



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Alleged Interference and
Failure to Comply with the
Pain Management Directive
and the Opioid Safety
Initiative at the VA Northern
Indiana Health Care System

Fort Wayne, Indiana



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the VA Northern Indiana Health Care System (system), Fort Wayne, Indiana, to determine the validity of confidential allegations that (i) system leaders interfered with primary care providers' opioid prescribing practices; (ii) requirements specified in Veterans Health Administration (VHA) Directive 2009-053, *Pain Management*, October 28, 2009, were not followed; and (iii) system leaders failed to meet all goals of VHA's Opioid Safety Initiative Update. The OIG also evaluated whether the system was conducting providers' exit interviews as recommended by a 2017 Office of Medical Inspector's report.

The OIG substantiated that on four occasions between summer 2016 and spring 2018, a system leader, the Chief of Staff (COS), interfered with primary care providers' opioid prescribing practices. The COS told the OIG team that "I inserted myself between a patient and provider" when the patient did not agree with the primary care provider's treatment recommendations that included the tapering of opioid medications. The OIG reviewed the electronic health records related to the four specific occasions and found that on the first occasion, the COS was very clear when instructing the primary care provider to approve an early opioid medication fill that affected a clinical outcome. On the second occasion, the COS requested that a primary care provider stop an opioid tapering plan. On third and fourth occasions, the COS directed the continuation of opioid prescribing at current dosages despite plans of care that included opioid tapers. The OIG determined that patients did not have identifiable adverse clinical outcomes; however, the continuation of patients' opioids may have prolonged dependence on opioids.

Apart from the four occasions noted above, OIG inspectors identified three of 29 interviewed primary care providers who reported experiencing pressure by the COS in some manner related to opioid prescribing practices.¹ One of the three primary care providers reported feeling an obligation, due to the COS's position, to comply with the COS's request for a patient's opioid refill despite the patient not having been seen at the frequency required by system policy for visits. The primary care provider saw the patient at issue during the lunch hour and prescribed an opioid refill to meet the COS's request.

The OIG substantiated that the system did not follow all requirements specified in VHA Directive 2009-053, *Pain Management*, October 28, 2009:

¹ The OIG interviewed current and former system primary care providers.

- The Pain Management Committee did not provide consistent oversight and monitoring of pain management activities.
- Leaders did not monitor the quality of pain assessments and effectiveness of pain management interventions.²
- Leaders did not develop and implement processes to evaluate the success of meeting the goals of the VHA National Pain Management Strategy on a regular basis, at least yearly.
- The system lacked a formal referral process for a tertiary, interdisciplinary pain rehabilitation program for complex cases.
- The system lacked an ongoing standardized pain management and opioid safety education program for providers.

The OIG also evaluated the system's compliance with VHA's requirement for pain management teams.³ While on-site, the OIG identified that the pain management team had been established but was not meeting because no cases had been referred. However, subsequent to the visit, the system reported that as of July 2018, the team was active.

The OIG team reviewed the system's compliance with its October 2017 pain management policy requirement that providers routinely use opioid risk assessment tools for patients on long-term opioid therapy. The OIG found that not all providers used the tools.⁴ The team found that 15 percent of primary care providers questioned did not use the risk assessment tools for opioids and other medications.⁵ Primary care providers reported the following reasons for not using the tools: time required to copy and paste the information into the electronic health record, burden of time to review the data, and not knowing how to use the tools.

In reviewing the system's pain management policy, the OIG team identified that system leaders were not in compliance with the policy as it related to veteran requests for provider changes.⁶ System policy specified a veteran request for a provider change would not be granted if the request was made due to the opioid prescribing practices of a provider. System primary care

² VHA Directive 2009-053, *Pain Management*, October 28, 2009. Monitoring measures may include "adherence to published clinical practice guidelines, timeliness of pain treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment including behavioral health and pain medicine consultation and treatment, and clinical outcomes such as improvements in pain control, patient satisfaction, physical and psychosocial functioning, and quality of life."

³ The Deputy Under Secretary for Health for Operations and Management issued a memo on May 18, 2017, that implemented the July 22, 2016, *CARA* mandate that each system designate a pain management team.

⁴ System Policy 11-89-17, *Long-Term Opioid Use for Chronic Pain MGMT*, October 2017; chronic opioid therapy is daily or near-daily use of opioids for at least 90 days, often indefinitely.

⁵ Risk assessment tools offer providers a list of evidence-based clinical recommendations for risk alleviation, such as drug screening tests, bowel regimens, and treatment alternatives to opioid prescription.

⁶ System Policy 11-89-17.

providers reported that veteran requests for provider changes were granted without regard to whether the requests were made due to opioid prescribing practices. Administrative staff reported that the System Director believed veterans should have the opportunity to find a provider they are comfortable with, so a meaningful relationship could develop.

The OIG found the system met six out of nine goals as outlined in VHA's Opioid Safety Initiative Update and partially met the remaining three:

- Goal 3—Facilitate the use of state Prescription Drug Monitoring Program (PDMP) databases—partially met. The system facilitated the use of PDMPs by offering provider training. However, not all primary care providers used the PDMP state databases when opioid medications were prescribed.⁷ PDMP reports showed that 26 of 63 (41 percent) primary care providers completed PDMP reports at least yearly greater than or equal to 80 percent of the time.
- Goal 4—Establish safe and effective Veterans Integrated Service Network (VISN) tapering programs for veterans using the combination of benzodiazepines⁸ and opioids—partially met. While system leaders reported having established tapering protocols for patients on a combination of opioids and benzodiazepines for primary care providers, seven of 10 (70 percent) interviewed primary care providers were unaware of the protocols and did not know how to find them.
- Goal 6—Establish processes for tapering veterans on high-risk opioids—partially met. While the system had protocols for tapering high-risk patients on opioids such as sustained action oxycodone, hydromorphone, and methadone, seven of 10 (70 percent) primary care providers interviewed were unaware of the protocols or did not know how to find them.⁹

The OIG team determined that the system was conducting voluntary exit interviews with primary care providers who left employment as the Office of Medical Inspector recommended in a 2017 report. From fall 2017 to fall 2018, three primary care providers left the system's employment. The system reported that all three primary care providers who left were given the opportunity for an exit interview; one of the three primary care providers participated.

The OIG made one recommendation to the VISN 10 Director related to the ethics of a system leader interfering with the opioid prescribing practices of primary care providers.

⁷ The requirement to use state PDMP databases was not established until October 19, 2016, when VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs* was issued. Prior to October 2016, it was not mandatory to query state PDMP databases.

⁸ Benzodiazepines are a class of drugs primarily used for treating anxiety but are also effective in treating other conditions. The exact mechanism of action of benzodiazepines is not known, but they appear to work by affecting neurotransmitters in the brain (chemicals that nerves release in order to communicate with other nearby nerves).

⁹ Sustained action is a drug product formulation that provides the required dosage initially and then maintains or repeats it at desired intervals.

The OIG made 11 recommendations to the System Director related the Pain Management Committee, pain assessments, annual evaluation of compliance with the Pain Management Strategy, tertiary pain rehabilitation programs, stepped care education and training, the pain management team, opioid risk assessment tools, veteran requests to change providers, PDMP reports, opioid and benzodiazepine tapering protocols, and tapering programs for veterans on high-risk opioids.

