational nurse (LVN).

4. Consults and encounters.

- a. [REDACTED] is performing self consults outside the VA's clinical screening and treatment procedures.
- b. [REDACTED] has been performing encounters without billing or engaging physician utilization.
- c. [REDACTED] has implemented centralized control over consults in Whole Health and the Pain Management Team that interferes with Veteran access to physician care.

IV. Conduct of Investigation

The VA team conducting the investigation consisted of the Acting Chief Senior Medical Investigator, a Senior Medical Investigator (on detail to OMI) and two Clinical Program

⁷ An X waiver refers to the Drug Addiction Treatment Act (DATA2000) "waiver" legislation that authorized the outpatient use of buprenorphine for the treatment of opioid use disorder. Any clinician can administer buprenorphine to a patient with opioid withdrawal symptoms in the hospital, but in order to write prescriptions for buprenorphine, clinicians must have an X-Waiver: <https://penncamp.org/education/what-is-an-x-waiver-and-who-needs-one/>.

Managers, all from OMI, the Deputy National Program Director for Pain Management, Opioid Safety, and the Prescription Drug Monitoring Programs (PMOP), the Physician Lead for the Office of Patient Centered Care & Cultural Transformation's (OPCC&CT) Integrative Health Coordinating Center (IHCC), a Health System Specialist from OPCC&CT, the Associate Chief Consultant, Pharmacy Benefits Management, a Clinical Integration Process Management Nurse, Clinical Integration, Veterans Health Administration (VHA) Office of Community Care, and a Human Resources (HR) Consultant, HR Center of Expertise in the Workforce Management and Consulting Office. We reviewed relevant policies, procedures, professional standards, reports, memoranda and other documents listed in Attachment A. We held entrance and exit briefings with Veterans Integrated Service Network (VISN) 17 and facility leadership that included:

- Network Director, VISN 17
- Deputy Network Director, VISN 17
- Chief Medical Officer (CMO) (acting), VISN 17
- Quality Management Officer (QMO), VISN 17
- Deputy QMO, VISN 17
- Health Care System Director
- Chief of Staff (CoS)
- Deputy CoS, Austin
- Associate Director for Patient Care Services (ADPCS)
- Deputy ADPCS
- Assistant Director for Operations, Waco
- Chief, Medical Administration Service
- Chief, Quality, Safety and Value (QSV) (acting)
- Administrative Officer (AO), QSV
- Health Systems Administrator to the Assistant Director
- AO, Patient/Nursing Service

We initially interviewed both whistleblowers on July 28, 2021, and again during the investigation. We also interviewed the following staff:

- CMO, VISN 17 (acting)
- Deputy QMO, VISN 17
- Health Care System Director
- CoS
- WHS Clinical Director
- PMS Chief
- Chief, Care in the Community (CITC)
- Pain Management Physicians (2)
- Chief, Surgical Service (former)/Otolaryngologist
- Associate Chief, Pharmacy
- Assistant Chief, Health Information Management (HIMS)
- Group Practice Manager

- Primary Care Physician
- Section Chief, Veteran Experience
- Nurse Manager, Surgical Specialty Clinics
- Nurse Manager, Surgical Service
- Risk Manager
- Pharmacists (3)
- PMOP Coordinator
- Addiction Therapist
- Nurse Practitioner (NP)
- RNs (4)
- Program Analyst
- LVN
- Advanced Medical Support Assistants (AMSA) (2)

V. Background, Findings, Conclusions and Recommendations

Allegation 1

Community Care and Referral management:

- a. [REDACTED] Clinical Director of Whole Health, violated the Mission Act by refusing to allow Community Care Referrals for pain management. This includes referrals determined by a physician to be in the best interest of the Veteran and those for improved continuity of care.

Background

The Department of Health & Human Services, *Pain Management Best Practices Inter-Agency Task Force Report*, dated May 9, 2019, was completed by the Task Force which was convened by the Department of Health and Human Services in conjunction with the Department of Defense (DoD) and the VA with the Office of National Drug Control Policy to address acute and chronic pain in light of the ongoing opioid crisis. The Task Force mandate is to identify gaps, inconsistencies, and updates and to make recommendations for best practices for managing acute and chronic pain.⁸

Section 2 of the report details clinical best practices and notes in pain management, a critical part of providing comprehensive care is a thorough initial evaluation, including assessment of both the medical and the probable biopsychosocial factors causing or contributing to a pain condition. A second critical step is to develop a treatment plan to address the causes of pain and to manage pain that persists despite treatment. A multimodal approach to pain management consists of using treatments from one or more clinical disciplines incorporated into an overall treatment plan. This plan allows for different approaches to address the pain condition (acute and/or chronic), often enabling a synergistic approach that addresses the different aspects of the pain

⁸ Department of Health & Human Services, *Pain Management Best Practices Inter-Agency Task Force Report*, dated May 9, 2019.

condition, including functionality. Multidisciplinary approaches address different aspects of chronic pain conditions, including biopsychosocial effects of the medical condition on the patient.⁹

The report's section 2.1 details the approach to pain management. It notes that recent clinical practice guidelines developed by the VA and DoD adopt the biopsychosocial model of pain. In this endeavor, they emphasize a collaborative, stepped care model. The biopsychosocial approach is applied clinically across pain experiences, including chronic pain. The development of a treatment plan should be preceded by a history and physical examination that aids in proper diagnosis. When clinically indicated, clinicians should consider an integrative and collaborative approach to care. Specialty interdisciplinary pain medicine team consultation, collaborative care and when indicated, mental health and addiction services should be readily available in the course of treatment of pain to help ensure the best patient outcomes. Acute and chronic pain management consists of 5 treatment approaches informed by 4 critical topics as illustrated below:¹⁰



The VHA Office of Community Care Field Guidebook, dated July 29, 2021, provides guidance for VA staff regarding the processes and tools related to eligibility, referral and care coordination for Veterans receiving community care. The guidebook defines systemic business and clinical processes for facility community care staff as they coordinate Veteran care with community partners. Chapter 2 of the guidebook, *Eligibility, Referral and Scheduling*, states that community care eligibility is based on the guidance set forth by the MISSION Act. It notes that in addition to being eligible for community care based on MISSION Act criteria, the Veteran must also meet specific eligibility criteria to obtain care within the VA. There are 6 community care eligibility criteria established by the MISSION Act:

⁹ Department of Health & Human Services, *Pain Management Best Practices Inter-Agency Task Force Report, Section 2, Clinical Best Practices*, dated May 9, 2019.

¹⁰ Department of Health & Human Services, *Pain Management Best Practices Inter-Agency Task Force Report, Section 2.1, Approaches to Pain Management*, dated May 9, 2019.

- Required care or services are not offered at the facility.
- There is a lack of a full-service medical facility.
- Care or services are not provided within designated access standards.
 - Drive time:
 - 30 minutes: Primary care, mental health care and non-institutional extended care.
 - 60 minutes: Specialty care.
 - Wait time:
 - 20 days: Primary care, mental health care and non-institutional extended care.
 - 28 days: Specialty care.
- Care or services are non-compliant with VA's standards for quality.
- Grandfathered eligibility from the Veterans Choice Program.¹¹
 - Those who received care under the title 38 rule during June 6, 2017, through June 6, 2020.
- Best medical interest (BMI) of the Veteran.¹²

The guidebook states BMI decisions are only to be made by clinical staff members that are part of the patient's care team. Administrative staff are not to make BMI community care eligibility determinations. The BMI criteria is not to be selected based on convenience or preference and the ordering provider must enter medical justification for the eligibility determinations which include nature or simplicity of service, frequency of service, need for an attendant, potential for improved continuity of care and difficulty in traveling.¹³ The potential for improved continuity of care is to be considered when the requested service, if it occurred in VA, would disrupt an established treatment plan with a community provider who delivers stable, consistent care to the Veteran during a specific episode of care (i.e., recent surgery or active chemotherapy).¹⁴

Standardized Episodes of Care (SEOC) is a listing of pre-approved, bundled services and procedures that relate to a specific category of care or sub-specialty and are comprised of a clinical and coding profile. The SEOCs have been developed through collaboration with National Clinical Program Offices across VHA, Veterans Affairs CMOs, CoSs, Office of Clinical Integration leadership and Third-Party Administrators to improve the quality and timeliness of care provided in the community. All referrals will include a consult order accompanied by a single clinically appropriate SEOC that outlines approved visits or services related to a specialty or category of care. Each SEOC defines a specific duration of care. The application of SEOCs greatly reduces the frequency of request for services. By grouping medical services for authorization and

¹¹ The Veterans Choice Program was a benefit that allowed eligible Veterans to receive health care from a community provider rather than waiting for a VA appointment or traveling to a VA facility. The program expired as of June 6, 2019, and was replaced by the Veterans Community Care program (which complies with the MISSION Act).

¹² VHA Office of Community Care Field Guidebook, dated July 29, 2021, Chapter 2, *Eligibility, Referral and Scheduling*: <https://dva.gov.sharepoint.com/sites/VHAOCC/CNM/CI/OCCFGB/SitePages/FGB.aspx>.

¹³ An attendant is any person who provides required aid and/or physical assistance to the Veteran, for a Veteran to travel to a VA medical facility for hospital care or medical services.

¹⁴ Ibid.

payment, the administrative burden on VA staff and community providers is significantly decreased.¹⁵

VHA Directive 2009-053, *Pain Management*, dated October 28, 2009, provides policy and implementation procedures for the improvement of pain management consistent with the VHA strategies and compliant with generally accepted pain management standards of care. It states that VHA employs a stepped-care model of pain care that provides for management of most pain conditions in the primary care setting. This is supported by timely access to secondary consultation from pain medicine, behavioral health, physical medicine and rehabilitation, specialty consultation and care by coordination with palliative care, tertiary care, advanced diagnostic and medical management and rehabilitation services for complex cases. Stepped care is instituted as a strategy to provide a continuum of effective treatment to a population of patients from acute pain caused by injuries or diseases to longitudinal management of chronic pain diseases and disorders that may be expected to persist for more than 90 days, and in some instances, the patient's lifetime. The stepped-care approach includes the following:

1. Step One, Primary Care: Requires the development of a competent primary care provider workforce (including behavioral health) to manage common pain conditions. To accomplish this, primary care requires the availability of system supports, family and patient education programs, collaboration with integrative mental health-primary care teams and post-deployment programs.
2. Step Two, Secondary Consultation: Requires timely access to specialty consultation in pain medicine, physical medicine and rehabilitation; Polytrauma programs and teams and pain psychology; occasional short-term co-management; inpatient pain medicine consultation; and the collaboration of pain medicine and palliative care teams.
3. Step Three, Tertiary and Interdisciplinary Care: Requires advanced pain medicine diagnostics and pain rehabilitation programs accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF).^{16,17}

Findings

The WHS Clinical Director is a physician board certified in internal medicine and addiction medicine. The Temple PMS of WHS is comprised of three pain management physicians, two at the Temple facility (one of whom is the PMS Chief) and one at the Austin CBOC. There is one AMSA assigned. There is also a WHS nurse practitioner (NP) who provides care in the Pain Clinic at the Temple facility one day per week.

Nurse staffing for the PMS is provided by Surgical Service and the Anesthesia Department. In October 2020, the CoS realigned PMS from the Surgical Service to the

¹⁵ VHA Office of Community Care Field Guidebook, dated July 29, 2021, Chapter 3, *How to Perform Care Coordination*: <https://dvagov.sharepoint.com/sites/VHAOCC/CNM/CI/OCCFGB/SitePages/FGB.aspx>.

¹⁶ VHA Directive 2009-053, *Pain Management*, dated October 28, 2009.

¹⁷ CARF provides accreditation services for health and human service providers including rehabilitation for a disability, treatment for addiction and substance abuse, home and community services, retirement living, or other health and human services. CARF assists service providers in improving the quality of their services, demonstrating value, and meeting internationally recognized organizational and program standards: www.carf.org.

