DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Review of Opioid Monitoring and Allegations Related to Opioid Prescribing Practices and Other Concerns at the Tomah VA Medical Center Wisconsin

HEALTHCARE INSPECTION | REPORT #18-05872-103 | MARCH 28, 2019

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Executive Summary

The VA Office of Inspector General (OIG) conducted a rapid response healthcare inspection in response to a request from Senator Tammy Baldwin and a series of allegations from a confidential complainant. The issues reviewed were related to opioid monitoring and prescribing practices and other concerns at the Tomah VA Medical Center (facility), Wisconsin.[1]

In 2013, the Veterans Health Administration (VHA) launched the Opioid Safety Initiative (OSI). The OSI's strategies include education, pain management, expanded access to non-pharmacologic treatment options, and risk mitigation. A key component of the OSI is clinician-, facility-, and system-level measurement of several indicators of opioid safety. A "dashboard" identifies patients who are on long-term and high dose opioid therapy or on opioids and benzodiazepines concurrently, and have documented risk mitigation strategies including informed consents, urine drug tests, prescription drug monitoring checks, naloxone rescue kits, and quarterly follow-up.[2]

The facility had an opioid monitoring program and processes were in place to follow up on outliers or other concerns. The facility's OSI Committee met weekly and reviewed cases meeting pre-established criteria or when requested by a provider. The OSI Committee completed 181 case reviews on 157 patients during the first three quarters of fiscal year (FY) 2018.

To evaluate the provision and documentation of risk mitigation strategies and whether providers were offering alternative treatment opportunities in accordance with the OSI, the OIG team completed electronic health record reviews of 106 patients who received at least a 90-day supply of opioids at some point between October 1, 2017, and June 30, 2018. Patients reviewed also had a diagnosis of chronic pain with a current opioid prescription of greater than or equal to 100 morphine equivalent daily dose (≥ 100 MEDD) or were on an opioid medication concurrently with a benzodiazepine. The OIG review revealed opportunities to improve compliance with risk mitigation strategies, but overall, it appeared that the facility was attempting to comply with OSI risk mitigation strategies. Further, the facility's dashboard measures as of June 30, 2018, reflected substantial improvements when compared with previous quarterly results, suggesting that facility staff were largely following OSI guidelines.

The OIG did not substantiate that "gap" providers' opioid prescriptions were not monitored.[3] Providers' opioid prescribing practices were monitored, irrespective of whether the provider was

[1] In this report, discussion of the facility included clinical care locations other than the medical center such as the community based outpatient clinics.

[2] Naloxone is used along with emergency medical treatment to reverse the life-threatening effects of a known or suspected opiate overdose.

[3] The OIG team interpreted "gap" provider to be a temporary or covering provider.

permanently following a panel of patients or covering on a short-term basis, via OSI Committee or Veterans Integrated Service Network prioritization processes.

Due to insufficient information, the OIG was unable to determine whether mental health providers were combining benzodiazepine and opioid prescriptions for patients after another provider would discontinue them. However, the decision to prescribe opioids and benzodiazepines was made on a case-by-case basis and was not a prohibited practice.

The OIG did not substantiate that facility managers failed to provide adequate guidance and support regarding opioid prescribing or that opioids were being handed out "like candy." VHA's and the facility's efforts to promote the safe use of opioids have resulted in a myriad of clinician-level training, prescribing guidance and support, alternative therapies, and risk reduction tools for providers. The OIG did not find evidence that opioids were being indiscriminately prescribed.

The OIG did not substantiate allegations centered around the availability of pain management consults. Of the 488 consults reviewed, 54 were discontinued or canceled but all included an explanation for the discontinuation or cancellation. Community based outpatient clinic (CBOC) providers told the OIG team of a variety of pain management-related services they recommended to patients that were provided by the facility including battlefield acupuncture, Healing Touch, and chiropractic care.[4] Further, the OIG did not substantiate that facility leaders failed to impose restrictions on the number of times a patient on opioids could change providers. However, the facility was not consistently following procedures outlined in its standard operating procedure for processing provider change requests related to opioids.

The OIG substantiated that a physician was not consistently on site at the Wausau CBOC during FY 2018; however, the OIG team did not find this to be improper. Collaborating physicians were available, as required by VHA, for those periods when a physician was not on-site at the CBOC. A permanent physician started at the Wausau CBOC in April 2018. The OIG also substantiated that, due to rural locale, filling provider vacancies was sometimes difficult. As of September 2018, the facility was recruiting for float nurse practitioners, outpatient nurse practitioners, float physician assistants, outpatient physician assistants, and primary care physicians.

The OIG did not substantiate allegations that centered around physician assistants reportedly being forced to write opioid prescriptions, being harassed such that the work environment was psychologically unsafe, or that patients were being endangered because of these practices. None of the current physician assistants interviewed reported being forced or pressured to write opioid prescriptions, and providers interviewed, including physicians and nurse practitioners, reported that leaders were supportive of tapering opioids and that non-opioid pain management resources were available and encouraged.

[4] Battlefield Acupuncture is a specific application of ear acupuncture.

The OIG substantiated environment of care deficiencies at the Wausau CBOC. However, the facility had largely identified and, when possible, addressed the deficient conditions prior to the OIG receiving the allegations. Therefore, the OIG did not make a recommendation on this matter.

The OIG made one recommendation for the facility to continue efforts to educate providers and improve compliance with risk mitigation strategies.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendation and provided an acceptable action plan. (See Appendixes A and B, pages 20–22 for the comments.) The OIG considers the recommendation open and will follow up on the planned action until it is complete.