Comments

The VISN and System Directors concurred with the recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 30–38, for the Directors’ comments.) Based on information provided, the OIG considers recommendation 7 closed. For the remaining open recommendations, the OIG will follow up on the planned and recently implemented actions to ensure that they have been effective and sustained.



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Abbreviations

CARA	Comprehensive Addiction and Recovery Act
CBOC	community based outpatient clinic
CIH	Complementary and Integrative Health
COS	Chief of Staff
DoD	Department of Defense
EHR	electronic health record
FY	fiscal year
MEDD	morphine equivalent daily dose
OIG	Office of Inspector General
OMI	Office of Medical Inspector
OSI	Opioid Safety Initiative
OTRR	Opioid Therapy Risk Report
MRI	magnetic resonance imaging
PCP	primary care provider
PDMP	prescription drug monitoring program
RIOSORD	Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression
RN	registered nurse
STORM	Strategic Tool for Opioid Risk Management
TMS	Talent Management System
UDS	urine drug screen
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Northern Indiana VA Health Care System (system), Fort Wayne, Indiana, to determine the validity of allegations that (i) system leaders interfered with the opioid prescribing practices of primary care providers (PCPs); (ii) requirements specified in Veterans Health Administration (VHA) Directive 2009-053, *Pain Management*, October 28, 2009, were not followed; and (iii) system leaders failed to meet all goals of VHA's Opioid Safety Initiative (OSI) Update.¹⁰ The OIG further evaluated system compliance with the Office of Medical Inspector's (OMI) November 2017 Blue Cover Report, TRIM 2017-D-2031, that recommended exit interviews for system providers who have left.

Background

The system, part of Veterans Integrated Service Network (VISN) 10, serves veterans in northern Indiana and is composed of two campuses. The Fort Wayne campus has 26 hospital beds; it offers primary and secondary medical and surgical services. The Marion Campus has 75 acute psychiatry beds and 150 nursing home care unit beds; it offers a range of psychiatry services, nursing home care, and extended care services. Primary care clinics are available at both campuses and at community based outpatient clinics (CBOCs) located in Peru, Goshen, South Bend (St. Joseph County VA Clinic), and Muncie, Indiana.¹¹ The system offers outpatient pain management services and mental health services that include Primary Care Mental Health Integration, Psychosocial Rehabilitation and Recovery, and treatment for substance use disorder.¹² In addition, the system utilizes the multidisciplinary team of pain specialists at the Louis Stokes Cleveland VA Medical Center, Ohio, for patients with complex pain management issues.

¹⁰ PCPs identified for the purpose of this report are VA medical doctors and advanced practice nurses who prescribe opioid medications and work in the primary care setting.

¹¹ VISNs deliver VHA health care services to veterans through 18 geographically divided areas in the United States.

¹² This model of care integrates mental health staff into each Primary Aligned Care Team (PACT), which allows care teams to provide services for depression, anxiety, posttraumatic stress disorder (PTSD), and substance use disorders without needing a separate consult with mental health providers outside of the PACT clinic area; Psychosocial Rehabilitation and Recovery Center is an outpatient multidisciplinary treatment program that provides mental health services for veterans suffering from severe and persistent mental illness (for example, schizophrenia, schizoaffective mood disorder, bipolar disorder, major affective disorder, and PTSD with significant functional impairment).

VHA National Pain Management Strategy and Directive

The VHA National Pain Management Strategy was initiated on November 12, 1998, and established pain management as a national priority. It addressed the need to better control untreated pain. The overall goal of the national strategy was to develop a comprehensive, multicultural, integrated, system-wide approach to pain management that reduced pain and improved quality of life for patients experiencing acute and long-term pain.¹³ The VHA Pain Management Directive requires implementation of procedures for the improvement of pain management consistent with the VHA National Pain Management Strategy and generally accepted pain management standards of care.

Opioid Therapy

The use of opioids in the management of pain can be an effective treatment option.¹⁴ Although opioids are commonly prescribed to reduce and/or alleviate pain, long-term opioid use can be harmful because of the increased risk for accidental overdose, abuse, addiction, and diversion.¹⁵ Overdose deaths involving prescription opioids have quadrupled since 1999. In 2016, more than 46 people died every day from overdoses involving prescription opioids.¹⁶ Veterans have almost twice the risk for accidental overdose compared to the general United States population.¹⁷ As a result, clinicians should carefully weigh the benefits of long-term opioid therapy against the potential harmful effects to patients.

Risks with Higher Doses, Long-Term Use, and Forced Tapering

With increasing opioid overdose deaths, the emphasis on opioid prescribing has shifted to opioid dose reduction, increased assessment, and monitoring of patients on long-term opioid therapy. Patients who are prescribed higher doses of opioids are at increased risk of drug overdose death. Several studies observed an increase in the risk of drug overdose deaths when patients are

¹³ VHA Directive 2009-053, *Pain Management*, October 28, 2009. This directive expired October 31, 2014 and has not been updated.

¹⁴ The National Institute on Drug Abuse states, “Opioids are a class of drugs naturally found in the opium poppy plant. Some prescription opioids are made from the plant directly, and others are made by scientists in labs using the same chemical structure. Opioids are often used as medicines because they contain chemicals that relax the body and can relieve pain.”

¹⁵ Drug diversion is the illegal distribution or abuse of prescription drugs or their use for unintended purposes by the prescriber. Centers for Medicare and Medicaid Services. *Partners in Integrity: What is the Prescriber’s Role in Preventing the Diversion of Prescription Drugs?* January 2014.

¹⁶ Centers for Disease Control and Prevention, Prescription Opioid Overdose Data. <https://www.cdc.gov/drugoverdose/data/overdose.html> (The website was accessed on May 23, 2018.)

¹⁷ Elizabeth M. Oliva et al., “Opioid Overdose Education and Naloxone Distribution: Development of the Veterans Health Administration’s National Program.” Supplement, *Journal of the American Pharmacists Association* 57, no. 2 (March/April 2017): S168-S179, <https://doi.org/10.1016/j.japh.2017.01.022>.

prescribed more than 100 morphine equivalent daily dose (MEDD).¹⁸ The Centers for Disease Control and Prevention (CDC) recommends providers avoid prescribing more than 90 MEDD or carefully justifying a decision to prescribe such dosages.¹⁹ VHA's decision opioid tapering tool requirements are consistent with the 90 MEDD CDC prescribing recommendation.

Long-term opioid use carries risks, but rapid or forced opioid tapering in otherwise stable patients can present greater harm. Opioid withdrawal symptoms, or the possibility that the patient substitutes heroin, are important considerations when long-term opioids are discontinued abruptly.