WHS. We interviewed the Health Care System Director who stated the decision to move PMS under the WHS was made because the PMS needed better structure and leadership. The CoS reiterated the need for better management of PMS and stated the goal of the realignment of PMS under WHS was the development of a comprehensive pain program and a one-consult process that includes all necessary modalities for pain treatment (i.e., pain procedure, acupuncture, yoga, etc.). The CoS also realigned the Rehabilitation Service under WHS to assist in meeting the intent of this goal.

The Temple Memorandum 011-001, *Pain Management and Assessment* dated April 24, 2018, outlines policy and procedure for the assessment and management of pain in patients within its health care system and to provide direction for the education of staff, patients and families regarding the evaluation and management of pain. The policy states the Pain Management Clinic will serve as a resource for interventional pain management modalities.¹⁸ The PMS providers stated their role has historically been the performance of interventional pain management procedures at Temple and did not involve medication management. Temple Memorandum 011-001 states patients may be referred to another medical center through Non-VA Pain Care Consultation in the following cases:

- If their pain problem requires expertise or treatment that is beyond the scope of the available services at this facility.
- If higher level of expertise is needed for pain management interventions after such have been tried without significant pain relief, whether these unsuccessful interventions were tried locally or elsewhere as reported per the patient's medical history.
- If it is determined that there will be significant delay in the interventional pain management procedure due to the lack of scheduling appointments within a reasonable period.¹⁹

The facility provided us with a draft copy of a revised medical center policy (MCP) Temple MCP 011-001, *Pain Management*, that is in the concurrence process. The MCP establishes policy for the assessment and management of Veterans' pain using a stepped model of pain care and VHA accepted standards of pain care. It notes the responsibilities of the PMS Chief which include, but not limited to, ensure that pain management specialists are delivering the standard of care for pain management set by VHA. These standards also include medication management and interventional approaches, in collaboration with the Pain Management Team and referring providers. Additionally, responsibilities of the Chief of CITC include ensuring compliance with the MISSION Act as it pertains to pain management by establishing a process for surveilling Community Care Network Prescribing of Opioids, to ensure the care provided is appropriate.²⁰

¹⁸ Interventional pain management uses techniques to block pain. Invasive techniques such as nerve blocks, surgery, or implantable drug delivery systems are all types of interventional therapies.

¹⁹ Temple Memorandum 011-001, *Pain Management and Assessment* dated April 24, 2018.

²⁰ Temple MCP 011-001, *Pain Management Draft*.

During interview, PMS staff explained the process for accessing care in their department. Patients are referred to PMS by their Primary Care provider due to pain issues. The PMS providers review the consults to determine the appropriate disposition. If the first available appointment is greater than 28 days or the patient's drive time is greater than 60 minutes, the patient will be referred for CITC. If the patient's drive time is less than 60 minutes and the first available appointment is less than 28 days, the patient will be scheduled for care in the department. All PMS providers stated they have used the BMI criteria for referring patients to the community in the past, but since the department was moved under the WHS in October 2020, they have received instructions from the WHS Clinical Director to cease doing so. The PMS Chief stated that previously patients had been routinely referred to CITC when a consult to PMS included a request from the Primary Care provider to continue care with a community care pain provider with whom care of the patient was already established.

The CoS requested an external review of the PMS's clinical operations to evaluate the large amount of community care referrals. The review was completed in January 2019 by the PMS Chief from a different facility within VISN 17. The findings noted the major factor contributing to the large number of community care consults was inefficiencies in clinic operations i.e., a large number of follow up visits and the types of selected clinical interventions. The results of this review were shared by the CoS with the PMS Chief in February 2019 and the PMS Chief was advised to make efforts to improve the issues noted in the review.²¹

We reviewed numerous emails sent from the WHS Clinical Director to PMS staff regarding referring patients to CITC which included inaccurate guidelines for BMI criteria, not in alignment with the MISSION Act guidelines. On January 22, 2021, the WHS Clinical Director sent an email to the PMS Chief that stated:

"Veterans will only be referred to the community if they qualify on the basis of scheduling and drive time. Continuity of care only applies immediately post-operatively to address complications until they are resolved. Otherwise, you may refer Veterans to the community only after having evaluated them and determined that they require interventions that the VA cannot provide."²²

The WHS Clinical Director requested that the PMS Chief ensure staff were aware of these instructions. The PMS Chief forwarded this email to the other PMS providers and responded to the WHS Clinical Director on the same day and advised him that he also called each PMS provider to ensure understanding of the instructions. In his email response, the PMS Chief expressed his concern that this change in practice may not be in the best interest of Veterans. Additional emails were sent by the WHS Clinical Director in February and March 2021 advising the PMS Chief that consults requesting community care for pain management for "continuity of care" must be scheduled in VHA. The WHS Clinical Director stated that CITC consults must be based on CITC eligibility guidelines; however, some of the instruction he included for BMI criteria were

²¹ Temple External Review of PMS Clinical Operations, dated February 9, 2019.

²² Emails provided by WHS and PMS staff.

not in alignment with the MISSION Act. The following conditions were identified as acceptable for pain management consults to be referred to community care:

- Service not available at this VA.
- Drive Time exceeding 60 minutes and the patient chooses Community Care.
- Wait Time exceeding 28 days and the patient chooses Community Care.
- Continuity of care only in case of a complication produced by the Community Care Pain Provider.
- Cases for Spinal Cord Stimulators or other devices are to be seen at this VA Pain Management Clinic before approval for referral to Community Care Pain Providers for the requested procedure.²³

The VA CITC Pain Management SEOC authorization covers services for 180 days and includes initial outpatient evaluation and treatment for the referred condition indicated on the consult order, relevant diagnostic imaging and studies, labs, injections, procedures, follow-up visits and physical and occupational therapy. The SEOC notes that medication management, including any opioid therapy, should be consistent with VA/DoD clinical practice guidelines.²⁴ When the 180-day period expires, the patient will require a new pain management consult entered by their Primary Care provider. The consult will then be reviewed by PMS providers for disposition. The PMS providers stated that when a consult is entered to renew ongoing pain management treatment and the patient is established with a community care provider, the Primary Care provider will note this on the consult and request to renew the service in the community for "continuity of care."

The PMS providers and the WHS NP stated that patients who have pain management care established with a community care provider have voiced complaints and frustration when their consult for pain management is not renewed in the community. Complaints have also been received from Primary Care providers who have requested that their patient's consult be referred to the community and the patient is instead scheduled in the VA for care. A review of the Patient Advocate Tracking System (PATS) from FY 2020 through August 2021, noted 6 patient complaints regarding PMS, of which 3 were related to not having established care in the community renewed. One patient complaint from June 2021 included the following:

"I have been told the VA will not allow me to continue seeing the Pain Management Specialist I have been seeing for the last 2 years. I am told I MUST start seeing the Pain Management doctor at the VA in Temple now. This is unacceptable. My quality of care will NOT be the same and getting an appointment in a timely manner is something the VA knows nothing about. Who do I need to speak with to get my referral renewed so I can continue treatment at Texas Sport and Spine in Killeen, Texas?"²⁵

²³ Emails provided by WHS and PMS staff.

²⁴ VA Community Care SEOC, *Pain Management Comprehensive 1.2.7*, effective date July 16, 2021: <file:///Z:/Temple/View%20SEOC%20Pain%20Management%20Comprehensive%201.2.7.html>.

²⁵ PATS complaint no. P-674.2021766122-01, dated June 30, 2021.

The WHS Clinical Director, who has been in his role since June 2020, stated that when PMS was moved under WHS in October 2020, PMS was a high outlier on monies spent on community care. The WHS Clinical Director reviewed CITC consults and noted some patients were scheduled monthly appointments for pain medication management only and not for other services included in the SEOC. This concerned him due to the cost of the care being provided. He noted that Primary Care providers were requesting broad pain management services, including requests for pain medication management which PMS providers were not doing at that time. This would then require a referral to the community. The WHS Clinical Director explained for community care pain referrals, the patients who meet the drive time or wait time criteria will be automatically referred to the community, but for other referral criteria, a clinical evaluation is required by the PMS provider before being referred. He stated he spoke to the Chief of CITC to clarify the BMI criteria requirements and was advised that to meet the BMI criteria for referral, the patient would have to have a complication resulting from previous care provided in the community. He stated he followed that interpretation of the guidelines and communicated it to the PMS providers.

In FY 2021, from October 1, 2020, through August 4, 2021, there were 2,620 consults to PMS. Of these, 2,419 (or 92%) were for community care and 201 (or 8%) were accepted for care in-house at Temple. Of the 2,620 referrals to PMS, 1,248 (or 48%) were completed or scheduled, 990 (or 38%) were discontinued and the remainder were active, pending or had partial results. As of July 2021, over the previous 90 days, community wait times for pain management appointments averaged 35 days. As of July 28, 2021, for in-house PMS appointments, the average wait was 49.3 days for new patients and 18.4 days for established patients.²⁶ The AMSA, who is the primary scheduler for PMS, stated once the providers review the consults and approve them, she then schedules the patient as indicated on the consult. The AMSA contacts the patient and offers an appointment date, and if the date is more than 28 days away, she offers the patient the option of community care. If the patient opts in and agrees to community care, the AMSA forwards the consult to CITC for processing. The AMSA estimated that 50% of patients agree to opt into community care and the other 50% choose to receive care with VA.

We randomly reviewed 10 consults referred to the community for pain management services from December 2020 to June 2021 and noted 3 were referred because they met the drive time criteria, 6 met the wait time criteria and 1 was for a service not offered at Temple. We noted a large number of discontinued consults for pain management, with most discontinued due to the patient's failure to respond to scheduling attempts.

We were advised by the WHS Clinical Director that an Integrated Pain Management Service Agreement has been developed but remains in a draft status awaiting concurrence. The draft service agreement states it is in alignment with the VA paradigm shift from simply managing pain to providing a comprehensive pain rehabilitation plan. Objectives of the service agreement include implementing the VHA stepped-care

²⁶ VSSC Clinic Utilization Dashboard.

approach to pain management, involving teaching Veterans self-management skills and providing pain management in all appropriate settings, including primary care and specialty care. The service agreement provides guidance for consulting pain management services in outpatient and inpatient locations but did not include a reference to collaborating with the palliative care team, which is a requirement of the stepped care model. Additionally, the service agreement states that patients will be referred to community care if they meet MISSION Act criteria for drive time and wait time, or if they require a service that is not available at Temple.²⁷ The service agreement does not include an accurate description of BMI criteria and is not fully in alignment with the MISSION Act. The pain management consult referral template which operationalizes the service agreement is also still in draft form awaiting concurrence.²⁸

Conclusions for Allegation 1

- We **do not substantiate** the WHS Clinical Director refused to allow community care referrals for pain management.
- We **partially substantiate** that the WHS Clinical Director violated the MISSION Act by refusing to allow community care referrals for pain management based on BMI criteria. There is confusion regarding multiple interpretation of BMI criteria and instructions given by the WHS Clinical Director regarding BMI approval which are not fully in alignment with MISSION Act.
- There are a large number of consults that are referred to the community (90% of new consults).
- The WHS Clinical Director identified concerns regarding community care referrals for pain management lacking comprehensive provision of care as described in the referrals' associated SEOs.
- Temple Memorandum 011-001, dated April 24, 2018, notes the Pain Management Clinic is a resource for interventional pain management modalities, primarily pain management interventions for pain relief only; however, the new draft of the policy (currently in the concurrence process) establishes policy for the assessment and management of Veterans' pain using the stepped-model of pain care in alignment with VHA guidelines.
- The draft PMS service agreement lacks collaboration of pain medicine and palliative care teams, as described in VHA Directive 2009-053's stepped care model and includes verbiage regarding the MISSION Act for community care referrals that is not inclusive of all criteria; however, it does expand PMS services and discusses collaboration in the provision of pain management in appropriate settings, including primary care and specialty care, in alignment with VHA guidelines regarding the stepped-care model of pain care.