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Contents

Abbreviations

CBOC	community based outpatient clinic
EHR	electronic health record
FY	fiscal year
MEDD	morphine equivalent daily dose
OIG	Office of Inspector General
OSHA	Occupational Safety and Health Administration
OSI	Opioid Safety Initiative
PDMP	prescription drug monitoring program
RIOSORD	Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression
SOP	standard operating procedure
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a rapid response healthcare inspection in response to an August 14, 2018, request from Senator Tammy Baldwin and a series of allegations from a confidential complainant. The issues reviewed were related to opioid monitoring and prescribing practices and other concerns at the Tomah VA Medical Center (facility), Wisconsin.[5]

The purpose of the inspection was to address Senator Baldwin's request and to assess the merit of the allegations.

Background

The facility, part of Veterans Integrated Service Network (VISN) 12, is a low-complexity[6] medical center that provides primary care, mental health, and nursing home care. The facility has community based outpatient clinics (CBOCs) in La Crosse, Owen, Wausau, and Wisconsin Rapids, Wisconsin. In fiscal year (FY) 2018, the facility served 25,870 patients and had a total of 281 operating beds, including 21 inpatient beds, 70 domiciliary beds, 180 community living center beds, and 10 Compensated Work Therapy Transitional Residence beds.

Chronic Pain and its Treatment

Chronic pain is defined as pain lasting more than three months. Because chronic pain is a personal experience and can affect many different parts of the body, "[t]he goal of treatment is to reduce pain and improve function, so the person can resume day-to-day activities."[7]

Opioid medications (opioids) are controlled substances effective in treating pain by reducing the intensity of pain signals that reach the brain.[8] Commonly prescribed opioids include: codeine sulfate (codeine), hydrocodone (Vicodin®), oxycodone (OxyContin®), morphine sulfate

[5] In this report, discussion of the facility includes clinical care locations other than the medical center such as the community based outpatient clinics.

[6] The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex.

[7] National Institutes of Health (NIH) Medline Plus, *Chronic Pain: Symptoms, Diagnosis, & Treatment,* Spring 2011 Issue: Volume 6 Number 1 Page 5-6.

[8] Under the Controlled Substances Act of 1970, 21 U.S. Code § 812, drugs are classified by their potential for abuse.

(morphine), hydromorphone (Dilaudid®), methadone, and fentanyl.[9] Veterans Health Administration (VHA), in collaboration with the Department of Defense (DoD), has published several versions of clinical practice guidelines for the management of opioid therapy, with the latest guidelines published in 2017.[10] The guidelines are intended to guide the treatment of patients with chronic pain by providing evidence-based information but are not intended to define a standard of care.

In clinical settings, most patients with acute and chronic pain will initially see their primary care provider. Primary care providers can be physicians, nurse practitioners, or physician assistants. Over half of primary care providers treat chronic pain and one out of five outpatient visits is for primary symptoms or diagnoses of pain. [11]

Opioid Epidemic and Opioid Safety Initiative

According to the Centers for Disease Control and Prevention, there were more than 42,000 U.S. overdose deaths in 2016 involving opioid drugs including prescription opioids, heroin, and illicitly manufactured fentanyl, a powerful synthetic opioid. As chronic pain is more common in veterans than in the non-veteran U.S. population, and is often severe and occurring in the context of mental health comorbidities, veterans are at high risk for harm from opioid medication.[12]

In 2013, VHA launched the Opioid Safety Initiative (OSI), the first of several system-wide initiatives to address opioid overuse.[13] VHA 2018 training materials reflect that a goal of the OSI is "[t]o reduce the reliance on opioid analgesics for pain management and to promote safe and effective use of opioid therapy when clinically indicated."[14] OSI's strategies include education, pain management, expanded access to non-pharmacologic treatment options, and risk mitigation.

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[9] US National Library of Medicine National Institutes of Health. *Correlates of Prescription Opioid Initiation and Long-term Opioid Use in Veterans with Persistent Pain*, Page 7, Table 3.

[10] *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.* May 2010. The introduction states that the first VA/DoD Clinical Practice Guideline was published in 2003. *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*. May 2017.

[11] Breuer B, Cruciani R, Portenoy RK. Pain management by primary care physicians, pain physicians, chiropractors, and acupuncturists: a national survey. South Med J. 2010 Aug;103(8):738-47; Daubresse M., Chang H., Yu Y., et al. *Ambulatory diagnosis and treatment of nonmalignant pain in the United States, 2000–2010*. Med Care. 2013; 51:870–878.

[12] VHA's Behavioral Health Autopsy Program reported in 2015 that the most frequently identified risk factor among veterans who died by suicide was pain.

[13] Walid F. Gellad, Chester B. Good, David J. Shulkin. *Addressing the Opioid Epidemic in the United States Lessons from the Department of Veterans Affairs*. JAMA Intern Med. 2017;177(5):611-612.

[14] Friedhelm Sandbrink, Von Moore. The VA Opioid Safety Initiative – how did we get here and what is ahead? Presentation February 6, 2018. https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/2353-notes.pdf. (The website was accessed on November 25, 2018.)

VHA implemented several strategies to identify potentially at-risk patients and to support and track risk mitigation activities for opioid therapy. An OSI "dashboard" identifies patients who

- Are on long-term opioid therapy, which is defined as greater than (>) 90 days,
- Are prescribed a high dose of opioids, which is defined as >100 morphine equivalent daily dose (MEDD),[15]
- Are on long-term opioid therapy and are concurrently prescribed benzodiazepines, which constitutes a serious risk for unintentional overdose death,[16]
- Have an informed consent, which discusses risks of long-term opioid therapy and alternatives to opioid therapy,[17]
- Have a urine drug test, which helps in determining a patient's adherence to the prescribed drug regimen and is required, at a minimum, within the past 12 months,[18]
- Have prescription drug monitoring program (PDMP) checks, which are required at least annually, for > five-day opioid supplies,[19]
- Have been offered or received naloxone kits to reverse overdose, and[20]
- Have received quarterly follow-up appointments with their opioid prescriber.