Opioid Safety Initiative and Update

In 2013, the VA Principal Deputy Under Secretary for Health informed Congress that more than 50 percent of veterans receiving care at VHA facilities were affected by chronic pain; that the management of chronic pain in veteran populations was complex; and that VHA developed a two-part system-wide approach to improve the safety and management of long-term pain in veterans. The first part of the system-wide approach was the OSI, and the second part enabled VHA providers to participate in state prescription drug monitoring programs (PDMPs).²⁰ On April 2, 2014, the VA Under Secretary for Health issued a memorandum outlining an expanded framework to the original OSI implemented in 2013, that included nine goals aimed at improving the safety and care of veterans who are prescribed opioids for pain.²¹

¹⁸ Jane A. Gwira Baumblatt et al., "High-Risk Use by Patients Prescribed Opioids for Pain and Its Role in Overdose Deaths." *JAMA Internal Medicine* 174, no. 5 (May 2014): 796-801,

<https://doi.org/10.1001/jamainternmed.2013.12711>; Amy S. Bonhert et al., "Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths." *JAMA* 305, no. 13 (April 2011): 1315-21;

Paulozzi LJ, Kilbourne EM, Shah NG, Nolte KB, Desai HA, Landen MG, Harvey W, Loring LD. *Opioids, Substance Abuse & Addictions Section, Original Research Article: A History of Being Prescribed Controlled Substances and Risk of Drug Overdose Death*. *Pain Med.* 2012 Jan; 13(1): 87-95.

¹⁹ Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. *JAMA.* 2016;315(15):1624-1645.

²⁰ OSI is a comprehensive effort to improve the quality of life for patients suffering from chronic pain and is considered a personalized, proactive, and patient-centered approach to health care; VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*, October 19, 2016. PDMPs are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs. VHA began requiring that providers query state PDMPs at least once annually when prescribing opioids to determine whether the veteran received prescriptions for opioid medications or other controlled substances from non-VA providers.

²¹ Under Secretary for Health Memorandum, *Opioid Safety Initiative Requirements*, April 2, 2014. On December 10, 2014, the Under Secretary for Health issued a second memorandum, *Opioid Safety Initiative (OSI) Updates* that included timelines for five of the nine OSI goals. The timeline for OSI goals 2, 3, 7, and 8 was March 30, 2015; the timeline for Goal 9 was September 30, 2015.

Comprehensive Addiction and Recovery Act

In response to a growing national opioid epidemic and to support the management of patients experiencing acute and long-term non-cancer pain, the Comprehensive Addiction and Recovery Act (CARA) was signed into law on July 22, 2016.²² CARA contained additions to the original OSI goals including a new requirement for VA systems to create pain management teams.²³ VHA required the teams to be in place no later than the following year.²⁴ CARA also required VA systems ensure the use of the Opioid Therapy Risk Report (OTRR) tool, establish standards for the use of routine and random urine drug screens (UDS) before and during opioid therapy, and require all VA employees responsible for prescribing opioids to receive education and training.²⁵

Allegations and Related Concern

On June 12, 2017, the OIG received a confidential complaint alleging that the System Director and Chief of Staff (COS) had interfered with PCPs' opioid prescribing practices and system providers were not adhering to pain management and OSI directives. The OIG Office of Healthcare Inspections Hotline Working Group referred the allegations to the system on September 20, 2017, and the system provided a response on December 13, 2017. The Hotline Working Group found the system's response to be inadequate and initiated a healthcare inspection to review the validity of the allegations:

- System leaders interfered with PCPs' opioid prescribing practices.
- The requirements specified in VHA Directive 2009-053, *Pain Management*, October 28, 2009, were not followed.
- System leaders failed to meet VHA's OSI Update goals.

The OIG also evaluated whether the system was conducting exit interviews as recommended by the 2017 OMI report.

²² CARA of 2016, Pub. L. 114-198, 130 Stat. 695 (2016). CARA authorizes the Attorney General and Secretary of Health and Human Services to award grants to address the opioid abuse crisis.

²³ Under Secretary for Health Memorandum, *Opioid Safety Initiative Requirements*, April 2, 2014; National Association of State Alcohol and Drug Abuse Directors, CARA of 2016 Conference Report: A Section-by-Section Analysis, July 2016.

²⁴ Deputy Under Secretary for Health and Operations Memorandum, CARA Requirements from Section 911 (c) Pain Management Team Facility Report (VAIQ# 7791174), May 18, 2017.

²⁵ VHA states "OTRR is a patient-focused, actionable and provider-specific report that is available to primary care providers, primary care managers, PAC Teams, clinical pharmacists and others who need to identify patients receiving long-term opioid therapy."

Scope and Methodology

The OIG initiated a healthcare inspection on April 20, 2018, and conducted a site visit at the system from June 18 through June 22, 2018.

The OIG team interviewed the complainant, the System Director, COS, Associate COS for Primary Care, Chief of Mental Health, Chief of Education, Risk Manager, Pain Champion, Administrative Officer for Primary Care, Patient Advocate, and pain clinic staff, pharmacy staff, primary care staff from the system and CBOCs, former PCPs, and the Nurse Manager for the Office of Community Care.

Relevant VA/Department of Defense (DoD) and CDC guidelines, OMI reports, VHA directives, VHA handbooks and memoranda, system policy and procedures, committee meeting minutes, medical literature, and the Indiana opioid prescribing law and guidelines were reviewed.

OIG inspectors also reviewed UDS, PDMP, and fiscal year (FY) 2016–FY 2017 opioid prescribing practice data from the Corporate Data Warehouse for VISN 10. The data population included veterans prescribed long-term opioids. When reviewing the data for a completed UDS and PDMP report, the veteran's most recent prescription was selected with a review of the past 365 days to identify further opioid prescriptions. The OIG also reviewed electronic health records (EHRs) for specific veterans discussed in this report who received long-term opioid therapy for pain.

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.

Inspection Results

1. A System Leader Interfered with PCP Opioid Prescribing Practices

The OIG substantiated that a system leader, the COS, interfered with PCP opioid prescribing practices.²⁶ OIG inspectors also received reports of providers feeling “pressure” from the COS regarding their prescribing practices. None of the PCPs interviewed reported being contacted by the System Director regarding their prescribing of opioid medications.

Codes of Conduct

The system’s Medical Staff Bylaws code of conduct addresses behaviors that undermine a culture of safety.²⁷ The Medical Staff Bylaws state,

VA strongly urges its providers to fulfill their obligations to maximize the safety of patient care by behaving in a manner that promotes both professional practice and a work environment that ensures high standards of care...[c]onduct that could intimidate others to the extent that [it] could affect or potentially may affect quality and safety will not be tolerated.

The Indiana Standards of Professional Conduct and Competent Practice of Medicine establishes “standards and protocols for physicians in the prescribing of opioid controlled substances for pain management treatment.”²⁸ According to the COS and a review of the system pain management policy, the system adopted the terms of this rule in October 2017; therefore, the law governs the opioid prescribing practices for system providers.²⁹ Following passage of the law, the state distributed a separate publication, *First Do No Harm*, that stated “the responsibility for proper prescribing is upon the prescribing practitioner.”³⁰

²⁶ The OIG interpreted the term “interfere” to mean interpose in a way that hinders or impedes.

²⁷ Medical Staff Bylaws and Rules of Veterans Health Administration VA Northern Indiana Health Care Systems, Ft. Wayne, Indiana, 2017; Culture of safety in an organization entails maintaining an environment of professionalism that encourages communication and promotes high-quality care. Behavior that undermines a culture of safety, including disruptive or intimidating behavior, has a negative effect on the quality and safety of patient care.

²⁸ 844 IND. ADMIN. Code 5-6-1 (2017).