²⁷ Temple Integrated Pain Management Service Agreement Draft.

²⁸ Temple Pain Management Specialty Clinic Consult Template Draft.

- Large numbers of pain management consults are referred to the community; however, the facility has not thoroughly analyzed the reasons behind the large number or implemented actions to address all causes of the large referral numbers. Additionally, there are many discontinued consults to the community due to the inability to contact the patient.

Recommendations to Temple

1. Consult with VHA Office of Community Care to assist in determining the parameters of BMI criteria to include continuity of care. Once BMI criteria parameters are determined, provide education to all PMS and WHS staff.
2. Monitor 10% of pain management consults referred to the community for 6 months to determine if SEOC guidelines for bundled services such as physical and occupational therapy are followed, if appropriate. Compare with consults within Temple PMS for similar levels of compliance with SEOC guidelines as done for community referrals. Develop actions to address nonconformities.
3. Complete and implement draft Temple MCP 011-001 to replace the existing policy dated April 24, 2018.
4. Revise the Integrated Pain Management Service Agreement to include collaboration of pain medicine and palliative care teams, as described in VHA Directive 2009-053's stepped care model and address the inaccurate MISSION Act criteria verbiage. Once revised, finalize, and implement the service agreement and pain management consult referral template and process as soon as possible.
5. Perform an in-depth analysis of pain management consults referred to the community and develop actions to improve quality, efficiency and if possible, decrease the numbers of consults to the community while maintaining alignment with VHA community care guidelines.
6. Implement a communication plan to proactively inform Veterans receiving pain management care of the possible change in care location (from the community to VA), if their care will be impacted.
7. Review the large number of discontinued pain management consults and develop mitigating strategies to ensure patients receive pain management care.

Allegation 2

Opioid Use Disorder treatment:

- a. [REDACTED] ordered PMS to become X-waivered by the DEA and start treating patients with OUD using Suboxone (Buprenorphine + Naloxone). CTVHCS has a Mental Health/ Substance Abuse Treatment Program that can professionally manage these medical problems and provide psychosocial support.

- b. [REDACTED] is circumventing SOPs and Professional Standards of Care for use of Buprenorphine and Suboxone.
- c. [REDACTED] requested a subordinate to delegate prescription of controlled substances to a Nurse Practitioner, Ms. Williamson, who works under his supervision and his orders.

Background

The Substance Abuse and Mental Health Services Administration under the U.S. Department of Health and Human Services provides the following description for Buprenorphine:

Buprenorphine is a medication approved by the Food and Drug Administration (FDA) to treat OUD as a medication-assisted treatment (MAT). As with all medications used in MAT, buprenorphine should be prescribed as part of a comprehensive treatment plan that includes counseling and other behavioral therapies to provide patients with a whole-person approach.

Buprenorphine is an opioid partial agonist. It produces effects such as euphoria or respiratory depression at low to moderate doses. With buprenorphine, however, these effects are weaker than full opioid agonists such as methadone and heroin. Because of buprenorphine's opioid effects, it can be misused, particularly by people who do not have an opioid dependency. Naloxone is added to buprenorphine to decrease the likelihood of diversion and misuse of the combination drug product.²⁹

VHA Notice 2020-30 *Buprenorphine Prescribing for Opioid Use Disorder* dated September 22, 2020, directed VISN and VA medical facilities to increase access and remove barriers to prescribing medications for treatment of OUD in response to the national opioid epidemic. It further states: "Medication for OUD, commonly referred to as medication assisted treatment, reduces the risk of overdose and all-cause mortality and is strongly recommended as first-line treatment by VA/DoD Clinical Practice Guidelines, but it is not universally offered within VHA points of care outside of Substance Use Disorder (SUD) treatment programs." To accomplish the goal, Medical Center Directors were to remove facility prohibitions on OUD therapy outside of SUD settings, to include but not limited to, Primary Care, Mental Health, CBOCs and Specialty Care environments (e.g., Pain Clinics and Emergency Departments). The notice provides multiple strategies to promote high quality, timely OUD treatment. Recommended strategies include but are not limited to:

- a. Reducing caseload expectations for those who provide medical management for OUD;

²⁹ <https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/buprenorphine>
Last Updated: 05/14/2021.

b. VA medical facility Directors fully staffing Primary Care Mental Health Integration Care Management to support implementation of the Collaborative Care model for OUD;

c. Providing incentive special pay for providers who obtain an X-waiver and prescribe buprenorphine to treat OUD; and

d. Reviewing staffing levels and the SUD continuum of care to ensure programming is meeting the current population need.³⁰

The VHA Notice 2020-30 also instructs medical centers to:

Review local operating procedures and remove any modifiable barriers for Veterans to access SUD treatment programs as OUD treatment may require access to a broader continuum of SUD services. Presence of medical illness must not be a barrier to medications for OUD treatment if the medical illness is not identified as a contraindication for treatment. Further, the presence of SUD must not be a barrier to other medical care when clinically indicated. If a provider does not possess the necessary skills to manage all of a patient's clinical needs, the expectation is for timely, collaborative co-management with providers who have the required expertise.³¹

VHA Handbook 1004.01(5), *Informed Consent for Clinical Treatments and Procedures*, dated August 14, 2009, clarifies and updates VHA's national policy on informed consent. It discusses the goals, scope, and key concepts related to patients' informed consent for clinical treatments and procedures and the related responsibilities of VHA staff. An amendment to the handbook on January 4, 2021, removed the requirement for signature informed consent for buprenorphine specific for SUD. Oral informed consent is sufficient for buprenorphine use in SUD treatment.³²

The VA/DoD Clinical Practice Guideline (CPG) for the Management of SUD, dated December 2015, recommends use of Buprenorphine with Naloxone in the screening and treatment of OUD.³³ Similarly, the VA/DoD CPG for Opioid Therapy for Chronic Pain recommends accessing specialized SUD care including medication assisted therapy (MAT).³⁴ The VA toolkit, *Acute Pain Management Meeting the Challenges, A VA Clinician's Guide* states:

MAT for OUD does not exclude a person from receiving treatment for acute pain; however, it is still important to weigh the risks and benefits of pain management strategies. Treatment of acute pain in patients with OUD on MAT should be done in coordination with a pain specialist and MAT prescriber. Care coordination for perioperative pain management for patients on MAT is critical and should include at a minimum the MAT prescriber, anesthesiologist, and the surgeon. The MAT

³⁰ VHA Notice 2020-30, *Buprenorphine Prescribing for Opioid Use Disorder*, dated September 22, 2020.

³¹ Ibid.

³² VHA Handbook 1004.01(5), *Informed Consent for Clinical Treatments and Procedures*, dated August 14, 2009.

³³ <https://www.healthquality.va.gov/guidelines/MH/sud/>.

³⁴ <https://www.healthquality.va.gov/guidelines/Pain/cot/>.

for patients with OUD 1st line: Buprenorphine/Naloxone or Methadone; 2nd line: Intramuscular Naltrexone.³⁵

VHA Handbook 1160.04 *VHA Programs for Veterans with SUD* dated March 7, 2012, states:

SUD specialty programs are designated inpatient, residential, and outpatient programs specifically designed to meet the needs of Veterans with SUD, particularly those Veterans with new onset, severe, or complex conditions (e.g., mental health and general medical co-morbidities). These programs provide a continuum of care from intensive inpatient and residential services to outpatient care. To enhance accessibility to specialized services and reduce stigma, efforts are made to provide services within other settings, such as primary care, CBOCs, PTSD clinics and residential settings without designated SUD bed sections. The SUD specialty programs must provide comprehensive services; for example, for Veterans with concurrent PTSD and SUD, services must be provided either within the SUD program or in close coordination with PTSD program staff with SUD treatment expertise.³⁶

VHA Handbook 1160.04 describes SUD outpatient treatment:

SUD Treatment Outpatient Clinics provide settings for initial and continuing outpatient care to patients with SUD other than those engaged in opioid agonist treatment in a regulated opioid treatment program. Treatment is designed to provide the full-range of clinically indicated treatment and rehabilitation services for patients with SUD, including ambulatory withdrawal management; treatment of the psychological and behavioral aspects of addiction with evidence-based addiction-focused pharmacotherapy and psychosocial interventions; and recovery-oriented services, including vocational rehabilitation services and other skills training needed to initiate and sustain SUD recovery.³⁷

Predating VHA Notice 2020-30, Temple Memorandum 116A-009 *Buprenorphine/Naloxone Therapy for Opioid Use Disorder*, dated June 25, 2019, outlines the procedures for OUD treatment. It requires Veterans receiving Buprenorphine with Naloxone (brand name *Suboxone*) treatment to also be enrolled in substance abuse treatment, the type of service based on individual assessment. The policy states:

"X-DEA is a Drug Enforcement Administration issued Waiver specifically and solely for the purpose of prescription of suboxone for opiate addiction as per the opinion of the treating psychiatrist. The DEA has clearly stipulated that attempts to utilize the X-DEA for purposes other than opiate addiction is deemed as

³⁵ VA Clinician's Guide, *Acute Pain Management Meeting the Challenges*, dated July 2017: https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/Pain_Provider_AcutePainProviderEducationalGuide_IB10998.pdf

³⁶ VHA Handbook 1160.04, *VHA Programs for Veterans with SUD*, dated March 7, 2012.

³⁷ *Ibid.*

"professional misconduct." According to the Drug Enforcement Administration the X-Waiver is unnecessary for other indications and any physician with a general DEA can write for buprenorphine (or off label use of suboxone) for pain."³⁸

Temple facility Memorandum 116A-009 also describes patient selection but lacks any discussion about treatment for complex pain and concomitant OUD except to say: "Given the high medical comorbidity in this patient population, it is strongly recommended that the patient follows up with her/his assigned Primary Care Provider (PCP). The patient will agree to go to Patient Aligned Care Team if needed for the general medical issues."³⁹

According to the Nursing Practice Act, Nursing Peer Review & Nurse Licensure Compact as prescribed in the Texas Occupations Code (as amended September 2019):

"In this section, "advanced practice registered nurse" means a registered nurse licensed by the board to practice as an advanced practice registered nurse on the basis of completion of an advanced educational program. The term includes a nurse practitioner, nurse midwife, nurse anesthetist and clinical nurse specialist. The term is synonymous with "advanced nurse practitioner" and "advanced practice nurse."

(b) The board shall adopt rules to:

(1) license a registered nurse as an advanced practice registered nurse;

(2) establish:

(A) any specialized education or training, including pharmacology, that an advanced practice registered nurse must have to prescribe or order a drug or device as delegated by a physician under Section 157.0512 or 157.054;

(B) a system for approving an advanced practice registered nurse to prescribe or order a drug or device as delegated by a physician under Section 157.0512 or 157.054 on the receipt of evidence of completing the specialized education and training requirement under Paragraph (A); and

(C) a system for issuing a prescription authorization number to an advanced practice registered nurse approved under Paragraph (B); and

³⁸ Temple Memorandum 116A-009, Buprenorphine/Naloxone Therapy for Opioid Use Disorder, dated June 25, 2019.

³⁹ Ibid.