Prior OIG Reports

In recent years, the facility has been at the center of several reviews involving opioid-related issues, some of which received national media attention. One of the facility's leaders referred to the events as the 2015 "crisis." Two OIG reports relevant to the issues under review in this report are

[15] Morphine equivalent daily dose is used to translate the dose and route of opioids a patient has received over the last 24 hours to a parenteral morphine equivalent using a standard conversion table.

[16] Benzodiazepines are a type of controlled substance prescription sedative commonly prescribed for anxiety or to help with insomnia. https://www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids. (The website was accessed November 6, 2018.)

[17] An informed consent is required when there is a change in the prescribing provider, upon initiation of opioid therapy, and when there is a significant change in opioid regimen. Additionally, if the veteran is prescribed buprenorphine/naloxone (Suboxone), the consent will be signed upon initiation and annually thereafter.

[18] With a urine drug test, a drug that is prescribed and taken as directed should show in the patient's urine. Additionally, the urine drug test can screen for drugs that are not on the patient's medication list and that should not be detectable in the urine.

[19] By providing information about controlled substance prescriptions that are dispensed in the state, the PDMP aids healthcare professionals in their prescribing and dispensing decisions.

[20] Naloxone is used along with emergency medical treatment to reverse the life-threatening effects of a known or suspected opiate overdose. The OIG team did not review separately for evidence of opioid overdose education, which is often conducted in conjunction with the naloxone distribution element.

- VA Office of Inspector General, *Healthcare Inspection—Unexpected Death of a Patient During Treatment with Multiple Medications, Tomah VA Medical Center, Tomah, WI*, Report No. 15-02131-471, August 6, 2015; and
- VA Office of Inspector General, *Healthcare Inspection—Alleged Inappropriate Prescribing of Controlled Substances and Alleged Abuse of Authority, Tomah VA Medical Center Tomah, WI*, Report No. 11-04212-127, February 6, 2015.

Other OIG reports involving the facility can be accessed at www.va.gov/oig.

Congressional Request

On August 14, 2018, the OIG received a letter from Senator Tammy Baldwin requesting a review of the facility's monitoring processes used to track opioid prescribing rates, outliers, corrective actions, and other concerns.

Allegations

In July 2018, a confidential complainant made multiple allegations:

- No one [from the facility] monitored "gap" providers' opioid prescriptions.[21]
- Mental health providers were combining benzodiazepine and opioid prescriptions for patients after another provider would discontinue them.
- Facility management did not provide adequate guidance and support regarding opioid prescribing.
- Opioids were being "handed out like candy" at the facility, and at the Wausau and Wisconsin Rapids CBOCs, for inappropriate indications such as osteoarthritis in a 30-year-old and any patient who simply demanded them.
- Pain management services were not readily available and consults for a pain management specialist in the community were denied without explanation. As a result, staff were forced to provide care to chronic pain patients.
- There was no limit to the number of times a patient could change providers to "doctor shop" and facility leaders did not impose restrictions.
- Periodically, there was no physician supervision for the physician assistants at the Wausau CBOC.
- The facility had been unable to fill primary care provider positions and had a high turnover rate for those positions.
- Physician assistants were being "forced" to write prescriptions for methadone and other opioids at dosages and frequencies that were outside of their scopes of practice, they were not comfortable writing, or writing the prescription was against their better judgement.

[21] The OIG team interpreted "gap" provider to be a temporary or covering provider.

- A "climate of psychological danger" existed as providers were verbally harassed and their jobs threatened if they did not comply with supervisors' orders to prescribe opioids.
- The practice [of supervisors forcing physician assistants to write opioid prescriptions they were not comfortable writing] was "endangering patient safety."
- The environment of care at the Wausau CBOC was poor, including a leaky roof that needed replacement; ventilation, mold, and air conditioning issues; and inadequate bathroom facilities.

Other personnel-related issues included in the confidential complaint were beyond the scope of this inspection.

Scope and Methodology

The OIG initiated the inspection on August 30, 2018, and conducted a site visit September 17–20, 2018. The review included selected data and documents from July 1, 2017, through September 30, 2018.

The OIG team interviewed the complainant on September 4, 2018. During the site visit, the OIG team interviewed the Facility Director, the acting Chief of Staff, the acting Chief of Pharmacy, the acting Chief of Human Resource Management, the Chief of Community Care, OSI Committee co-chairs, and CBOC providers including a mental health nurse practitioner, a psychiatrist, and a pharmacist.

Relevant facility policies and VHA directives and handbooks were reviewed. Additionally, the OIG team reviewed facility quality and internal management reports, OSI data, clinical privileging and scope of practice data, patient advocate reports, and other documents relevant to the allegations. The OIG team conducted electronic health record (EHR) reviews of 106 patients who either (a) had a diagnosis of chronic pain with a current (at the time of the review) opioid [dose] of ≥ 100 MEDD, or (b) was on an opioid medication (at any dose) concurrently with a benzodiazepine. Conditions (a) or (b) needed to exist for more than 90 days at some time between October 1, 2017, and June 30, 2018, and the opioid needed to be prescribed by a primary care provider to be included in the review.[22] The OIG team referred 45 of these cases to an OIG physician for review—10 cases where the patient died while prescribed an opioid and 35 cases where the patient was potentially at-risk for an adverse outcome. The OIG team defined potentially at-risk patients as those patients *not* on the OSI list who were on opioids and benzodiazepines concurrently, or who did not consistently receive risk mitigation interventions including urine drug screens, informed consent, or quarterly follow-up.[23] The OIG team also

[22] Many of the patients reviewed had multiple prescriptions and/or visits.