²⁹ Drug prescribing is a complex event influenced by various factors. The *VA/DoD Clinical Guideline for Opioid Therapy for Chronic Pain* acknowledges that variations in practice are inevitable and appropriately occur when providers consider the needs of individual patients and available resources.

³⁰ State of Indiana, Indiana Prescription Drug Abuse Task Force, *First Do No Harm: The Indiana Healthcare Providers Guide to the Safe, Effective Management of Chronic Non-Terminal Pain, Version 1.0*.

COS Interference with PCP Prescribing

The COS told the OIG that directing a provider in any way regarding opioid prescribing practices with patients is not typical; however, the COS admitted talking to providers on four occasions and “encouraged them to either lengthen the taper or increase the dosage in the taper back to the previous level because, in my judgement, they were being tapered too quickly and were not extending to the patient’s other forms of pain management. So, in a collaborative discussion ... that I can recall, I inserted myself between a patient and provider.” The OIG team reviewed the EHRs related to the four specified instances (occasions) and found that the COS interfered with providers’ opioid prescribing practices.

Occasion 1

A patient with a complex, challenging clinical situation, who was frustrated about their opioid medication management, voiced complaints to the Patient Advocate, COS, and local Congressional office about a planned medication taper.³¹

The patient had been receiving opioids in various preparations from the system since 2009.³² In spring 2016, the patient violated a consent for long-term opioid therapy agreement.³³ The PCP consulted with a pharmacist and started the patient on a taper. The patient objected to the taper, describing it as “neglect,” and reported that the local congressional office had been contacted. On June 30, after the COS called the patient’s PCP and asked that the PCP speak with the patient, the PCP documented “I spoke with vet at [the COS’s] request ... according to the tapering plan, [the patient] should be taking [opioid medication] times per day; vet states that [the patient] is taking it five times daily. I re-read the plan verbatim three times and vet refused to acknowledge the written plan ... the plan is to stay as is; vet is not following the plan and is taking too many [opioid medication]. I have reviewed the medication orders, asking that the next tapering dose #2 go out same day [in 15 days]. I do not intend to change the plan and I will not order more medicine as it is far too confusing and vet is already taking too many ... we are on track and it should proceed smoothly. I am open to discussion but will stay with the plan.” Later that day, the COS directed the PCP to authorize an early opioid medication fill. The EHR entry cited the

³¹ The PCP wrote in the EHR that the patient adheres to the tapering plan; however, the pharmacy refilled the medication 15 days early at the direction of the COS; The OIG uses the singular form of they (their/them) to protect the patient’s privacy.

³² Between 2009 and 2016, the patient received opioids in several forms from the system—hydrocodone with acetaminophen (Vicodin) and three different oxycodone preparations (10mg oxycodone sustained action, 10 mg immediate release, and 15 mg immediate release).

³³ According to the American College of Clinical Pharmacy, “Clinical pharmacists work directly with physicians, other health professionals, and patients with the goal of ensuring that the medications prescribed for patients contribute to the best possible health outcomes;” the patient received an opioid prescription from an outside provider. In May 2014, VHA replaced opioid pain care agreements with templated informed consents; and required that, prior to initiating long-term opioid therapy, prescribers must first complete the informed consent process whereby they discuss the risks, benefits, and alternatives of the treatment with the patient.

involvement of the COS as determinative in the pharmacy's early release of the opioid: "[opioid to be filled] 15 days early ... as directed by COS."

Two weeks later, the COS entered an administrative note in the patient's EHR stating that "Though I have urged [the patient] to continue with the current taper, [the patient] desires to decrease [their] daily dose by one pill each month. I indicated that this alternate regimen would not be supported." The patient told the COS that they would obtain continued opioid doses from an outside provider. The COS noted that, in doing so, the patient would not be able to receive opioids from the system to continue the taper. The patient requested that the COS reassign their care to a different provider and the COS accommodated the request. The COS's record entry stated, "I will notify [the new PCP] of the veteran's situation." The patient continued to receive opioids through the system with no additional opioid tapering during the one-year period under the care of the new PCP, remaining at a dose of 90 MEDD for the year. In summer 2017, another change in PCP assignment was made when the assigned PCP left the system. The latest PCP noted the patient had two consecutive negative UDSs for the opioid that was being prescribed for daily use.³⁴ The PCP informed the patient of the findings and tapered the patient off opioids entirely within a three-week period.

The OIG determined that the patient received an early refill at the direction of the COS, who was a non-prescribing superior, that the PCP would not have otherwise prescribed (in this case an "early fill" of opioid by 15 days).³⁵ The OIG determined that there was no identifiable adverse clinical outcome caused by the COS's actions.

Occasion 2

A PCP, who was concerned about a patient's exacerbation of mental health conditions and the risk of accidental overdose due to the high dosage prescribed, initiated a six-month taper of the patient's opioid medications after consulting with a clinical pain pharmacist.³⁶ The next month, the patient's PCP wrote a note in the EHR addressing it to the COS asking "to be recused from the care of this patient" with the reasoning being that the patient's pain issues were "multifactorial" and required a multidisciplinary team with expertise in pain management. The PCP next noted, "I stopped [the patient's] weaning plan at your [COS] request (which had been ongoing for months, with frequent disruption), and have returned [them] to a combination of long acting opioid (fentanyl patch) and higher frequency of short acting opioid (hydromorphone

³⁴ The Centers for Disease Control states that "Negative urine drug screens for prescribed opioids might indicate the patient is not taking prescribed opioids, although clinicians should consider other possible reasons for this test result." If tests for prescribed opioids are repeatedly negative, the Centers for Disease Control guidelines recommend discontinuing the prescription without a taper.

³⁵ The COS did not have a DEA license to prescribe controlled substances.

³⁶ Tapering describes a medication withdrawal schedule or plan for a patient that gradually reduces the amount of medication a patient is prescribed.

QID [four times a day]). I feel that such a regimen is best reserved for those with end stage or metastatic disease.” The PCP wrote again that the patient’s care was too complicated for the current primary care clinic and “I feel that to continue thus may lead to harm of the veteran, and I am duty-bound to avoid that if possible.” The PCP ended the note “[p]lease consider to reassign all pain issues for [veteran] to those with greater expertise; I will be open to any further suggestions from the executive leadership team.” The patient’s clinical care was subsequently transferred to another PCP.

The OIG determined that there was no identifiable adverse clinical outcome caused by the COS’s actions.

Occasion 3

The PCP of a patient who was undergoing a taper of opioid medications was contacted by the COS to delay the taper of opioid medication. The patient had been moved to the PCP’s panel until a community provider for pain management could be found. According to the PCP, there was not “much of a choice. ...” related to the patient’s opioid prescribing. The COS phoned to say that the “instruction was to just continue [their] opioids as is until [they] saw the pain management provider in the community.” The PCP continued the opioid medication for six weeks until the patient saw a community provider. The community provider performed a magnetic resonance imaging (MRI) scan and when no serious disease was detected, established an opioid tapering schedule. After a disruptive behavior incident at the community provider’s office, the patient was discharged from the community provider's care.

The OIG determined that there was no identifiable adverse clinical outcome caused by the COS’s actions, although it may have prolonged the patient’s dependence on the opioid medication.