(3) concurrently renew any license or approval granted to an advanced practice registered nurse under this subsection and a license renewed by the advanced practice registered nurse under Section 301.301.⁴⁰

Texas Occupations Code Section 157.0512. Prescriptive Authority Agreement states: "A physician may delegate to an advanced practice registered nurse or physician assistant, acting under adequate physician supervision, the act of prescribing or ordering a drug or device as authorized through a prescriptive authority agreement between the physician and the advanced practice registered nurse or physician assistant, as applicable."⁴¹

Findings

We reviewed the Temple Pain Management Oversight Committee minutes for December 3, 2020, where OUD treatment was discussed, including the use of Buprenorphine for both pain and OUD. The committee discussed requiring primary care providers to take "...the buprenorphine training course for the treatment of OUD in support of the SCOUTT⁴² initiative." This was supported by the PMS Chief.⁴³ We also reviewed an email dated February 3, 2021, in which the PMS Chief states: "Pain management at the CTVHCS is moving towards treating patients with medications (opioids) besides the interventional pain management procedures that we usually do. Surely, opioids will be prescribed only if indicated. Once we determine that the patient is stable enough, we may discharge the patient to the care of the PCP with a set of recommendations. [REDACTED] is working to streamline this process with Pain Management Pharmacy and with Primary Care in a comprehensive pain service agreement." In this same email, the PMS Chief states: "For this purpose, I encourage all of us to take the MOUD Classes.⁴⁴ Please register by speaking with [REDACTED]." A hyperlink to the X-waiver training registration site was included. Three training requirements were listed in the email along with "MOUD training" with a completion date of June 30, 2021. All PMS clinicians and the VHS Clinical Director were included on the email.⁴⁵

Temple's pay for performance documents for PMS clinicians for FY 2021 included: "Obtain X-waiver and manage 5 patients with concurrent chronic pain and complex persistent opioid dependence using appropriate medications."⁴⁶ This requirement was endorsed by the CoS in an email dated February 19, 2021:

⁴⁰ Nursing Practice Act, Nursing Peer Review & Nurse Licensure Compact, Texas Board of Nursing https://www.bon.texas.gov/laws_and_rules_nursing_practice_act.asp.

⁴¹ Texas Occupations Code Section <https://statutes.capitol.texas.gov/?link=OC>.

⁴² Stepped Care for Opioid Use Disorder Train the Trainer (SCOUTT). SCOUTT is an initiative by VHA to promote medication treatment for OUD. The SCOUTT Initiative's primary goal is to increase MOUD prescribing in VHA primary care, mental health and pain clinics by training providers working in those settings on how to provide MOUD and to facilitate implementation by providing an ongoing learning collaborative.

⁴³ Temple Pain Management Oversight Committee minutes, December 3, 2020.

⁴⁴ Medications for Opioid Use Disorder (MOUD). MOUD is an approach to opioid use treatment that combines the use of FDA-approved drugs with counseling and behavioral therapies for people diagnosed with opioid use disorder.

⁴⁵ Emails provided by staff.

⁴⁶ Pay for performance documents for PMS clinicians for FY 2021.

As discussed previously, I met a couple of weeks ago with the pain section. These are the final 3 agreements:

- 1. They must complete the X-Waiver as directed.*
- 2. I will pause implementation of the buprenorphine therapy program until we meet again.*
- 3. We will have an External Speaker come talk to us, to include Primary Care. After the talk, will discuss options for organization. Specifically look at successful programs in the VA; perhaps North Florida or elsewhere.*

I also insisted that Performance Pay and OPPE are legitimate avenues to address expectations and drive organizational priorities.⁴⁷

The addition of the performance measure to obtain the X-waiver and treat 5 Veterans is consistent with guidance provided in VHA Notice 2020-30. We were also provided evidence that two PMS physicians and an NP assigned to WHS completed the training by July 2021 but did not obtain the X-waiver.

The WHS Clinical Director stated that PMS clinicians were directed to complete 8 hours of DEA X-waiver training and included this as one PMS clinician's performance measure. The WHS Clinical Director indicated adding the DEA X-waiver requirement to the PMS clinician's performance expectations was an attempt to help solve the prescribing gap for Buprenorphine at Temple. The element was subsequently removed and is not currently a performance measure in the document following further discussions with the PMS providers and the CoS.

VHA Notice 2020-30 by direction of the Under Secretary for Health, instructed facilities to increase access to and remove barriers to prescribing medications for the treatment of OUD. The notice specifically includes "pain clinics" as a potential treatment area for OUD.⁴⁸ Temple is third from last across VA 1a complexity facilities for unique patients on Suboxone as percent of all patients on all drugs.⁴⁹ Temple's Mental Health/Substance Abuse treatment program has 14 clinicians assigned and has cared for 1,420 unique Veterans as of August 2021.⁵⁰ The Mental Health/Substance Abuse treatment program reports to the Deputy CoS according to the organization chart. Staff stated that Temple's Primary Care and Mental Health clinicians are unwilling to take responsibility for prescribing opioids or managing OUD for their patients, creating a care delivery vacuum that is supported by the low number of clinicians in the Buprenorphine directory. Temple's Buprenorphine directory indicates there are 32 clinicians (13 psychiatrists) with the DEA X-waiver. Five of the eight SUD psychiatrists have the DEA-X-waiver. Only one PMS physician has the waiver and only 7.2% of Temple's providers

⁴⁷ Emails provided by staff.

⁴⁸ Ibid.

⁴⁹ Source: CDW VHAPBHSQLANA.

⁵⁰ VSSC Provider Bookability Dashboard for SUD and Clinic Stops and Persons reports as of August 11, 2021.

are DEA X-waivered, lower than the National VA average of 9.6% for similar sized facilities.⁵¹

Temple has three pain clinical pharmacy specialists (all with Doctor of Pharmacy credentials) who are actively engaged in medication management of Veterans on chronic opioids. However, these clinicians cannot prescribe controlled substances (including Buprenorphine with Naloxone) and stated they are not supported by PMS and Primary Care providers (who can prescribe controlled substances) when attempting to provide medication support for opioids.

Our review of facility Memorandum 116A-009 noted it does not list the WHS as one of the services affected by the policy related to Buprenorphine/Naloxone therapy for opiate use disorders. At the time of the Memorandum's publication, PMS was under Surgical Service and was moved to the WHS in October 2020. Of note, Surgical Service is also not listed as affected by the policy.

We found no evidence the WHS Clinical Director is violating professional standards of care related to Buprenorphine and Suboxone.

The VHA Stratification Tool for Opioid Risk Mitigation (STORM) report is a family of decision support tools to support safe care of patients exposed to opioids and predicts risk of overdose or suicide-related health care events or death.⁵² The STORM report includes predictive analytics for risk stratification, flexible population management, summary information on risk mitigation implementation for targeting quality improvement and education, recommendation and tracking of risk mitigation and patient-level care review. We reviewed the STORM report for Temple and found, as of October 6, 2021, 390 Veterans identified as needing MOUD; 254 (or 65%) of these had not received an MOUD prescription in the last 90 days. Five of these Veterans were in the "Very High" risk group and had active VA provided opioid prescriptions but no MOUD treatment. The SharePoint site includes the following statement: "Warning: Discontinuing opioids does not necessarily reduce your patients' risk and may actually increase their risk. Always discontinue opioids with caution and clinical support." Because of this concern we requested all incidents from FY 2020 and FY 2021 of suicide attempts/completions with reference to pain in the description. Interviewees also expressed concern about abrupt discontinuation of opioids without proper care including MAT. We reviewed each of the 19 Veteran's charts from multiple services and found none related to pain consultation or lack of pain care services.

We did not assess the SUD program directly, and make no comments related to that service. The clinical elements described in VHA Handbook 1160.04 are present at Temple, but we found no consistent method for documenting interdisciplinary discussions and interventions. The VA/DoD CPG for SUD recommends pharmacotherapy including office-based Buprenorphine with addiction-focused medical

⁵¹ Directory of Buprenorphine Prescribers for Opioid Addition Treatment (OAT):

https://vaww.pbi.cdw.va.gov/PBIRS/Pages/ReportViewer.aspx?RVS/OMHSP_PERC/SSRS/Production/CDS/BuprenorphineDirectory.

⁵² https://dvagov.sharepoint.com/sites/VHAPERC/Reports/SitePages/STORM_home.aspx.

management and group mutual help such as peer or network support. The VA/DoD CPG for opioid therapy for chronic pain also describes the need for an interdisciplinary team addressing pain, SUD and mental health problems along with MAT for OUD. If opioid tapering is attempted, the CPG recommends opioid tapering supported by interdisciplinary services such as mental health, SUD, primary care and specialty pain care. CPG also recommends additional psychological therapies for reducing pain such as cognitive behavioral interventions, biofeedback, exercise treatments (e.g., aerobic exercise and physical therapy) and psychosocial rehabilitation.

We reviewed the current PMS consult template which includes the statement, "Does the patient understand that the Interventional Pain Clinic offers procedures for the management of chronic pain and does not prescribe chronic controlled substances in the management of chronic pain?"⁵³ There is a draft version of a new consult template which includes management of medications, consultation with an interdisciplinary team and eventual handoff of care back to the Primary Care provider once stabilized, but is still while awaiting concurrence.⁵⁴ This draft consult template version is more consistent with VHA Notice 2020-30 and other guidance.

We reviewed a Veteran's record (hereafter Veteran 1, provided by an interviewee, concerning OUD and pain management. Veteran 1 had multiple comorbidities and long-standing chronic pain treated with opioids. He saw a PMS clinician on June 3, 2020, who recommended interventional pain procedures once COVID-19 restrictions were lifted (COVID-19 restrictions limited the in-person visits to the PMS clinic). Additionally, the PMS clinician indicated there was discussion about chiropractic care, acupuncture and physical therapy which Veteran 1 declined. No other notes or evidence of intervention were found by PMS after this date. There are several notes in the record from different clinicians indicating Veteran 1 requested medication refills for opioids, and a consult to pharmacy pain management to assist with opioid taper. Veteran 1 had a virtual visit with the pharmacist on January 21, 2021, to discuss his treatment plan. On May 14, 2021, a consult was placed to the pharmacy pain management clinician to assist with initiation of Buprenorphine. The pharmacist completed this consult on May 24, 2021, and sent the recommendation to the Primary Care physician on the same day.

On June 4, 2021, Veteran 1 contacted the Primary Care clinician by secure messaging to request a refill on hydrocodone which was refilled on June 7, 2021. On June 22, 2021, the Primary Care physician had a telephone contact with Veteran 1 describing his condition as being in persistent pain and reporting his pain medications did not work. Veteran 1 also indicated he had difficulty getting in and out of his house and shower and was afraid of falling. The Primary Care physician entered a consult for occupational therapy to complete a home safety evaluation but continued the patient on his current pain and other medications. The Primary Care physician also consulted pharmacy pain management for alpha stimulation.⁵⁵

⁵³ PMS Consult template, current version.

⁵⁴ PMS Consult template, draft version.

⁵⁵ An electrotherapy device used to treat pain.

The occupational therapist completed a home visit to assess Veteran 1's home on June 28, 2021. During that visit, Veteran 1 expressed suicidal ideations directly linked to his inability to control his pain: "The pt reports that he has a lot of pain that limits his ADLs. At one point he spoke about his thoughts of "ending it" during these times when his wife is away from the home." The occupational therapist contacted the Primary Care physician immediately by email on June 28, 2021, and then contacted the RN assigned to the patient's Primary Care team on July 30, 2021. The RN contacted mental health who then made direct contact with Veteran 1 on July 30, 2021, and assessed an intermediate acute risk for suicide. We did not see a note by the Primary Care physician related to this June 28, 2021, email.

On August 2, 2021, the mental health clinic was unable to reach Veteran 1 to schedule an appointment; however, Veteran 1 contacted his Primary Care physician on the same day requesting a refill of hydrocodone.⁵⁶ The Primary Care physician consulted pharmacy pain management who contacted Veteran 1 on August 4, 2021. The pharmacist noted "worsening pain with opioid taper off hydrocodone/APAP. Recommend switch to Butrans. No taper required."⁵⁷ It is not clear when the taper started. The Primary Care physician wrote a prescription for Buprenorphine on August 4, 2021. On August 6, 2021, Veteran 1 was seen by the pharmacist for a trial of an alpha stimulator for pain control. On August 10, 2021, Veteran 1 was seen in the mental health clinic and the suicide prevention note indicated Veteran 1 started Buprenorphine with Naloxone and was much improved, both physically and mentally, since starting the medication.