[23] VISN staff told the OIG that, based on a prioritization system, the VISN prioritized cases for the OSI list based on > 100 MEDD and Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD) scores.

considered patients to be at-risk if they were taking methadone but their EHR lacked evidence that an electrocardiogram had been completed in the 12 last months.[24]

The OIG physician reviewed the 10 patient deaths for a definitive connection to opioids. The OIG physician reviewed the 35 potentially at-risk patients for the existence of reasonable explanations for non-compliance with risk mitigation strategies (for example, the patient did not attend a scheduled appointment), or, in the case of patients who were prescribed methadone but had not received an electrocardiogram (or the results had not been acknowledged by the provider), whether the patient experienced an adverse cardiac event definitively attributed to methadone. The OIG physician did not conduct a comprehensive review of the medical management for the 35 patients.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

[24] An electrocardiogram is a test that measures a heart's electrical activity. Because of methadone's unique pharmacodynamic properties that can affect heart rhythm, electrocardiograms are highly advised before and after initiating methadone.

Inspection Results

Issue 1: Monitoring of Opioid Prescribing Practices

Senator Baldwin's Request

At the request of Senator Tammy Baldwin, the OIG evaluated the facility's process for monitoring opioid prescribing practices, including review of outliers, and corrective actions, as indicated. The OIG team found that the facility had an opioid monitoring program and processes were in place to follow up on outliers.

Relative to the OSI, the facility's policy on pain management required, among other actions, that the facility [25]

- Review all complex patient cases [where the patient was] prescribed >100 MEDD and provide recommendations to [the] pain management treatment plan.
- Monitor and maintain [the] OSI dashboard performance measures and develop actions to ensure those measures are met and maintained.

In addition, OSI Committee activities should be reported to the facility's Health Systems Council quarterly.

Case Reviews

The facility's OSI Committee was chartered on May 30, 2018, with the purpose, per the National OSI and VISN 12 requirements, of improving the safety of patients at [the facility] on chronic opioid therapy for non-palliative conditions. The OSI Committee was co-chaired by the facility's Associate Director (who was also a clinical pharmacist) and the Deputy Chief Nurse for Patient Care Services. Committee membership included medical and mental health providers, pharmacists, physical therapy staff, and a performance improvement representative. The co-chairs told OIG team members that the facility's interdisciplinary OSI Committee met weekly to review EHRs and make recommendations for pain management and risk mitigation in accordance with OSI guidelines. Reportedly, as a function of OSI, all patients on ≥100 MEDD are reviewed for diagnosis, medication list, indication for opioid therapy, and aberrant behaviors; however, there may or may not be a note in the EHR depending on the review findings. The OSI Committee identifies cases through additional avenues.

- The VISN sends a list of high priority patients with MEDD ≥100 *and* a Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD) score of 8–10

[25] Medical Center Memorandum No. 11-15, *Pain Management*, April 6, 2017.

or RIOSORD score of 5–7 if the patient is also taking a benzodiazepine. RIOSORD scores include a patient's recent history of substance abuse or mental health disorders, among other conditions, prompting an outpatient clinic visit.

- Providers can request an OSI Committee consult for assistance with individual patient care planning or review of their panel of patients on opioids.
- The OSI Committee can identify patients who are in several of the OSI-related databases whose diagnoses or gaps in services prompt further review.

Data provided by the facility reflected that the OSI Committee completed 181 case reviews on 157 patients during the first three quarters of FY 2018. The OIG team confirmed that the OSI Committee members documented their reviews and recommendations in the patients' EHRs.

To evaluate the provision and documentation of risk mitigation strategies and whether providers were offering alternative treatment opportunities in accordance with the OSI, the OIG team completed EHR reviews of 106 patients who received at least a 90-day supply of opioids at some point between October 1, 2017, and June 30, 2018. Those patients also had a diagnosis of chronic pain with a current opioid prescription of ≥ 100 MEDD or were on an opioid medication concurrently with a benzodiazepine. The OIG's findings are shown in Table 1.

Table 1. Implementation of Risk Mitigation Strategies (N=106)

Risk Mitigation Strategy	Yes	No
A signed opioid consent form was present.	90 (84.9%)	16 (15.0%)
A recent or annual Urine Drug Screen was present.	95 (89.6%)	11 (10.0%)
The provider or nurse accessed the PDMP per facility policy.	96 (90.5%)	10 (9.40%)
The patient was prescribed a naloxone kit.	75 (70.7%)	31 (29.2%)
The provider followed up with the patient quarterly.	57 (53.7%)	49 (46.2%)
The provider offered other pain management options (or modalities).	62 (58.4%)	44 (41.5%)

Source: OIG staff EHR data analysis

As shown in Table 1, facility providers were not consistently implementing risk mitigation strategies, which could place patients at-risk for adverse outcomes such as overdose. While opportunities existed for provider education and improved compliance with implementation of risk mitigation strategies, it appeared that the facility was attempting to comply with OSI risk mitigation strategies.

OIG Physician Review of Potentially At-Risk Patients

Forty-five of the 106 patients were referred to the OIG physician for EHR review because they were potentially at-risk. While 10 patients died when they had a current prescription for an opioid, the OIG physician found no definitive evidence that the deaths were related to opioids. The OIG physician reviewed the remaining 35 patients for risk mitigation strategies noted to be

concerning or non-compliant and whether reasonable explanations existed for non-compliance. As of mid-December 2018, the OIG physician found full or current compliance for a majority of the questionable or deficient risk mitigation strategies included in the review. The OIG physician did not find documentation of an adverse cardiac event in the one patient who was on methadone but had not received an electrocardiogram in the 12 months preceding the OIG's review, or, in two other cases, where the provider did not document the results of the electrocardiogram.

Dashboard Monitoring

The OIG team reviewed the facility's OSI dashboard measures as of June 30, 2018, and found progressive and substantial improvements when compared with previous quarterly results dating back, in some measures, to FY 2012. Those measures included percentage of patients on opioids; number of patients on > 100 MEDD; number of patients on > 400 MEDD; percentage of patients on both opioids and benzodiazepines; percentage of patients receiving a urine drug test; and percentage of patients with completed informed consents.