Occasion 4

A patient who was on an opioid taper was found in the bathroom sedated during a visit to their assigned VA PCP. The patient reported taking more than the recommended dose of an over-the-counter medication. Laboratory tests performed showed the patient was in renal failure and was admitted to inpatient care.³⁷ While an inpatient, the opioid taper was halted and the patient received the non-weaning regimen of opioids. Within a week after discharge, the patient was informed by the then-VA PCP that the taper would continue due to the overdose and lack of significant disease.

The COS contacted the patient’s PCP after this encounter and recommended referring the patient to another pain doctor in the community and maintaining “the status quo for the time being” in reference to the opioid taper. When the community pain management providers declined to see

³⁷ Renal or kidney failure means that the kidneys have lost most of their ability to function.

the patient, the patient requested a change of system providers. The PCP was copied on an email from the COS to the system's Interventional Pain Specialist to ask if they should honor the patient's change of provider request. The Interventional Pain Specialist said they should honor the request for a provider change, and a new PCP who continued to prescribe opioid medications with no taper was assigned.

The OIG determined that no adverse clinical outcomes were caused by the COS's actions although, it may have prolonged the patient's dependence on the opioid medication.

PCPs Report of COS Pressure to Prescribe Opioids

OIG asked 26 system PCPs if they experienced pressure from the COS to prescribe opioids. Apart from the occasions noted above, the OIG team identified three PCPs who reported experiencing pressure from the COS regarding their opioid prescribing practices.

One of the three PCPs who reported experiencing pressure from the COS told the OIG team that although the COS did not direct the PCP to prescribe an opioid refill for a patient, the COS called the office manager and questioned the PCP's plan of care for the patient's opioid refill request. According to the PCP, the office manager stated the following " [the COS is] not telling you what to do but [the COS] wants to know what you can do about this patient." The PCP was covering for another practitioner at the time, was not familiar with the patient, and felt pressured to prescribe opioids due to the COS's leadership position. The PCP reviewed the EHR and noticed the patient had not been seen for at least four months, as required by Indiana state law, and therefore did not want to write the opioid prescription refill until the patient was seen.³⁸ In regard to the COS's message, the PCP stated:

I was uncomfortable with that because you know as a physician the COS calls [and said] see what you can do. You know [the COS] is influential by virtue of [the] position. ... I felt that [the COS] was a little bit overly involved in that case. And I felt like perhaps [the COS] might be pushing me to do something which was actually illegal to do if I just wrote the prescription and went on.

The PCP noted feeling a need to satisfy the COS's and patient's desires to do something and wanted to comply with Indiana law to see the patient every four months while prescribing opioids; therefore, the PCP saw the patient the same day during the lunch break and subsequently filled the opioid prescription.

³⁸ The state of Indiana required patients on opioids to be seen at least every four months. The facility adopted the terms of the Indiana statute into their pain management policy in October 2017, and required providers to see patients who are prescribed opioids at least every four months.

2. VHA's Pain Management Directive Requirements Not Followed

The OIG substantiated that not all requirements specified in VHA Directive 2009-053, *Pain Management*, were followed. The OIG team found the system did not adhere to the VHA requirements for pain management oversight and monitoring by the Pain Management Committee, monitoring the quality of pain assessments, evaluating the system's compliance with the goals of VHA's Pain Management Strategy, and implementing all aspects of the stepped care model for pain management.

System Director Responsibilities

The System Director is responsible for ensuring that

- A multidisciplinary Pain Management Committee is established;
- Outcomes and quality of pain management are evaluated;
- VHA National Pain Management Strategy objectives are met;
- A stepped model of pain care is fully implemented;
- Accepted standards of pain care specified by VHA, including pain assessment and treatment, are met; and
- Clinical competence and expertise in pain management is obtained and maintained by staff.³⁹

Pain Management Committee

VHA requires systems to “provide oversight, coordination, and monitoring of pain management activities and processes to facilitate the implementation of the VHA Pain Management Strategy in compliance with evidence-based standards of pain care and adherence to requirements of external accrediting bodies.”⁴⁰ System processes are required “to evaluate the success of meeting the goals of the VHA National Pain Management Strategy on a regular basis, at least yearly.”⁴¹ In some systems, this function may be the responsibility of an overarching clinical practice committee such as the system's Pain Management Committee. The OIG did not find that the system's Pain Management Committee was meeting the overarching goals required by VHA regarding oversight and monitoring of pain management activities.

The OIG reviewed Pain Management Committee minutes from FY 2016 Q1 through FY 2018 Q1 and found the system's Pain Management Committee met monthly with the exception of

³⁹ VHA Directive 2009-053.

⁴⁰ VHA Directive 2009-053.

⁴¹ VHA Directive 2009-053.

July, August, and November 2016. The committee agenda and meeting minutes did not show that oversight and monitoring of system pain management activities consistently occurred. A standing agenda item under the committee's new business items included OSI metrics.⁴² Documentation showed the OSI data were presented at five of the 12 (41 percent) meetings. Documentation of the discussion related to the OSI metrics was detailed in one of five (20 percent) committee meeting minutes. Overall, the Pain Management Committee meeting minutes showed inconsistency in the oversight and monitoring of the system's pain management activities.⁴³

System Leaders' Review of Quality Outcomes and VHA's National Pain Management Strategy Goals

The system's Clinical Executive Board (CEB) is responsible for the ongoing review, evaluation, and quality activities to ensure full compliance with VHA's directives and performance requirements. According to the COS, the CEB reported quarterly to the system's Executive Council, which the COS likened to a civilian Board of Directors.⁴⁴ Additionally, the COS stated, the Pain Management Committee reported the activities of the Pain Management Committee and OSI Subcommittee quarterly to the CEB (the system's "governing structure").⁴⁵

A review of the system's CEB meeting minutes from FY 2016 through FY 2017 lacked documentation that the system

- Monitored the quality of pain assessments and the effectiveness of pain management intervention, or

⁴² OSI metrics include an aggregate of data routinely provided to facilities for benchmarking that includes patients prescribed opioids, presence of UDS, concurrent opioids plus benzodiazepines, and patients on high dose opioids.

⁴³ According to VHA Directive 2009-053, the system director is responsible for oversight of a system's pain management activities.

⁴⁴ The CEB was co-chaired by the Associate COS and the facility pain psychologist. The Executive Council was chaired by the System Director and comprised the executive leaders, the Chief of Quality Management, and the Compliance Officer.

⁴⁵ The facility charter for the OSI Subcommittee complements the broader focus of the system's Pain Management Committee. The Subcommittee reviews EHRs for quality reviews and reports outcomes to the Pain Management Committee.

- Evaluated their success in meeting the goals of the VHA National Pain Management Strategy.⁴⁶

According to the COS, the CEB relied on the Pain Management Committee for the reporting of pain management activities. However, the Pain Management Committee failed to consistently report pain management activities to the CEB, the “governing structure” for quality oversight. Without this, the CEB was unable to consistently and effectively communicate the system’s pain management quality outcomes to the Executive Council, which according to the COS, relied on the CEB for pain management oversight. Further, without accurate and consistent pain management data and information, leadership was unable to effectively evaluate the system’s success in meeting the VHA National Pain Management Strategy goals. The OIG determined that system leadership lacked consistent commitment to the oversight of the system’s Pain Management Committee which potentially affected the quality of the system’s pain management activities.