It was evident in the care of the Veteran that different disciplines were working with the Veteran; however, it is not apparent it was an interdisciplinary team management approach. A Buprenorphine prescription was not entered until August 4, 2021, after a potential crisis. The PMS recommended interventions and other adjunct therapies for over a year prior to this event but did not complete any consults or provide interventional therapy.

The VHA considers an NP a licensed independent provider; however, depending on the state of licensure, the NP's role may have other considerations. The WHS NP is licensed in Texas and state law requires a collaborating physician to prescribe controlled substances. The WHS NP did complete DEA X-waiver training but could not get the X-waiver as there was no collaborating physician. The WHS Clinical Director did request a subordinate provider be the collaborating physician for the NP, but the subordinate physician declined. The reason for the request was the WHS Clinical Director is not currently licensed in Texas and could not serve as the collaborating physician. As a result, the WHS NP is not currently prescribing controlled substances.

There is no requirement to track Buprenorphine separately in the Opioid Safety Initiative (OSI). VHA Notice 2020-30 does state: "The ADS (Academic Detailing Service)⁵⁸ has

⁵⁶ Hydrocodone is an opioid medication used to treat moderate or severe pain.

⁵⁷ Butrans is a Buprenorphine transdermal patch.

⁵⁸ ADS is a component of the Pharmacy Benefits Management Service
<https://www.pbm.va.gov/PBM/academicdetailingservicehome.asp>.

developed multiple tools to assist VA medical facilities with identifying X-waivered providers and managing patients receiving buprenorphine from VA.⁵⁹ The General Data Tools Page on the ADS site tracks Veterans in treatment for SUD, and includes OUD monitoring, but is not specific to Buprenorphine monitoring.⁶⁰ Although there is no requirement to track Buprenorphine, Temple pharmacy tracks this medication as a schedule 3 narcotic.

Conclusions for Allegation 2

- We **substantiate** that the WHS Clinical Director ordered PMS providers to become X-waivered by the DEA and start treating patients with OUD using Suboxone (Buprenorphine and Naloxone); however, he chose not to enforce the providers' getting the X-waiver and none currently have the waiver.
- We **do not substantiate** the WHS Clinical Director is circumventing SOPs and Professional Standards of Care for use of Buprenorphine and Suboxone.
- We **substantiate** the WHS Clinical Director requested a subordinate be the collaborating physician to the WHS NP, who works under his supervision and his orders; however, the subordinate declined and no further requests were made.
- As a result of not having a collaborating physician with a Texas license, the WHS NP cannot prescribe controlled substances which limits her care of patients in the PMS.
- Memorandum 116A-009 does not list the WHS as one of the services affected by the policy related to Buprenorphine/Naloxone therapy for OUD.
- PMS clinicians failed to manage Veterans with complex pain beyond offering interventional pain management services.
- Veteran 1's case illustrates the potentially serious consequences of opioid tapers and the impact of poorly managed chronic pain.
- Pharmacy clinicians are the central point of pain management care for patients with complex pain; however, they have difficulty obtaining opioid prescriptions from providers.
- Although the Integrated Pain Management Service Agreement draft integrates the consultation process for comprehensive, interdisciplinary pain management, it has not yet been approved for publication.

⁵⁹ <https://dva.gov.sharepoint.com/sites/vhaacademicdetailing/SitePages/Data-Resources.aspx>.

⁶⁰ *ibid.*

Recommendations to Temple

8. Assign a collaborating physician licensed in Texas to the WHS NP and ensure the WHS NP's privileges are updated to permit prescribing controlled substances once complete.
9. Revise the facility Memorandum 116A-009 and add WHS under "Affected Services" to address Buprenorphine/Naloxone therapy for opiate use disorders.
10. Modify the existing Memorandum or create a new document/SOP that outlines responsibilities for care of patients with complex pain.
11. Expand the PMS scope beyond interventional pain management services and include pain medication management.
12. Provide education to all facility providers regarding the Integrated Pain Management Service Agreement and new consult template once approved.

Allegation 3

Pain Management Alignment and Resourcing:

- a. *Aligning Pain Management under Whole Health places Veteran patients at risk.*
- b. [REDACTED] *is planning to diminish Interventional Pain resources and reallocate them to Whole Health.*
- c. [REDACTED] *planned to exchange Pain Management's long-term RN in the pain procedure room by an LVN.*

Background

Deputy Under Secretary for Health Operations and Management Executive Decision Memorandum *Engaging Veterans in Lifelong Health, Well-Being and Resilience Integrated Project Team* dated March 4, 2020, addresses the integration of the Whole Health approach to care delivery into Primary Care and Mental Health encounters. It does not address reporting structure but does indicate expansion of the Whole Health program would require ongoing evaluation of resources required to integrate WH clinical care into Primary Care and Mental Health. Specifically, it does not require placement of Whole Health organizationally under/with either Primary Care or Mental Health.⁶¹

VHA Directive 1137(2), *Provision of Complementary and Integrative Health*, dated May 18, 2017, states:

VA practitioners proactively offer and include, as appropriate (based on the individual clinical facts of each patient), any of the Complementary and

⁶¹ Deputy Under Secretary for Health Operations and Management Executive Decision Memorandum *Engaging Veterans in Lifelong Health, Well-Being and Resilience Integrated Project Team* dated March 4, 2020.

Integrative Health (CIH) approaches identified in the electronic lists described in paragraph 6, and to effectively integrate their delivery with Veterans' receipt of conventional care. It is VHA policy that CIH is not to be used as an alternative to conventional medicine; it must only be used to complement conventional medicine. VA practitioners are not to offer a CIH approach that is not on one of the two lists described in paragraph 6, below.⁶²

Paragraph 6 of VHA Directive 1137(2) includes the following clinical caveats and descriptions:

List I. Subject to the clinical caveats 1 and 2 below, and given the level of evidence, this list of CIH approaches must be made available to Veterans across the system, either within a VA medical facility or in the community.

(1) Clinical Caveat 1: Adequate evidence exists to support the use of the above subject practices together with conventional care, reflecting current opinion and practice in the medical community. This listing serves, however, as only guidance: whether any of these CIH approaches is in fact appropriate for a particular Veteran patient must still be determined by the practitioner (together with the responsible treating provider if the practitioner is not also that) in the exercise of their joint clinical judgment (accounting for the patient's individual clinical factors). Where there is no consensus between them, practitioners will defer to the opinion of the responsible treating provider (who will take into consideration the Veteran's preference, if known, and any contraindications to treatment).

(2) Clinical Caveat 2: Because identification of CIH approaches for use in Veterans' personalized health plans is fluid and dynamic with some evolving into conventional care modalities over time and the potential for some later being pulled from practice, VHA practitioners need to consult VHA's Intranet SharePoint site before delivering a CIH approach, to verify theirs is still on either List I or List II. These listings will be up-to-date and should be relied on over the listings below, which must await formal policy revisions to be updated.

List II. Optional CIH approaches. Subject to Clinical caveats 1 and 2, stated above, in addition to the approaches identified in paragraph (1), the Under Secretary for Health, acting through the IHCC under OPCC&CT, sanctions the optional use of the CIH approaches on this list because they are generally considered, by those in the medical community, to be safe when delivered as intended by an appropriate VHA practitioner or instructor, and may be made available to enrolled Veterans, within the limits of VA medical facilities.⁶³

The SharePoint site provides the following on List I: Acupuncture, Battlefield Acupuncture and Battlefield Auricular Acupressure, Biofeedback, Clinical Hypnosis,

⁶² VHA Directive 1137(2), *Provision of Complementary and Integrative Health*, dated May 18, 2017.

⁶³ *Ibid*.

Guided Imagery, Massage Therapy (including Acupressure), Meditation, Tai Chi/ Qi Gong, Yoga, Chiropractic Care. List II includes: Aromatherapy, Healing Touch and Reiki. List II CIH approaches do not have the level of evidence to require or mandate use in facilities.⁶⁴

The VHA Pain Management home page outlines VA's efforts to transforming VA Pain Care:

The Six Essentials Elements of Good Pain Care:

1. Educate Veterans/families to promote self-efficacy and shared decision making; provide access to all relevant resources.
2. Educate/train all team members to their discipline specific competencies, including team-based care.
3. Develop and integrate non-pharmacological modalities into care plans
4. Institute evidence-based medication prescribing, use of pain procedures and safe opioid use (universal precautions)
5. Implement approaches for bringing the Veteran's whole team together such as virtual pain consulting (SCAN-ECHO, e-consults, tele-health, clinical video tele-consultation and education) and for maintaining ongoing communication between team members.
6. Establish metrics to monitor pain care and outcomes at both the individual level and the population level.⁶⁵

The Department of Health & Human Services, *Pain Management Best Practices Inter-Agency Task Force Report, Section 2.6, Complimentary and Integrative Health*, dated May 9, 2019, states clinical best practices may recommend a collaborative, multimodal, multidisciplinary, patient-centered approach to treatment for various acute and chronic pain conditions to achieve optimal patient outcomes. For improved functionality, activities of daily living and quality of life, clinicians are encouraged to consider and prioritize, when clinically indicated, nonpharmacologic approaches to pain management. Complementary and integrative health approaches for the treatment or management of pain conditions consist of a variety of interventions, including mind-body behavioral interventions, acupuncture and massage, osteopathic and chiropractic manipulation, meditative movement therapies (e.g., yoga, tai chi) and natural products. It notes that the National Institutes of Health National Center for CIH defines "complementary approaches" as those nonmainstream practices that are used together with traditional medicine; it defines "alternative approaches" as those used in place of conventional medicine, noting that most patients who use nonmainstream approaches do so with conventional treatments. There are many definitions of "integrative" health care, but all involve bringing together conventional, complementary and integrative health approaches in a coordinated way.⁶⁶

⁶⁴ <https://dva.gov.sharepoint.com/sites/VHAOPCC/IHCC/SitePages/Home.aspx>

⁶⁵ <https://www.va.gov/painmanagement/>.

⁶⁶ Department of Health & Human Services, *Pain Management Best Practices Inter-Agency Task Force Report, Section 2.6, Complimentary and Integrative Health*, dated May 9, 2019.

The May 18, 2017, VHA Pain Management Team (PMT) Memorandum (VIEWS 7791174) provided guidance on implementation of PMTs including the function of the PMTs and their mandated composition in its Appendix A:

National Leadership Council (NLC) guidance on the requirements for a pain management team (PMT):

Interdisciplinary Pain Management Team will provide the following:

- Evaluation and when needed, follow-up for patients with complex pain conditions.
- Pain consultation for medication management, and when needed option for actual prescribing of pain medication for patients requiring close follow up for medication adjustments.
- Review of patients with high-risk opioid prescriptions with provision of recommendations (OSI Team).

Composition of the Pain Team will include:

- Medical provider with pain expertise.
- Addiction medicine expertise to provide evaluation for Opioid Use Disorder (OUD) and access to Medication Assisted Treatment (MAT).
- Behavioral medicine with availability of at least one evidence-based therapy at Medical Center.

Additionally, NLC recommends the following key elements of successful pain management programs to consider as resources when implementing a PMT:

- Availability of e-consultation.
- Availability of immediate consultation for assistance with prescriptions.
- Pain consultation by Telehealth.
- Inclusion of Complementary and Integrative Medicine (CIM) on Pain Team.
- A 0.25 full time equivalent Primary Care Pain Champion.
- Interventional Pain Care.
- Inpatient pain consultation (higher complexity VAMCs).
- Interdisciplinary pain management case review forum.⁶⁷

The American Board of Pain Medicine provides the following definition:

The specialty of Pain Medicine, or Algiatry, is a discipline within the field of medicine that is concerned with the prevention of pain, and the evaluation,

⁶⁷ VHA Pain Management Team Memorandum (PMT) Memorandum (VIEWS 7791174), dated May 18, 2017.

treatment and rehabilitation of persons in pain. Some conditions may have pain and associated symptoms arising from a discrete cause, such as postoperative pain or pain associated with a malignancy or may be conditions in which pain constitutes the primary problem, such as neuropathic pains or headaches.