The OSI Committee chairperson told the OIG that the Committee has not identified patterns or trends [in opioid-related practices]; however, education is provided to individual providers on a case-by-case basis.

OSI Committee Reporting

Health Systems Council meeting minutes for May 2017 through September 2018 largely reflected quarterly OSI reporting and discussion, as required.[26]

The OIG team found that the facility had additional opportunities to improve compliance with risk mitigation strategies and alternative treatments. Nevertheless, based on the facility's opioid-related improvements in the past several years, including training and development of alternative treatment options, the OIG concluded that OSI monitoring and follow-up processes were functional and effective.

Allegations Related to Opioid Prescribing Practices and Other Concerns

In addition to the congressional request, the OIG evaluated allegations made by a confidential complainant.

[26] One set of meeting minutes was not provided to OIG.

Allegation 1. No one [from the facility] monitored "gap" providers' opioid prescriptions.

The OIG team did not substantiate the allegation. The complainant did not provide the name or names of temporary providers whose opioid prescribing practices may have been concerning, and the OIG was not able to reasonably identify who was a gap provider and who was a permanent provider temporarily covering for a colleague on any given day. Therefore, the OIG team considered whether the facility's processes for monitoring providers' opioid prescribing practices would identify a temporary provider's deficient practices and outliers.

Methods by which a provider's opioid prescribing practices were monitored, irrespective of whether the provider was permanently following a panel of patients or covering on a short-term basis, included

- OSI Committee reviews of patients deemed to be at-risk for overdose or other negative outcomes as reflected in the OSI dashboard or as determined by their provider; if a temporary provider's patients met criteria,[27] the OSI Committee would review those cases and make recommendations regarding alternate or additional pain management strategies, and
- VISN reviews of OSI dashboard data to identify provider-specific opportunities to improve practices; the VISN prioritized those opportunities and offered those providers academic detailing sessions with clinical pharmacists.[28]

The OIG team concluded that both monitoring methods would identify deficiencies in a temporary provider's prescribing practices.

Allegation 2. Mental health providers were combining benzodiazepine and opioid prescriptions for patients after another provider would discontinue them.

The OIG team was unable to determine whether providers were combining benzodiazepine and opioid prescriptions after another provider would discontinue them, primarily because the complainant did not provide details or specific examples of who was involved and when this problem allegedly occurred. However, the team acknowledges that the scenario is plausible. Nevertheless, while concurrent use of benzodiazepines and opioids can place patients at-risk for adverse outcomes and is not a recommended practice, it is not a prohibited practice. The decision

[27] The OSI Committee reviewed chronic opioid patients' EHRs when they were prescribed > 100 MEDD, were at-risk for opioid-related misadventures, or when a provider requested a review.

[28] The academic detailers enhance veteran outcomes by promoting the use of evidence-based treatments using the intervention of academic detailing by clinical pharmacy specialists.

to prescribe opioids and benzodiazepines is made on a case-by-case basis.[29] The OIG team reviewed the EHRs of the 70 patients (of the 106 patients in the review population) who were prescribed both benzodiazepines and opioids from October 1, 2017, through June 30, 2018, to determine whether prescribers were implementing risk mitigation strategies for these potentially at-risk patients. The OIG noted opportunities to improve compliance with risk mitigation strategies. For this population, the EHR review reflected compliance with relevant guidance:

- 81 percent–opioid consents
- 86 percent–urine drug testing
- 90 percent–PDMP
- 63 percent–naloxone kits
- 60 percent–quarterly follow-up

Issue 2: Leadership Oversight and Support

Allegation 3. Facility management did not provide adequate guidance and support regarding opioid prescribing.

The OIG did not substantiate the allegation. VHA's and the facility's efforts to promote the safe use of opioids has resulted in a myriad of clinician-level training, prescribing guidance and support, alternative therapies, and risk reduction tools for providers. Facility providers had multiple strategies available:

- Pain workshops and battlefield acupuncture training for providers[30]
- VISN academic detailers to meet with providers one-to-one. In FY 2018, VISN 12 conducted 26 academic detailing encounters with 17 Tomah providers that were related to OSI or opioid use disorder
- VISN-run quarterly OSI calls and other in-service training
- OSI Committee consultation for providers seeking assistance and suggestions for managing patients on opioids
- Policies covering pain management, buprenorphine/naloxone (suboxone), and adverse drug events
- Associate Chief of Staff for Medicine guidance on pain management expectations, communicating with patients, and documentation requirements
- Embedded pharmacists at the Wausau and La Crosse CBOCs, remote pharmacist assistance at the Wisconsin Rapids and Owen CBOCs, and pharmacy consults in general

[29] *VA/DoD Clinical Practice Guideline* May 2017.

[30] Battlefield acupuncture is a specific application of ear acupuncture.

- Integrated health modalities including chiropractic care, yoga and tai chi, meditation, Healing Touch, and physical therapy

Another support tool, the Stratification Tool for Opioid Risk Mitigation (STORM), augments the OSI dashboard and was developed to "go beyond the prescriptions to address the biopsychosocial factors that contribute to suicide and overdose mortality, addiction and other adverse events." STORM helps individual providers to identify "patients at increased risk for overdose or suicide-related events and provide them with patient-centered risk mitigation strategies."[31] Facility-wide monitoring data reflected a 44-percent relative decrease in opioid prescribing rates from 2012 to 2018, suggesting that, in general, providers had the necessary knowledge and resources to address patients' pain without an over-reliance on opioids.

Allegation 4. Opioids were being "handed out like candy" at the facility, and at the Wausau and Wisconsin Rapids CBOCs, for inappropriate indications such as osteoarthritis in a 30-year-old and any patient who simply demanded them.