VHA’s Stepped Care Model for Pain Management

VHA’s Pain Management directive describes a stepped care pain management model that provides a continuum of treatment to patients suffering from acute pain that typically lasts for more than 90 days, and requires use of the model in clinical practice.⁴⁷ Six of seven (86 percent) PCPs who were asked about stepped care by the OIG reported they were not aware of the step-wise approach to pain management, while one confirmed being aware of the model but unable to describe the approach. Despite the lack of PCP awareness of the model, the OIG found the system had generally implemented all steps of the model other than the establishment of a formal referral process when patients needed tertiary pain management care at another facility.

⁴⁶ VHA Pain Management Directive gives examples of ways to measure quality of pain assessments and the effectiveness of pain management interventions to include: adherence to published clinical practice guidelines, timeliness of pain treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment including behavioral health and pain medicine consultation and treatment, and clinical outcomes such as improvements in pain control, patient satisfaction, physical and psychosocial functioning, and quality of life. The Medical Staff Bylaws state the CEB is a committee responsible for the system’s medical executive function. The CEB considers findings from ongoing monitoring and evaluation of the quality and appropriateness of patient care and treatment.

⁴⁷ VHA Directive 2009-053. In contrast to chronic pain, acute pain is pain that typically lasts less than three to six months, or pain that is directly related to soft tissue damage such as a sprained ankle or a paper cut. Acute pain is of short duration, and it gradually resolves as the underlying cause has been treated or heals.

Step 1: Primary Care

Step 1 of the pain management care model requires the development of a competent PCP workforce to manage common pain conditions.⁴⁸ The system demonstrated compliance with Step 1 through

- Development of a competent PCP workforce evidenced by documentation of PCPs' one-time requirement of online Talent Management System (TMS) pain management education and pain management education provided during monthly primary care team meetings,⁴⁹
- Primary care clinic access to mental health providers either through mental health staff integration on teams or access to mental health providers through a consult process,
- Provision of pain education groups for patients, and
- Use of patient informed consent forms documented in the EHR.

The informed consent form includes patient and family education of the risks, benefits, and alternatives to long-term opioid therapy for pain management. Additionally, it details education about the appropriate use and dispensing of opioids; and the fact that VA is authorized to disclose and obtain patient information from the state PDMP to prevent misuse and diversion of prescription medication. The OIG reviewed the system's informed consent compliance data of PCPs from FY 2016 Q1 to FY 2018 Q1 and found that 58 of 63 (92 percent) providers completed informed consents when prescribing opioids greater than or equal to 80 percent of the time.

Besides opioid therapy for pain management, the system offered at least two Complementary and Integrative Health (CIH) therapies. CIH therapies are treatment methods used to treat long-term pain without the utilization of opioid prescriptions. Providers often prescribe CIH therapies for their "holistic, individualistic, empowering, and educational nature."⁵⁰ CIH therapies encourages veterans to have self-determination when it comes to their own health and promotes healing.⁵¹

⁴⁸ In this report, behavioral health is referred to as mental health.

⁴⁹ TMS is a VA web-based application that serves as the single point of access for all VA employees to view national and local learning catalogs, register for available offerings, launch on-line courses, record completed learning activities, and access their learning transcript.

⁵⁰ Sara Fleming et al. "CAM Therapies among Primary Care Patients Using Opioid Therapy for Chronic Pain." *BMC Complementary and Alternative Medicine* 7:15, (2007): 1, <https://doi.org/10.1186/1472-6882-7-15>.

⁵¹ Self-determination is defined as free choice of one's own acts or states without external compulsion.

The system CIH alternatives included: Battlefield acupuncture, aqua therapy, traditional acupuncture, massage therapy, tai chi, yoga, taekwondo, and mental health services.⁵²

Step 2: Secondary Consultation

Step 2 of the pain management care model requires PCP access to specialty consultation for pain management. While the system had two pain psychologist positions, one of the positions was vacant, and as of April 2019, the system was not pursuing filling it.⁵³ The pain psychologist offered cognitive behavioral therapy to veterans and completed biopsychosocial assessments of veterans' pain for providers.⁵⁴ The pain psychologist stated other mental health staff were also trained in cognitive behavioral therapy and that the system offered chronic pain self-management workshops. In addition, according to the system pain interventionalist, who was a medical doctor with expertise in pain management, the position provided consultation services to providers and offered surgical based treatment options for chronic pain management.

Step 3: Tertiary Interdisciplinary Care

Step 3 of the pain management care model requires that each VISN have an advanced pain medicine diagnostic and pain rehabilitation program by the Commission on Accreditation of Rehabilitation Facilities.⁵⁵ The system used the VISN 10 advanced pain management program at Louis Stokes Cleveland VA Medical Center for veterans with complex pain management problems.⁵⁶ According to staff, "because of the lack of a formal referral process, the cost of housing and transportation was not available which may have limited access to the program for those without the needed financial resources who would have benefited from an in-person

⁵² Battlefield acupuncture is a variation of acupuncture that uses one or more needles inserted into any of five points on the ear. It is reported to influence central nervous system pain processing through its effects on the body by releasing endorphins to elicit short term analgesic or anti-inflammatory effects.

⁵³ Consultation providers include the pain clinic, physical medicine, and rehabilitation, polytrauma programs, inpatient pain medicine, and collaboration with palliative care.

⁵⁴ The Mayo Clinic defines cognitive behavior therapy as "a common type of talk therapy or psychotherapy." *Foundations of Psychology* states, "Biopsychosocial assessments use a comprehensive, integrative framework for understanding human development, health and functioning based on a perspective that humans are inherently biopsychosocial organisms in which biological, psychological, and social dimensions are inextricably intertwined."

⁵⁵ VHA Directive 2009-053. Commission on Accreditation of Rehabilitation Facilities is an independent, nonprofit accreditor of health and human services. Through accreditation, Commission on Accreditation of Rehabilitation Facilities assists service providers in improving the quality of their services, demonstrating value, and meeting internationally recognized organizational and program standards.

⁵⁶ VISN 10 comprises 10 medical centers, the independent Columbus, Ohio, Ambulatory Care clinic, and a network of 58 CBOCs.

evaluation.” There was, however, some availability of services from Louis Stokes via Clinical Video Telehealth.⁵⁷

Clinical Expertise in Pain Management

VHA’s Pain Management Directive outlines nine specific objectives.⁵⁸ Two objectives in VHA’s Pain Management Directive provide guidance on clinical competence and expertise in pain management. The goal of the first objective is to “[e]stablish expectations for attitudes, knowledge, and skills in pain management in primary, secondary, and tertiary care.” The goal of the eighth objective seeks to “[p]romote standardized education and training to ensure that clinicians achieve standard competencies appropriate to their clinical setting ([for example], primary care, acute pain, pain medicine) and clinical role.”⁵⁹ Education and training must be relevant to the specific needs of the veteran population and clinical setting that provider groups serve. Clinical staff should receive initial orientation and five hours annually of ongoing education and training related to the principles of pain assessment and management.⁶⁰

A staff member told the OIG, “[t]he system lacked an ongoing standardized pain management and opioid safety education program for providers.” System documentation showed that 20 of 42 (47 percent) PCPs received ongoing training in pain management and opioid safety. Ongoing training included opioid presentations at staff meetings, town halls and seminars, additional TMS courses, and acupuncture certification which were tracked and monitored by the primary care Associate Chief of Staff. Primary Care staff indicated system PCPs were assigned the TMS course, “Pain Management and Opioid Safety,” as a one-time requirement. A review of the TMS records showed that 38 of the 42 (90 percent) PCPs completed the mandatory TMS pain education course.