Pain Medicine Specialists use a broad-based approach to treat all pain disorders, ranging from pain as a symptom of disease to pain as the primary disease. The pain physician serves as a consultant to other physicians but is often the principal treating physician (as distinguished from the primary care physician) and may provide care at various levels, such as treating the patient directly, prescribing medication, prescribing rehabilitative services, performing pain relieving procedures, counseling patients and families, directing a multidisciplinary team, coordinating care with other health care providers and providing consultative services to public and private agencies pursuant to optimal health care delivery to the patient suffering from pain. The objective of the pain physician is to provide quality care to the patient suffering from pain. The pain physician may work in a variety of settings and is competent to treat the entire range of pain encountered in delivery of quality health care.

Pain Medicine specialists typically formulate comprehensive treatment plans, which consider the patients' cultural contexts, as well as the special needs of the pediatric and geriatric populations. Evaluation techniques include interpretation of historical data; review of previous laboratory, imaging, and electrodiagnostic studies; assessment of behavioral, social, occupational, and avocational issues; and interview and examination of the patient by the pain specialist.⁶⁸

VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, dated May 13, 2020, establishes policy requiring patient education and signature informed consent for long-term opioid therapy for pain, and policy prohibiting the use of opioid pain care agreements (OPCA).⁶⁹ It states to ensure safe, patient-centered care, practitioners prescribing long-term opioid therapy for pain must educate patients about the risks, benefits, and alternatives to long-term opioid therapy and engage them in a discussion about a proposed long-term opioid therapy management plan. The directive notes in the past, a number of VA opioid prescribers and VA medical facilities used locally created OPCAs, also known as "pain contracts", to document discussions with patients regarding long-term opioid therapy. The OPCAs are based on an adversarial rather than therapeutic model, and their use of threatening language has the potential to undermine patient-provider trust. Prior to initiating long-term opioid therapy for pain, VHA opioid prescribers must engage Veterans (or surrogate decision maker) in an informed consent discussion, including providing patient education materials, to ensure that the Veteran (or surrogate) understands the risks, benefits, and alternatives to the

⁶⁸ <http://www.abpm.org/what>.

⁶⁹ Long-term opioid therapy for pain is the medically indicated use of opioids on a daily or intermittent basis for 90 or more calendar days to treat non-cancer pain.

treatment and must obtain signature informed consent from the Veteran (or surrogate).⁷⁰

While VHA has been adopting High Reliability Organization (HRO) practices since the 1990s, the commitment to HRO was formalized in February 2019 with targeted improvements necessary to translate passion and commitment into outcomes. Creating a change management plan that is tied to the overarching organizational strategy and the HRO implementation plan will increase the probability of success on VHA's Journey to High Reliability, providing strategies for driving and sustaining change. Change management involves both an individual and an organizational perspective. It requires action and involvement by leaders and managers throughout the organization and is most effective when launched at the beginning of an initiative or project and is integrated into all initiative-related activities. The focus of change management is helping individuals make their transition through the change process. Change management drives project success by supporting individual transitions required by organizational projects and initiatives. The change management plan template is organized according to Prosci's structured process for managing the people side of change on a project or initiative and is illustrated below.⁷¹



Findings

We interviewed clinicians to determine if the alignment of PMS under WHS placed Veterans at risk, and with one exception were told this was not the case. Evidence of risk provided by this individual was attributed to the addition of alternative medicine to a historically traditional medicine specialty. We were provided a series of articles comparing prior failed or disproven interventions to those outlined in VHA Directive 1037(2). One article provided involved a comparison of a proposed treatment program for Candidiasis hypersensitivity syndrome from 1986, which was vigorously rejected by the Allergy and Clinical Immunology Practice Standards Committee. The interviewee indicated there were similarities with Buprenorphine and acupuncture included in Whole Health and the recommendations presented in this article. The VA/DoD CPGs include evidence tables for a variety of interventions including Buprenorphine and acupuncture. In the SUD CPG both Buprenorphine with naloxone and Methadone, in an opioid

⁷⁰ VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, dated May 13, 2020.

⁷¹ VHA High Reliability Organization (HRO) Change Management Plan Template, July 2021.

treatment program, show strong support in the literature. In the CPG on low back pain, acupuncture for acute low back pain has insufficient evidence to support use; and for chronic low back pain, there is weak support.

There is no national VA policy requiring PMS to be aligned under a specific service. The Whole Health Implementation Guide does not preclude the decision by an organization to realign services under Whole Health, leaving this decision up to facility leadership.⁷² We assessed a lack of appropriate change management in the transition of PMS to the WHS. Communication was impersonal and last-minute, many indicating they were notified as late as the day of transition. The CoS stated he anticipated the realignment of PMS under WHS would meet resistance and not be well received by the PMS staff. He stated he did not notify the PMS of the realignment himself but rather assumed the Chief, Surgical Service would advise them as PMS was under Surgical Service at that time. He did not follow up with the Chief, Surgical Service to ensure timely notification occurred.

A Fact Finding was completed in April 2021 to address allegations from the PMS providers that a hostile work environment existed in the PMS since the realignment under WHS Clinical Director. The investigation was completed by the Chief of Anesthesiology and Pain Management from a different facility within VISN 17. The investigation found a difficult environment in pain management with a loss of respect and trust between leadership and the pain providers following the realignment of PMS under WHS. The PMS providers believed they should have been consulted before the execution of the realignment. The investigation noted numerous issues such as poor communication regarding the changes in direction of PMS with the realignment under WHS, a lack of trust and respect between the PMS providers and the WHS Clinical Director, and a lack of professionalism by the Temple PMS providers. The Fact Finding also noted that apart from one PMS provider, who works at Austin, the productivity of the other two PMS providers is very low. The investigation did not substantiate a hostile work environment was created by the WHS Clinical Director but rather a difficult environment created by all involved.⁷³

The review included a list of recommendations to address the findings of the investigation from which the CoS and WHS Clinical Director had developed an action plan. Recommendations including assigning a mentor to the WHS Clinical Director was completed with the assignment of one from within VISN 17. Temple sent an invitation to the VHA National Program Office for Pain Management, Opioid Safety and the Prescription Drug Monitoring Program to conduct a site review of the PMS, that was pending at the time of our investigation. Other actions planned addressed various issues within PMS such as productivity targets, setting expectations on acceptable behavior, communication strategies, and relationship building with Primary Care and PMS.⁷⁴

⁷² VA Whole Health Implementation Guide, Version 4.0, July 2021.

⁷³ Temple Fact Finding, Service Level Review of the Pain Clinic, dates April 7, 2021.

⁷⁴ Temple Action Plan to Address PMS Fact Finding Recommendations.

We reviewed Temple's *Charter of the Comprehensive Addiction and Recovery Act Mandated Pain Management Team*, approved on July 18, 2017. All required elements in the VHA Pain Management Team Memorandum were in the document. The charter document indicates in the "Function" paragraph that the PMT will "...evaluate and follow-up, as needed patients with complex pain conditions...process pain consultation for medication management and actual prescribing of pain medication, if needed." However, the charter then contradicts this in the "Elements" paragraph by stating: "The patient's PCP [primary care provider] maintains the primary responsibility of following through on the PMT's advice as this relates to the prescription of medications and referrals to other specialties as indicated." The charter also indicates the "Inclusion of Complementary and Integrative Medicine (CIM) on Pain Team: That is included as part of the function of the Rehabilitation Medicine Expert on the team." Additionally, the charter states: "Interventional Pain Care: That is included as part of the function of the Pain Management Expert on the team." The charter includes a requirement for at least monthly meetings to review and discuss all consultations accepted to the PMT. The stated purpose of the meeting is to review one pain case per hour and interview the Veteran involved, then generate a note in the medical record directed to the Veteran's PCP for "fulfillment and implementation."⁷⁵ We requested any documentation related to these PMT consultations but were told these are more informal and would be in the medical record. Temple provided a partial list of five Veterans with Comprehensive Addiction and Recovery Act (CARA) mandated pain management team consults, and we reviewed Veteran 2 discussed below.

Veteran 2 has complex co-morbidities on long-term opioids and severe chronic pain. A consult for pain management was placed on November 26, 2019, and was sent back to the requesting provider due to concerns noted on a radiology exam. The request was re-sent on January 23, 2020, and again sent back with the following note from the PMS physician:

As indicated in the template above, the Pain clinic primarily performs interventional spinal procedures and does not prescribe pain medications. For medication management with chronic opioids, treatment should be based on the VA/DoD Clinical Practice Guidelines For Opioid Therapy For Chronic Pain. In addition, may consider consultation to pharmacy pain clinic (including for advice on tapering medications; pain clinic may also offer advice). For complex cases including drug aberrancy, may consider pain advisory board as advised by pharmacy pain clinic. If drug dependency/addiction is observed, may consider SATP.

We found no further action on this consult; however, we did see a consult to pain management pharmacy on June 11, 2020, and found evidence that pharmacy actively engaged with Veteran 2 ultimately discharging Veteran 2 from the clinic on October 28, 2020, after reaching acceptable levels of pain control and medication management. A note by Veteran 2's palliative care provider on August 3, 2020,

⁷⁵ Temple *Charter of the Comprehensive Addiction and Recovery Act Mandated Pain Management Team*, approved on July 18, 2017.

indicated they were awaiting a consult from the PMS clinic. As noted on the previous page, this consult was discontinued in January 2020. On March 12, 2021, a CARA consult was placed by Veteran 2's Primary Care physician. The CARA consult was accepted by the PMT for processing and scheduling in the PMS clinic directed to the pain management pharmacists. An additional comment on April 16, 2021, requests the consult be forwarded to the pain management clinic. There is no evidence of a consult to pain management or any reference to the PMS clinic after this date. We assess a reluctance of PMS physicians to engage with Veterans suffering from complex pain unless the case meets very strict criteria. The only active engagement on Veteran 2 by the PMT was the pain management pharmacist. We also noted this in the case review of Veteran 1 in Allegation 2.

We reviewed Pain Oversight Committee (POC) minutes for FY 2020 and 2021. There was mention of PMT cases discussed in the November 2019 through August 2020 minutes. In August 2020, the WHS Clinical Director set a requirement for PMT members to see the Veteran to be discussed in PMT prior to the meeting. There was no further mention of PMT cases in the POC after this discussion. According to interviewees, the PMT functions informally using Microsoft Teams, and does not take notes or minutes.⁷⁶ There is no record of Veterans reviewed by PMT that we could locate. Interviewees also told us the POC and PMT meetings have changed to primarily administrative discussions about policy and procedure, with little emphasis on discussion of individual Veteran cases. Review of the POC minutes supports this observation beginning in FY 2021.

The nurses currently covering PMS come from Surgical Service and the Anesthesia Department, as PMS does not have their own nurses assigned. Pain clinic coverage is provided by LVNs and RNs to cover pain management procedures. On occasion, due to staffing shortages, an IV certified LVN covers pain management procedures. Since moderate sedation is not used for pain management procedures at Temple, there is no requirement for an RN to monitor the patient. Additionally, interviewees told us the physician is in the room from the start of the procedure throughout the patient's recovery to assess and determines when the patient can be discharged. This level of supervision is required if an LVN covers pain management as assessment is not within scope of practice of LVNs. The RN can complete the discharge assessment and determine if the patient meets discharge criteria and discharge the patient without additional input from the physician unless indicated.