The OIG team did not substantiate the allegation. As stated above, facility-wide monitoring data reflected a decrease in the percentage of patients on opioids between 2012 and 2018. Further, the facility outperformed both the VISN and VHA nationally in this measure.

As noted previously, chronic pain is a personal experience and the treatment of that pain is a decision made between the provider and the patient. The OIG team did not attempt to determine whether the clinical indication appropriately "warranted" opioid treatment. Rather, the OIG team focused on whether risk mitigation strategies and alternative treatment modalities were offered and/or implemented.

The OIG team concluded that while the facility had additional opportunities to improve compliance with risk mitigation strategies and alternative treatments, the team did not find evidence that opioids were being indiscriminately prescribed.

Allegation 5. Pain management services were not readily available and consults for a pain management specialist in the community were denied without explanation. As a result, staff were forced to provide care to chronic pain patients.

The OIG team did not substantiate the allegation. For the period October 1, 2017, through September 19, 2018, providers submitted 488 Community Care Pain Management consults. Of

[31] Elizabeth M. Oliva, et al. "Development and Applications of the Veterans Health Administration's Stratification Tool for Opioid Risk Mitigation (STORM) to Improve Opioid Safety and Prevent Overdose and Suicide." Psychological Services, Vol. 14, No. 1, 34–49 (2017).

the 488 consults, 54 were discontinued or canceled. All 54 consults included an explanation for the discontinuation or cancellation such as the patient no longer desired the consult, the patient had an active physical therapy consult, or the patient expired.

During interviews, CBOC providers told the OIG team of a variety of pain management-related services they recommended to patients that were provided by the facility. Some examples given were battlefield acupuncture, Healing Touch, chiropractic care, physical therapy, and Pain University. [32]

Allegation 6. There was no limit to the number of times a patient could change providers to "doctor shop" and facility leaders did not impose restrictions.

The OIG team did not substantiate the allegation. However, the facility was not following procedures outlined in its unsigned and undated Request for Change in Primary Care Provider standard operating procedure (SOP). For the period October 1, 2017, through August 17, 2018, OIG inspectors identified 16 patients who were on an opioid medication and a provider change was requested related to prescribing practices of opioids.[33] Medicine Service's SOP required the OSI Committee to review the request and the patient's EHR, and provide feedback related to the patient's opioid management and primary care provider assignment. This feedback should be documented on the Change of Provider request form and returned within two weeks to the Medicine Service. However, the Associate Director informed the OIG that "[i]f the information is not documented on the change of provider form, it is included in an email that is sent by one of the OSI team members to medicine service."

For 7 of the 16 patients, the OIG team did not find evidence on the Change of Provider form or in e-mails provided by the facility that the OSI team reviewed and approved the request per Medicine Service's procedure; however, the OIG team did determine that the 16 patients were assigned to new providers.

The SOP stated that continuity is important to the therapeutic relationship and development of an optimal treatment plan, and that "frequent requests for change in providers (more than once every six months) will generally be disapproved." The OIG team did not find examples of frequent requests for a change in provider.

[32] Pain University is a program that puts patients in charge of their care by affording them the opportunity to learn about all the factors that impact their pain and choose the best treatment path to improve their pain. Pain University follows the VA Patient Centered Care model, focusing on whole health (physical, emotional, mental health, and well-being).

[33] In 2 of the 16 cases, the providers requested a provider change for patients who were on opioids but recently weaned off and were unhappy with their pain management.

Allegation 7. Periodically, there was no physician supervision at the Wausau CBOC.

The OIG team substantiated that there were periods in FY 2018 when a physician was not on-site at the Wausau CBOC; however, the team did not find this to be improper as VHA policy states that the collaborating physician (for physician assistants) is responsible for providing readily available consultation and collaboration, which can be accomplished in person, by telephone, or by other suitable means (for example, video conference, telehealth).[34]

One physician provider worked in the Wausau CBOC until late fall 2017. A second provider started at the Wausau CBOC in early 2018 and worked for a short period of time, then a third provider started at the Wausau CBOC in early spring 2018.[35]

The Associate Chief of Staff for Medicine (Associate Chief) told the OIG that in instances when an on-site collaborating physician was not available, physician assistants have historically contacted the Associate Chief for clinical assistance or guidance. A physician at the La Crosse CBOC reportedly covers for the Associate Chief when the Associate Chief is out of the office for an extended period of time. In these cases, a Medicine Office representative notifies providers at the facility and the CBOCs who the Acting Associate Chief will be and the dates that he/she will serve as collaborating physician for nurse practitioners and physician assistants and as a clinical/administrative resource for all providers.

Allegation 8. The facility had been unable to fill primary care provider positions and had a high turnover rate for the positions.

The OIG team substantiated the allegation. The acting Chief of Human Resource Management told the OIG team that the facility's, and some CBOCs' rural locations made physician, nurse practitioner, and physician assistant recruitment difficult. For example, a physician position was approved in 2015 for the Owen CBOC, but the position had not been filled as of the OIG team's site visit. The estimated population of Owen, Wisconsin, in 2017 was less than 1,000.

The facility reportedly recruits for these positions year-round, works with national recruiters to fill positions, and offers enhanced tier-level pay, compressed tours-of-duty, and recruitment and retention incentives." As of September 2018, the facility was recruiting for float nurse practitioners, outpatient nurse practitioners, float physician assistants, outpatient physician assistants, and primary care physicians.

[34] VHA Directive 1063, *Utilization of Physician Assistants (PA)*, December 24, 2013. This directive is expired and has not yet been replaced.

[35] The second provider passed away in early 2018.