Pain Management Team

To evaluate compliance with VHA’s requirement for pain management teams as outlined in the May 18, 2017, Deputy Under Secretary for Health for Operations and Management Memorandum, the OIG reviewed the system’s implementation of the pain management team. The OIG determined that the system had identified team members and created a consult template. A charter had been created but was unsigned. Pain management team membership included representation from the pain clinic, physical medicine and rehabilitation, behavioral pain medicine, addiction medicine, the pain pharmacist, and ad hoc members. The COS stated a pain management team had been established but was not meeting because no cases had been

⁵⁷ Clinical Video Telehealth technology in VA is videoconferencing-based and enables patient and provider participants at separate locations to see and hear each other and interact in real-time.

⁵⁸ VHA Directive 2009-053.

⁵⁹ VHA Directive 2009-053.

⁶⁰ VHA Directive 2009-053.

referred. The COS acknowledged there was not a formal consult process in place. Staff reported they were unaware a team existed. The system subsequently told the OIG that as of July 2018, the pain management team was active.

The system pain champion identified the biggest challenge in managing the care of veterans with complex pain management issues who were often on long-term opioid therapy was the lack of consultative help.⁶¹ These veterans were either referred to the community or sent to another VA facility that had providers who specialized in treating veterans with complex pain management problems.⁶² The OIG determined that at the time of the site visit, the absence of a pain management team showed not only that the system was not in compliance with the Deputy Under Secretary for Health for Operations and Management memorandum but also that leadership lacked commitment to VHA's overall Pain Management Strategy.

System Pain Management Policy

System policy, *Long-Term Opioid Use for Chronic Pain MGMT*, required PCPs to routinely review opioid risk assessment tools when monitoring patients on long-term opioid therapy.⁶³

Patient Risk Mitigation Informatic Tools

VHA utilizes informatic tools for opioid risk assessments to assist PCPs in mitigating the risk for veterans who are prescribed opioids and other potentially harmful medications.⁶⁴ The risk assessment tools offer providers a list of evidence-based clinical recommendations for risk alleviation, such as drug screening tests, bowel regimens, and treatment alternatives to opioid prescription. Routine use of the following informatic tools by providers permits VHA to fulfill its commitment to enhancing the safe and efficacious health care of veterans who are prescribed opioids:

⁶¹ A Primary Care Pain Champion is a health care provider responsible for making certain other doctors adhere to opioid safety strategies. The VHA Pain Management Strategy created this position in 2015 and mandates each facility maintain someone in that role.

⁶² The VA offers pain management care through community providers paid for by the Department of Veterans Affairs. If the VA cannot provide the care that a patient needs in a timely manner or the nearest VA medical facility is too far away or too difficult to get to, then the patient may be eligible for care through the VA community care program(s).

⁶³ Long-term opioid therapy is also considered chronic opioid therapy; VAIHCS 11-89-17, *Long-Term Opioid Use for Chronic Pain MGMT*, October 2017.

⁶⁴ Risk mitigation involves tools or strategies to prevent, monitor and /or manage specific serious risk to the patient associated with a drug. Health informatics is defined as the interdisciplinary study of the design, development, adoption, and application of information technology-based innovations in health care services delivery, management, and planning. Health informatics tools include clinical guidelines, formal medical terminologies, computers, and information and communication systems.

- The Stratification Tool for Opioid Risk Mitigation (STORM) tool is available to providers in the Computerized Patient Record System (CPRS) pain management note.⁶⁵
- The Acting Associate COS of Primary Care stated that the OSI Committee used the STORM tool to identify high-risk patients on opioids for quality of care reviews of patient records and also indicated that the OSI Committee used the information to “let the PCP know that these are the very high STORM score [*sic*], and based on this we need to have action plan on starting non-opioid, trying to start discussion with patient that opioid needs to be tapered.”
- The Opioid Therapy Risk Report (OTRR) tool is a provider-specific tool that identifies patients on long-term opioid therapy. System’s Administrative Officer for Primary Care stated the OTRR is accessible through the VHA Support Service Center that he accessed monthly and provided a report to each PCP with the names of their patients on long-term opioid therapy.
- The Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIOSORD) tool identifies a risk score for respiratory depression and overdose on opioids. Administrative Officer for Primary Care indicated that RIOSORD was accessible through the VHA Support Service Center within the OTRR tool.

Usage of Risk Assessment Tools

The OIG asked 13 PCPs if they used VHA opioid risk mitigation tools such as the STORM, the OTRR, and the RIOSORD to manage veterans on opioid therapy:

- Thirty percent of PCPs interviewed used OTRR.
- Sixty-nine percent of PCPs interviewed used STORM.
- Twenty-three percent of PCPs interviewed used RIOSORD.
- Fifteen percent of PCPs interviewed reported they did not use any type of opioid risk management tools.

Providers reported the following reasons for not using the risk assessment tools:

- Although the STORM hyperlink was present in the system’s pain management note, the information had to be cut and pasted into the note, which required additional time.
- The STORM tool was difficult to use, and no training had been provided.
- Lack of awareness of other tapering protocols and reliance on the pharmacist for opioid consults.

⁶⁵ The Computerized Patient Record System is a Veterans Health Information Systems and Technology Architecture computer application that allows the user to enter, review, and continuously update patient information.

- Unfamiliarity with the STORM too altogether.

Veteran Requests for a Provider Change Due to Provider Opioid Prescribing

When interviewed, the COS reported that provider changes made at the request of patients because of providers' opioid prescribing practices started to be permitted on a case-by-case basis upon the arrival of the new System Director. System PCPs reported that veteran requests for provider changes were granted. Administrative staff reported that the System Director believed veterans should have the opportunity to find a provider they are comfortable with so a meaningful relationship could develop. A review of Primary Care opioid safety analysis documentation showed that PCPs requested that the system stop this practice. System policy, *Long-Term Opioid Use For Chronic Pain MGMT*, provided guidance that patient "shopping" or seeking a change in provider with the intent to seek opioids or to increase their opioid dose from another prescriber, is inappropriate and will not be condoned.⁶⁶ The system practice of allowing patients to change providers' due to complaints about opioid prescribing was not consistent with system policy and disrupted prescribers' attempts to effectively and safely manage opioid use.

3. OSI Update Goals

The OIG substantiated that system leaders did not meet all nine goals of the OSI Update; six were met, and three were partially met. (See Table 1.)

⁶⁶ System Policy 11-89-17, Long-Term Opioid Use for Chronic Pain MGMT, October 2017.