We found no evidence that the WHS Clinical Director attempted to exchange PMS's long-term RN (detailed from the Anesthesia Department) in the procedure room with an LVN. To the contrary, we found the WHS Clinical Director was submitting a request for additional clinical and administrative resources and personnel for the PMS clinic. During the tour of the PMS Clinic, we found an unused room called the recovery room. The patient remains in the procedure room until discharge rather than moving to this available room which extends the amount of time to turn over e.g. cleaning, etc. the

⁷⁶ Microsoft Teams is a proprietary business communication platform which offers workspace chat and videoconferencing, file storage and application integration.

procedure room and prepare the next patient thus limiting the number of procedures that can be performed.

The WHS Clinical Director notified PMS staff in July 2021 regarding a plan to optimize the utilization of space in the Temple Pain Clinic area to accommodate WHS providers. The plan included:

- Replacing all desktop computers with laptops and docking stations.
- Having nurses bring patients to the exam room for the nursing evaluation.
- When PMS providers are in the procedure clinic and not using the clinic exam rooms, any other provider can use the exam rooms that are being used as office space.
- The room currently used for check-in/vitals by nursing will be available as an exam room.
- All team members will use the workroom for charting.⁷⁷

The PMS providers had many concerns regarding the proposed changes. They stated that they do not have a formal office and the clinic room doubles as their office. They described the workroom as the break room which lacks privacy when they need to discuss patients with other providers on the phone or to call patients to discuss their care. One provider stated he required the use of a larger computer monitor due to an eye condition and a laptop screen would not accommodate his condition. Another provider stated he required the use of two computer monitors to assist in viewing imaging results while charting. As of August 2021, the proposed plan by the WHS Clinical Director has not been implemented.

The PMS clinic is underutilized. Accounting for current COVID-19 restrictions, metrics from the current and prior years indicate low productivity of the PMS providers at Temple. One PMS clinician has written only 18 prescriptions since January 2019 and averaged 38 procedures per month. This clinician's schedule reflects 17 1-hour procedure slots per week, of which 90% were sacroiliac joint injections. Another PMS clinician has written 13 prescriptions since July 2020 and averaged 24 procedures per month in the last 10 months. This clinician's schedule reflects slots for 18 1-hour procedures per week. Not accounting for time off or sick time, these schedules equate to 78 1-hour procedure slots left open per month at Temple, or 936 potential additional one-hour slots per year. Pain clinic appointments are 30 minutes for follow ups and 1 hour for new patients. All clinic appointments were 1 hour until approximately May 2021 when the WHS Clinical Director initiated the change. Low in-house PMS productivity and the large numbers of community referrals pre-date realignment of PMS under the WHS.

We also reviewed the utilization of the WHS NP. We interviewed the WHS NP who stated she works one day per week in PMS clinic seeing patients in 1-hour clinic appointments (seven patients per week). The NP does not have office space in the PMS clinic, but instead works in a separate building that is approximately a 10-minute

⁷⁷ Emails provided by staff.

walk from the clinic in the main hospital facility. The NP stated other duty days are devoted to special projects and some follow up with PMS patients. She characterized the PMS encounters as managing complaints from patients either not getting timely consults or consults that were not approved or discontinued. The WHS NP does not perform interventional pain management procedures and cannot prescribe controlled substances.

We found no evidence of implementation of the Stepped Care Model of Pain Management as required by VHA Directive 2009-053. Temple lacks a single standard through which to implement interdisciplinary, patient centered and biopsychosocial pain care. We reviewed the STORM report, and of 380 patients at Temple with "OUD diagnosis, No Opioid Rx (Elevated Risk)," 226 (or 59%) are missing at least one element of appropriate treatment. Pharmacy pain clinicians were the primary advocate for patients with complex pain as described in the two reviewed cases. The PMS clinicians were not actively involved.

Prior to our visit, Temple requested a comprehensive review of the PMS from the National Program Office for Pain Management, Opioid Safety, and the Prescription Drug Monitoring Programs due to various concerns Temple leadership had regarding the program; however, the review has not yet occurred.

Conclusions for Allegation 3

- We **do not substantiate** aligning PMS under the WHS places patients at risk. However, the realignment was poorly communicated to sections directly impacted by the decision.
- There are no reporting structure requirements or recommendations in the Executive Decision Memo *Engaging Veterans in Lifelong Health, Well-being and Resilience Integrated Project Team* dated March 4, 2020, thus leaving the reporting structure to the facility's discretion.
- There is a potential risk to patients due to the lack of direct involvement by PMS clinicians in the management of patients with complex pain.
- We **do not substantiate** the WHS Clinical Director plans to reduce PMS resources and reallocate them to the WHS. We found a plan to increase resources including RN and LVN nurse staffing for PMS.
- The PMS clinic is underutilized due to inefficient use of space, clinic appointment length, a focus on interventional procedures, underutilization of the WHS NP and a lack of permanently assigned nursing staff.
- The WHS Clinical Director made plans to change the utilization of space in the Pain Clinic area to accommodate WHS providers which may impact the need for a larger computer monitor to accommodate a provider's vision needs.

- Temple's implementation of the Stepped Care Model of Pain Management is problematic. The primary clinicians involved in managing opioids at Temple are the pain pharmacists who do not have the ability to prescribe controlled substances.
- We found no evidence of interdisciplinary planning or consultation regarding pain management patients, and the focus of both the PMT and POC meetings have changed to policy discussions and not patient care discussions.
- Although the components for an interdisciplinary pain management team are present at Temple, there is limited evidence of interdisciplinary team interaction.
- The CARA mandated PMT charter as written discourages use of PMS physicians except in the event of an interventional pain procedure. Guidance in the charter conflicts from the "Function" section to the "Elements" section.
- The review requested by Temple for a comprehensive review of the PMS by the National Program Office for Pain Management, Opioid Safety and the Prescription Drug Monitoring Programs has not yet occurred at the time of our investigation.

Recommendations to Temple

13. Implement a change management plan in coordination with the Quality Management Department/HRO Department for the alignment of PMS under the WHS using HRO implementation activities.
14. Immediately increase PMS involvement in the care of patients with complex pain in modalities other than interventional pain procedures. Audit PMS consults monthly to ensure compliance.
15. Complete resource requests process for PMS. Once additional resources are obtained, analyze clinic grids and pain management flow, ensure appropriate time allocation for procedures, appropriate procedures and maximize productivity of PMS.
16. If the WHS Clinical Director's plan regarding changing the utilization of space in the Pain Clinic area proceeds, such plans must provide for reasonable accommodations such as dual monitors and/or large monitors for staff.
17. Review the WHS NP's assigned duties and adjust to ensure the role is fully utilized to manage PMS patients and provide care within the NP's scope of practice.
18. Fill current vacant PMS clinic slots with appropriate PMS patients as outlined in Step 2 of VHA Directive 2009-053 Pain Management.
19. Review CPGs and other VHA evidence-based sources with PMS clinicians to clarify appropriate use of List I and II recommendations in VHA Directive 1137(2).

20. Implement pain care across the Temple health care system using the Stepped Care Model of Pain Management and provide education to pertinent staff. Ensure best ethics practices described in VHA Directive 1005 are incorporated.
21. Fully comply with VHA PMT Memorandum, VHA Directive 1137(2) and VHA Directive 2009-053 sections identified in this report. Discontinue efforts to develop specific local policies. Until compliance with these national policies are reached, further develop guidelines to comply with national policies based on local need.
22. Appropriately utilize the interdisciplinary PMT in caring for patients with pain conditions as described in both CARA and Temple's charter for this team.
23. Revise the CARA mandated PMT charter to include broadening the scope of services PMS physicians may provide and resolve the conflicting guidance in the "Function" and "Elements" section.
24. Ensure there is an interdisciplinary pain management team.

Recommendation to VHA

1. Complete the external review requested from the National Program Office for Pain Management, Opioid Safety, and the Prescription Drug Monitoring Programs as soon as possible.

Allegation 4

Consults and encounters:

- a. [REDACTED] is performing self consults outside the VA's clinical screening and treatment procedures.
- b. [REDACTED] has been performing encounters without billing or engaging physician utilization.
- c. [REDACTED] has implemented centralized control over consults in Whole Health and the Pain Management Team that interferes with Veteran Access to Physician Care.

Background

VHA Directive 1065, *Productivity and Staffing for Specialty Provider Group Practice*, dated December 22, 2020, states it is VHA policy that each VA medical facility monitors and assesses specialty and discipline provider group practice clinical productivity and staffing at least annually using standardized methods to ensure providers can deliver appropriate, high-quality and timely health care and services to Veterans. In VHA provider productivity data, productivity is defined as workload, measured in relative value units (RVUs), divided by workforce, measured in clinical provider full time equivalent (FTE(C)). The FTE(C) refers to both physician allopathic doctors (MD),

Doctor of Osteopathic Medicine (DO) FTE and other licensed providers. Provider FTE(C) measures the worked (removing leave) portion of a provider's time that is devoted to clinical care time as assigned in Managerial Cost Accounting (MCA) labor mapping. This portion of FTE is used in productivity calculations. An RVU is a measure of the time and intensity of a professional service. The RVUs are assigned to VHA workload by extracting Current Procedural Terminology (CPT) coding from the electronic health record (EHR).⁷⁸

VHA Directive 1065, Appendix B, provides summary guidance on labor mapping categories which include:

- Clinical time (MCA Direct Patient Care Time) includes time to prepare, to provide for and follow-up on the clinical care needs of patients. It is the time left when justifiable administrative, education and research hours have been subtracted.
- Administrative time includes activities such as scheduling employees, completing performance reviews, fulfilling hospital or national reporting requirements, managing a clinical program and participating on VA medical facility or national committees, advisory boards or professional societies.
- Education time is limited to the hours spent by VA clinical staff preparing and delivering classroom training, formal presentations or lectures as well as time spent managing a resident, fellow or other type of student teaching program.
- Research time is time spent working on research that is approved by the local VA medical facility Research and Development Committee and does not produce clinical workload in the EHR.⁷⁹

Findings

The whistleblowers alleged that when the WHS Clinical Director became involved in the PMT meetings, he called patients prior to the PMT and documented this contact in the record resulting in inappropriate billing for these self-consults. We compared the Temple PMT consult process with the May 18, 2017, VHA PMT Memorandum (VIEWS #7791174) related to the expectations of evaluation and follow-up for Veterans with complex pain conditions. During interviews, the WHS Clinical Director stated he did contact Veterans prior to their scheduled PMT meetings to establish a relationship. This is consistent with American Medical Association Current Procedural Terminology (CPT) Manual criteria for medical team conferences which include a minimum of three qualified health professionals from different specialties or disciplines who provide direct care to the patient must participate in the team conference.⁸⁰

The Temple *Charter of the Comprehensive Addiction and Recovery Act Mandated Pain Management Team*, approved July 18, 2017, outlines the processes of the CARA mandated PMT at Temple. The PMT reviews patients with high-risk opioid prescriptions and provides recommendations to clinical providers. It states a function of the PMT is to

⁷⁸ VHA Directive 1065, *Productivity and Staffing for Specialty Provider Group Practice*, dated December 22, 2020.

⁷⁹ VHA Directive 1065, Appendix B, *Establishing Specialty Provider Group Practice Productivity Standards*, dated December 22, 2020.

⁸⁰ <https://www.asha.org/practice/reimbursement/coding/CaseManagement/>.

evaluate and follow-up as needed Veterans with complex pain conditions, and following each Veteran encounter, a note will be generated by members of the PMT and documented in the EHR. Charting by the lead clinician for the team members claiming service time is allowed. Billing for services by individuals on the team requires documentation that includes the unique contribution made by each team member. Team members who are present but not making a unique contribution may not bill but may record service as non-billable time.⁸¹

We interviewed the Assistant Chief of HIMS who stated she was contacted by the Temple PMS providers in September 2020 regarding concerns about the WHS Clinical Director's consulting with patients and whether those were appropriate encounters for billing purposes. She was asked to review eight PMT cases and comment on the coding of each encounter. She explained that each participating provider should have some contact with the patient prior to the PMT conference or it can't be coded as a team conference. The provider would see or contact the patient prior to the conference and establish the relationship, recording the visit with the appropriate codes that fit the modality of care, such as audio, face-to-face, etc. Her review of the cases noted that all patients were contacted by the WHS Clinical Director prior to the PMT meeting, and the patient had no other prior contact from any other PMT provider participant prior to the meeting.