Issue 3: Physician Assistants and Opioid Prescriptions

Allegation 9. Physician assistants were being "forced" to write prescriptions for methadone and other opioids at dosages and frequencies that were outside of their scopes of practice, they were not comfortable writing, or writing the prescription was against their better judgement.

The OIG team did not substantiate the allegation. The team interviewed three physician assistants. The physician assistants denied feeling pressured to write opioid prescriptions. The co-chair of the OSI Committee told the OIG team that in the event a provider was uncomfortable writing an opioid prescription for a patient, it would be incumbent upon that provider to discuss those concerns with his/her supervisor.[36] A change of provider could be approved through the OSI Committee, if indicated.

The physician assistants were approved to prescribe opioids, including methadone, and their privileges and scopes of practice did not set limits on dosages or frequencies for these prescriptions.

Allegation 10. A "climate of psychological danger" existed as providers were verbally harassed and their jobs threatened if they did not comply with supervisors' orders to prescribe opioids.

The OIG team did not substantiate the allegation. Providers from the Wausau, Wisconsin Rapids, Owen, and La Crosse CBOCs who were questioned about this allegation stated they had not been subjected to harassment or intimidation by supervisors in relation to opioid prescriptions.

Completed on an annual basis, the VA All Employee Survey is VA's internal feedback tool from employees to management about how staff experience the VA workplace, including job satisfaction, psychological safety, work/life balance, and engagement, among others. Employee feedback gained through the All Employee Survey results are used to calculate a Best Places to Work composite score ranging from 0–100 points.

The All Employee Survey Coordinator told the OIG that, to "build trust" [after the 2015 "crisis"], the facility initiated psychological safety classes for all of supervisors, to "start the conversation" of how to help supervisors and employees "feel safe." The facility had also been

[36] The OIG interviewer gave the example of a provider absorbing a panel of patients after another provider who retired. In that case, the retiring provider could have prescribed opioids at doses that the provider who was absorbing the panel of patients was not comfortable prescribing.

an active participant in the VA Voices program, which is designed to help leaders engage staff, providers, and care teams with ICARE values.[37] The All Employee Survey Coordinator reported that those efforts had contributed to improved employee satisfaction at the facility in the past several years. While data reflected that the facility underperformed in the Best Places to Work measure in FYs 2013–2016, the facility's ranking substantially improved in FYs 2017–2018. As of March 31, 2018, the facility scored above the VHA-wide average in the Best Places to Work measure.

Allegation 11. The practice [of supervisors forcing physician assistants to write opioid prescriptions they were not comfortable writing] was "endangering patient safety."

The OIG team did not substantiate the allegation. None of the current physician assistants interviewed reported being forced or pressured to write opioid prescriptions. The providers interviewed, including physicians and nurse practitioners, largely reported that leaders were supportive of tapering opioids and that non-opioid pain management resources were available and encouraged. The OIG's review revealed that providers, including physician assistants, had opportunities to improve compliance with risk mitigation strategies as noted in Table 1.

Issue 4: Environment of Care—Wausau CBOC

Allegation 12. The environment of care at the Wausau CBOC was poor, including a leaky roof that needed replacement; ventilation, mold, and air conditioning issues; and inadequate bathroom facilities.

The OIG team substantiated environment of care deficiencies at the Wausau CBOC. However, the facility had largely identified and, when possible, addressed the deficient conditions prior to the OIG receiving the allegations. Therefore, the OIG did not make a recommendation on this matter.

Roof Leak

An Issue Brief dated April 18, 2018, reflected that heavy snowfall on April 14 and 15 caused water leaks which stained some ceiling tiles. The issue became significantly worse overnight on April 17, necessitating the CBOC to close on Wednesday, April 18.[38]

[37] ICARE Core Values - Integrity, Commitment, Advocacy, Respect, and Excellence define VA's culture and strengthen dedication to the veteran population. They provide a baseline for the standards of behavior expected of all VA employees. https://www.va.gov/icare/. (The website was accessed on March 15, 2019.)

[38] Seventy-one patients with appointments on April 18 were triaged by clinic staff prior to closure of the CBOC. No patients had immediate needs that required same-day services. All patients were rescheduled.

The Wausau CBOC is in a leased building (not a VA property). The building landlord hired a restoration company to complete a deep cleaning and replace damaged ceiling tiles and attic insulation. The Wausau CBOC re-opened Thursday, April 19. The facility conducted environment of care rounds following the roof leak incident and the Safety and Occupational Health Manager reported that there have been no roof-related issues since the repairs in April. OIG team members did not identify ongoing deficiencies related to the roof leak during an environment of care review on September 19, 2018.

Air Quality

An Issue Brief outlined that in early August 2016, Wausau CBOC staff reported a "strong odor in the back half of the building causing staff to have nausea and headaches." The source of the odor was a sealant being used to seal the sidewalk. Patients and staff were evacuated from the building, and while several employees became ill and were treated at a local emergency room, no patients reported being ill. According to the Issue Brief, an Occupational Safety and Health Administration (OSHA) representative investigated the event and "determined that the permissible level of exposure was below the threshold for a safety concern." All affected employees were released back to work with no further follow-up. The Issue Brief also outlined that during interviews in August 2016, the OSHA inspector was told about potential mold in the building, and the facility subsequently arranged for a consultant to conduct an air quality assessment, which revealed ongoing concerns and made recommendations for improvement. The facility reported corrective actions including issuance of air purification machines, terminal carpet cleaning, and mold remediation activities. The building landlord replaced the CBOC's air filters. According to the facility, no additional air quality concerns have been reported.

The OIG was unable to find evidence of air conditioning problems although OIG team members noted some air vents that had been "papered over" in an apparent attempt to reduce air flow. Because people experience temperature differently, what constitutes a comfortable temperature is subjective. Therefore, the OIG could not validate the existence of air conditioning problems.

During the OIG's environment of care inspection in September 2018, team members found clean ventilation grills and no foul odors.