The Assistant Chief of HIMS stated the CPT placed on the PMT meeting for each patient she reviewed was the code 99243, which is an office consultation for a new or established patient, that requires a detailed history, a detailed examination and medical decision-making of low complexity. She noted it was difficult for the documentation to support that CPT code. She was asked by the PMS providers if it was acceptable for a provider to reach out to a patient prior to the PMT meeting, and she responded yes, if the provider is performing services within their scope of practice and documenting the service they could assign whatever CPT code is appropriate for that documentation. As the WHS Clinical Director was performing services within his scope of practice and documented the encounter with the patient in preparation for the PMT meeting, the encounter would be justified.

The Assistant Chief of HIMS stated the CPT code 99243 used for a consultation was not an appropriate code as the PMT meeting should have been coded using a team meeting code. She stated that in order for the meeting to be a team conference and be coded as such, it required all members have a firsthand knowledge of the patient, which per the documentation in the EHR, did not occur. She noted in her opinion the PMT meetings lacked supporting documentation to code it as a consultation or a team conference and as a result none of the cases were billable and none were sent to billing.

The WHS Clinical Director is mapped at 30% clinical and 70% administrative time since May 2021. He was previously mapped at 8.75% clinical and 91.25% administrative

⁸¹ https://optumsandiego.com/content/dam/san-diego/documents/organizationalproviders/references/TREATMENT_TEAM_doc_standards.pdf.

except for the first 6 weeks in his role when he was mapped at 100% administrative.⁸² A review of the DWH's workload noted his productivity target fiscal year to date as of August 23, 2021, is 2,926 RVUs and his productivity is at 2,421.42 RVUs (83% of target).⁸³ This illustrates the WHS Clinical Director has been performing encounters and delivering health care and services to patients.

The PMT meetings are scheduled to occur once a month on a Tuesday for 4 hours. Typically, 4 patients were reviewed, with 1 hour being allocated to each patient reviewed. The team would contact the patient and include them in the discussion if they could be reached. The team would develop a plan for the patient to provide to the patient's Primary Care provider to then implement. Following the realignment of PMS under WHS, the WHS Clinical Director stopped the scheduling of patients and the meeting time is now devoted to restructuring policies, getting all the background/research work done, updating any other documents as indicated and making future plans for the PMT. Our review of Temple PMT consults indicated the last completed PMT patient encounter occurred in December 2020.

Interviewees advised us that there is a weekly informal meeting that includes the pharmacists and the WHS Clinical Director and noted it is almost the same type of meeting held previously with PMT. In the weekly meeting patient cases are discussed such as those having difficulty tapering or the provider does not want to continue opioids, and how to manage those high-risk patients. These weekly informal meetings are not documented in the patient's EHR. The informal meeting provides an avenue for the pharmacists to get recommendations from the WHS Clinical Director.

Conclusions for Allegation 4

- We **do not substantiate** that the WHS Clinical Director is performing self-consults outside the VA's clinical screening and treatment procedures or has been performing encounters without billing or engaging physician utilization.
- We **substantiate** that the WHS Clinical Director ceased the review of patients during the PMT meeting in December 2020 and instead is utilizing this meeting for administrative purposes in violation of the Temple *Charter of the Comprehensive Addiction and Recovery Act Mandated Pain Management Team*, the facility-designated body responsible for coordinating and overseeing pain management therapy for patients experiencing acute and chronic pain (non-cancer related) as required by the CARA Act.
- The use of the consultative visit CPT code 99243 for the PMT meeting is inappropriate.

⁸² National Labor Mapping Tool (NLMT) Mapping History by Employee:
<https://mcareports2.va.gov/ReportServer/Pages/ReportViewer.aspx?%2fDSOAnalytics%2fLaborMapping%2fLaborMappingByEmployee&rs:Command=Render>.

⁸³ Open Physician Productivity Cube Dashboard: <https://pyramid.cdw.va.gov/direct/?id=eea0bfc1-2a91-4103-844c-4b4da54dc080&backToApp>.

- The informal weekly meeting outside of the PMT implemented by the WHS Clinical Director has resulted in patient care discussions and decisions regarding patients with pain diagnoses which has not included all members of the PMT, and which have not been documented in the EHR. The lack of presence of the entire PMT interdisciplinary team may have resulted in a less thorough review of each patient's case. The lack of recording these discussions in the patient's EHR may impact communication related to that patient's plan of care.

Recommendations to Temple

Immediately resume the review and oversight of pain management therapy for patients experiencing acute and chronic pain (non-cancer related) during the PMT meeting as described in the Temple *Charter of the Comprehensive Addiction and Recovery Act Mandated Pain Management Team*. The chair of the PMT will ensure the review completed in the PMT meeting is documented in the patients' EHR.

25. Consult with HIMS and determine the appropriate CPT coding for the PMT meeting and what criteria is required of the CPT code.
26. Determine if the weekly informal meeting reviewing patients with pain diagnoses should continue and if so, ensure the discussion and/or relevant information is documented in the patients' EHR.

VI. Summary Statement.

We have developed this report in consultation with other VHA and VA offices to address OAWP's concerns that improper or inadequate care in the Temple PMS have put Veteran patients' safety at risk. We reviewed the allegations and determined the merits of each. VHA HR has examined personnel issues to establish accountability, and the National Center for Ethics in Health Care has provided a health care ethics review. We found that leadership have implemented changes in the types of pain management services offered and have attempted to address the large number of pain management consults sent to the community; however, we found no resulting risks to patient safety as a result of the changes. We identified inefficiencies in pain clinic utilization, the lack of health care system wide pain management practices which do not use the Stepped Care Model of Pain Management, and weak interdisciplinary PMT processes.

Attachment A

Comprehensive Addiction and Recovery Act (CARA) from July 22, 2016, (P.L. 114-198)

Nursing Practice Act, Nursing Peer Review & Nurse Licensure Compact as prescribed in the Texas Occupations Code (As Amended September 2019)

Texas Occupations Code Section 157.0512. Prescriptive Authority Agreement

Department of Health & Human Services, *Pain Management Best Practices Inter-Agency Task Force Report*, dated May 9, 2019

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

VHA Handbook 1004.01(5), *Informed Consent for Clinical Treatments and Procedures*, dated August 14, 2009

VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, dated May 13, 2020

VHA Directive 2009-053, *Pain Management*, October 28, 2009

VHA Directive 1078(1) *Privacy of Persons Regarding Photographs, Digital Images, and Video or Audio Recordings* of November 4, 2014

VHA Directive 1137(2) *Provision of Complementary and Integrative Health*, May 18, 2017

VHA Directive 1065, *Productivity and Staffing for Specialty Provider Group Practice*, dated December 22, 2020

VHA Notice 2020-30 *Buprenorphine Prescribing for Opioid Use Disorder*, September 22, 2020

VHA Pain Management Team Memorandum (PMT) Memorandum (VIEWS 7791174), May 18, 2017

The VA/Department of Defense (DoD) Clinical Practice Guideline (CPG) for the Management of Substance Abuse Disorder (SUD), December 2015

VA Clinician's Guide, *Acute Pain Management Meeting the Challenges*, dated July 2017:

https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/Pain_Provider_AcutePainProviderEducationalGuide_I_B10998.pdf.

VHA Office of Community Care Field Guidebook, dated July 29, 2021, Chapter 2-3, Eligibility, Referral, and Scheduling:
<https://dvagov.sharepoint.com/sites/VHAOCC/CNM/CI/OCCFGB/SitePages/FGB.aspx>

VHA Office of Productivity, Efficiency, and Staffing, Facility Complexity Level Model Fact Sheet (2017)

VHA High Reliability Organization (HRO) Change Management Plan Template, July 2021

VA Whole Health Implementation Guide, Version 4.0, July 2021

VHA Support Service Center (VSSC) Consult – Patient Details Report

VHA National Labor Mapping Tool (NLMT) Mapping History by Employee:
<https://mcareports2.va.gov/ReportServer/Pages/ReportViewer.aspx?%2fDSOAnalytics%2fLaborMapping%2fLaborMappingByEmployee&rs:Command=Render>

VSSC Provider Bookability Dashboard for SUD and Clinic Stops and Persons reports as of August 11, 2021

VSSC Clinic Utilization Dashboard

VHA Open Physician Productivity Cube Dashboard

Directory of Buprenorphine Prescribers for Opioid Addiction Treatment (OAT):
https://vaww.pbi.cdw.va.gov/PBIRS/Pages/ReportViewer.aspx?/RVS/OMHSP_PERC/SRS/Production/CDS/Pharm/BuprenorphineDirectory

https://dvagov.sharepoint.com/sites/VHAPERC/Reports/SitePages/STORM_home.aspx

<https://dvagov.sharepoint.com/sites/vhaacademicdetailing/SitePages/Data-Resources.aspx>

VA Community Care SEOC, Pain Management Comprehensive 1.2.7, effective date July 16, 2021:
[file:///Z:/Template/View%20SEOC %20Pain%20Management%20Comprehensive%201.2.7.html](file:///Z:/Template/View%20SEOC%20Pain%20Management%20Comprehensive%201.2.7.html)

<https://dvagov.sharepoint.com/sites/VHAOPCC/IHCC/SitePages/Home.aspx>

<https://www.va.gov/painmanagement/>

CDW VHAPBHSQLANA

<https://www.regulations.gov/document/VA-2019-VHA-0008-23586>

<https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/buprenorphine> Last Updated: 05/14/2021

<https://www.healthquality.va.gov/guidelines/MH/sud/>

<https://www.healthquality.va.gov/guidelines/Pain/cot/>

<http://www.abpm.org/what>

<https://www.asha.org/practice/reimbursement/coding/CaseManagement/>

https://optumsandiego.com/content/dam/san-diego/documents/organizationalproviders/references/TREATMENT_TEAM_soc_standards.pdf

Nursing Practice Act, Nursing Peer Review & Nurse Licensure Compact, Texas Board of Nursing https://www.bon.texas.gov/laws_and_rules/nursing_practice_act.asp

Texas Occupations Code Section <https://statutes.capitol.texas.gov/?link=OC>

Stepped Care for Opioid Use Disorder Train the Trainer (SCOUTT)

Temple Medical Center Memorandum 116A-009 *Buprenorphine/Naloxone Therapy for Opiate Use Disorder*, June 25, 2019

Temple Charter of the Comprehensive Addiction and Recovery Act Mandated Pain Management Team approved on July 18, 2017

Temple Memorandum 011-001, *Pain Management and Assessment*, dated April 24, 2018

Temple MCP 011-001, *Pain Management Draft*

Temple *Integrated Pain Management Service Agreement Draft*

Temple Pain Management Specialty Clinic Consult Template Current and Draft versions

Temple PMS complaint no. P-674.2021766122-01, dated June 30, 2021

Temple Pain Management Oversight Committee minutes, December 3, 2020

Temple Pay for performance documents for PMS clinicians for FY 2021

Temple Fact Finding, Service Level Review of the Pain Clinic, dates April 7, 2021

Temple Action Plan to Address PMS Fact Finding Recommendations

Temple External Review of PMS Clinical Operations, dated February 9, 2019
Emails provided by staff

Review of the EHR of selected patients

RELEASED TO HOUSE AND SENATE VETERANS' AFFAIRS COMMITTEES