Bathroom Facilities

The OIG team substantiated that the lack of adequate bathroom access at the Wausau CBOC continued to be problematic. Facility engineers determined that the toilet to staff and patient ratio did not meet VA requirements; however, the Wausau CBOC was in a leased building that could not reasonably be renovated to add bathroom facilities. Facility leaders were aware that the number of available bathrooms at the Wausau CBOC was insufficient, and at the time of the OIG's site visit, leaders were looking for new clinic space to correct the problem.

Conclusion

The facility had an opioid monitoring program and processes were in place to follow up on outliers or other concerns. The facility's OSI Committee met weekly and reviewed cases meeting pre-established criteria or when requested by a provider. The OIG team's review of the study population revealed opportunities to improve compliance with risk mitigation strategies, but overall, it appeared that the facility was attempting to comply with OSI risk mitigation strategies. Further, the facility's dashboard measures as of June 30, 2018, reflected substantial improvements when compared with previous quarterly results.

The OIG did not substantiate that "gap" providers' opioid prescriptions were not monitored. Providers' opioid prescribing practices were monitored, irrespective of whether the provider was permanently following a panel of patients or covering on a short-term basis, via OSI Committee or VISN prioritization processes.

Due to insufficient information, the OIG was unable to determine whether mental health providers were combining benzodiazepine and opioid prescriptions for patients after another provider would discontinue them. However, even if true, it is not a prohibited practice. In these cases, implementation of risk mitigation strategies is important to promote patient safety. The OIG noted opportunities to improve compliance with risk mitigation strategies.

The team did not substantiate that facility managers failed to provide adequate guidance and support regarding opioid prescribing or that opioids were being "handed out like candy." VHA's and the facility's efforts to promote the safe use of opioids has resulted in a myriad of clinician-level training, prescribing guidance and support, alternative therapies, and risk reduction tools for providers. Facility-wide monitoring data reflected a decrease in the percentage of patients on opioids between 2012 and 2018, and while the facility had additional opportunities to improve compliance with risk mitigation strategies and alternative treatments, the OIG did not find evidence that opioids were being indiscriminately prescribed.

The OIG did not substantiate allegations centered around the availability of pain management consults. Of the 488 consults reviewed, 54 were discontinued or canceled but all included an explanation for the discontinuation or cancellation. Further, the OIG did not substantiate that facility leaders failed to impose restrictions on the number of times a patient on opioids could change providers. However, facility leaders were not consistently following procedures outlined in their SOP for processing provider change requests related to opioids.

The OIG substantiated that there were periods in FY 2018 when a physician was not on-site at the Wausau CBOC; however, the OIG team did not find this to be improper. A permanent physician started at the Wausau CBOC in April 2018. The OIG also substantiated that, due to rural locale, filling provider vacancies was sometimes difficult. As of September 2018, the facility was recruiting for float nurse practitioners, outpatient nurse practitioners, float physician assistants, outpatient physician assistants, and primary care physicians.

The OIG did not substantiate allegations that centered around physician assistants reportedly being forced to write opioid prescriptions, being harassed such that the work environment was psychologically unsafe, or that patients were being endangered because of these practices. The physician assistants interviewed did not report being forced or pressured to write opioid prescriptions, and providers interviewed, including physicians and nurse practitioners, reported that leadership was supportive of tapering opioids and that non-opioid pain management resources were available and encouraged.

The OIG team substantiated environment of care deficiencies at the Wausau CBOC. However, the facility had largely identified and, when possible, addressed the deficient conditions prior to the OIG receiving the allegations. Therefore, the OIG did not make a recommendation on this matter.

Recommendation

The Tomah VA Medical Center Director continues efforts to educate providers and improve compliance with risk mitigation strategies.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: March 12, 2019

From: Director, VA Great Lakes Health Care System (10N12)

To: Director, VA-OIG, OHI Rapid Response Team, (54RR)
Director, Management Review Service (VHA 10EG GOAL Action)

Subj: Healthcare Inspection—Review of Opioid Monitoring and Allegations Related to Opioid Prescribing Practices and Other Concerns at the Tomah VA Medical Center, Wisconsin

1. I would like to thank the OIG inspections team for a thorough review of allegations related to Opioid Prescribing Practices and other concerns at the Tomah VAMC. Evidence of the corrective action plan with quality improvements to address the recommendation is provided.
2. If additional information is needed please contact the Performance Improvement Director Tomah VA Medical Center at 608-372-3971 ext. 66013, Tomah VAMC, Tomah, Wisconsin.

(Original signed by:)

James W. Rice
Acting Network Director, VISN 12

Appendix B: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: March 5, 2019

From: Director, Tomah VA Medical Center (676)

Subj: Healthcare Inspection—Review of Opioid Monitoring and Allegations Related to Opioid Prescribing Practices and Other Concerns at the Tomah VA Medical Center, Wisconsin

To: Director, VA Great Lakes Health Care System (10N12)

1. Thank you for the opportunity to view the draft report of the Tomah Veterans Affairs Medical Center inspection. I have reviewed the document and concur with the recommendations.
2. A corrective action plan has been implemented as detailed in the attached report. If additional information is needed please contact the Tomah VAMC.

(Original signed by:)

Victoria P. Brahm, MSN, RN, VHA-CM
Medical Center Director

Comments to OIG's Report

Recommendation

The Tomah VA Medical Center Director continues efforts to educate providers and improve compliance with risk mitigation strategies.

Concur.

Target date for completion: July 1, 2019

Director Comments

The facility will educate providers on opioid safety and risk mitigation strategies via the following methods: Professional Services meetings held by the Chief of Staff, provider staff meetings, and education disseminated via electronic mail to all providers. The facility will continue to monitor current risk mitigation data for compliance.

OIG Contact and Staff Acknowledgments

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