Table 1. OSI Goals Compliance Status

	Goals	Status
Goal 1	Educate prescribers of opioid medication regarding effective use of UDS.	Met
Goal 2	Increase the use of UDS.	Met
Goal 3	Facilitate the use of state PDMP databases.	Partially Met
Goal 4	Establish safe and effective VISN tapering programs for patients using the combination of benzodiazepines and opioids.	Partially Met
Goal 5	Develop tools to identify higher risk patients.	Met
Goal 6	Establish systems for tapering high-risk opioids.	Partially Met
Goal 7	All VHA facilities will identify patients on greater than 200 mg/ MEDD.	Met
Goal 8	Offer at least two CIH modalities for chronic pain at all facilities.	Met
Goal 9	Develop new model of mental health and primary care collaboration to manager prescribing of opioid and benzodiazepines in patients with chronic pain.	Met

Source: Acting Deputy Undersecretary for Health for Operations and Management Memorandum, Opioid Safety Initiative (OSI) Updates, December 10, 2014; OIG analysis of system data, information, and interviews

Goal 1: Education for Providers on the Use of UDS

The system provided education on the safe and effective use of UDS through a TMS course called “Pain Management and Opioid Safety.” The OIG reviewed TMS certificates for the course and found 38 of 42 (90 percent) of current PCPs completed the course.

Goal 2: Increase the Use of UDS

The system had increased the use of UDS for patients who were prescribed opioids. According to the *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, a UDS is recommended for all patients prior to and during opioid therapy, and the VA Educational Guide,

VA Pain Management Opioid Safety, recommends a UDS be completed at least yearly and more frequently based on patients' risk.⁶⁷

The OIG reviewed provider UDS data for patients on long-term opioids at the system for FY 2016 and FY 2017 and found that the use of UDS at the system had increased by one percent during this period (see Figure 1).

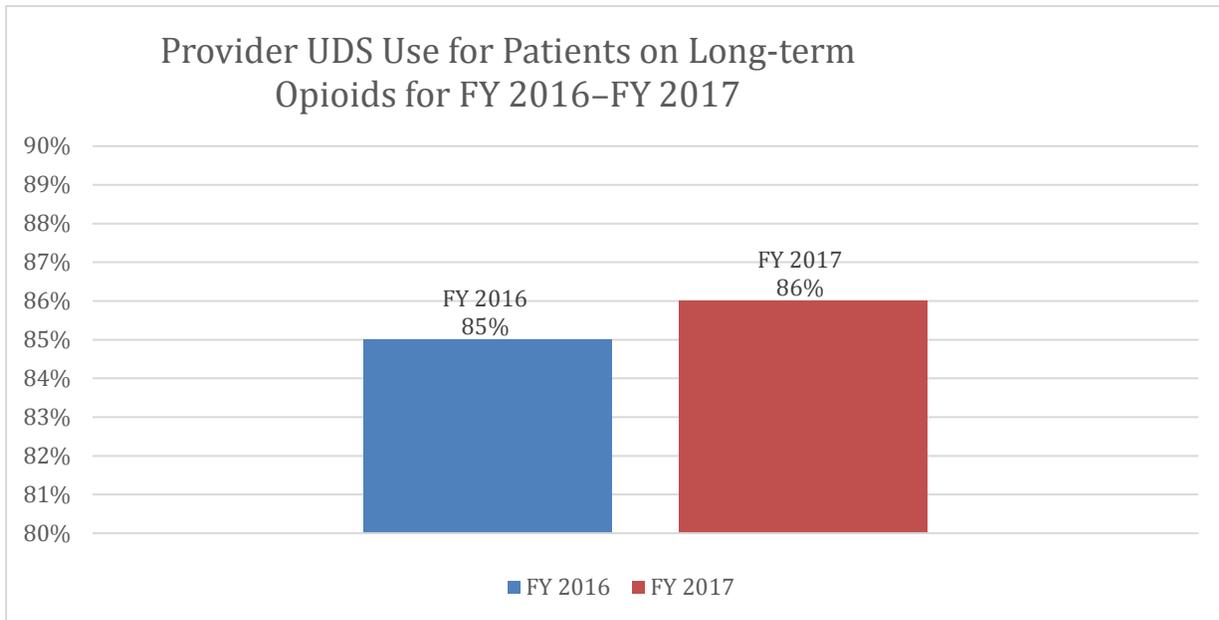


Figure 1. Percentages of completed UDS for FY 2016 and FY 2017; FY 2018 data were incomplete at the time of the OIG analysis and not included in the evaluation.

Source: OIG analysis of VISN 10 data from the Corporate Data Warehouse

Although some PCPs did not consistently use UDS, the OIG team found 52 of 63 (83 percent) providers completed a UDS at least yearly for patients greater than or equal to 80 percent of the time.⁶⁸ In addition, the OIG found that 770 of 845 (91 percent) patients had a UDS as recommended.

⁶⁷ *VA/DoD Clinical Practice Guideline: Management of Opioid Therapy for Chronic Pain*, (May 2010). In February 2017, Version 3.0 of the guideline was issued to help clinicians improve pain management therapies, as well as the quality of life and care of patients with long-term non-cancer pain. The guideline includes criteria to help clinicians determine if opioid therapy is an appropriate treatment option and includes protocols for patient assessment and monitoring, evaluation of a patient's response to opioid therapy, and protocols for adjusting and discontinuing opioid therapy; VA Pain Management Opioid Safety, VA Educational Guide (2014).

⁶⁸ Eighty percent is the benchmark agreed upon by the OIG team for the OSI metrics.

Goal 3: Facilitate the Use of State PDMP Databases

The OIG found the system facilitated the use of PDMPs through providing provider training; however, some PCPs were not consistently utilizing the state PDMP databases when prescribing opioid medication. Providers were given education on the use of state PDMPs through the TMS course “Pain Management and Opioid Safety.” The OIG reviewed TMS certificates for the course and found 38 of 42 (90 percent) of current PCPs had completed the course.

In October 2016, VHA required PDMP reports to be completed at least yearly on patients being prescribed opioids.⁶⁹ The OIG reviewed PDMP use data from FY 2016 Q1 through FY 2018 Q1 and determined that the use of the state databases was increasing. The OIG found 26 of 63 (41 percent) providers completed PDMP reports at least yearly greater than or equal to 80 percent of the time.

Seventeen of the 19 (89 percent) PCPs questioned reported that PDMP reports were being completed for patients on long-term opioid therapy. PCPs noted that PDMP reports were time consuming to complete and that up until a year ago, registered nurses (RNs) were obtaining the reports for them. The Chief Nurse for Ambulatory Care stated that the RNs ceased accessing the PDMP report after guidance received from the VA Central Office in October 2017 stating that RNs did not meet the definition of a practitioner in Indiana.⁷⁰ RNs could not access PDMP reports because they were not included in the category of persons permitted by Indiana law to receive this information.⁷¹

Goal 4: Establish Safe and Effective VISN Tapering Programs

The system had established VISN opioid tapering protocols for utilization by PCPs; however, 9 of 10 (90 percent) PCPs reported they did not know where to find tapering protocols and that they consulted with the clinical pain pharmacist when tapering patients off opioids. The OIG concluded that PCPs’ reliance on the clinical pain pharmacists for opioid tapers due to their own

⁶⁹ VHA Directive 1306, Querying State Prescription Drug Monitoring Programs, October 19, 2016.

⁷⁰ The Indiana Code defines a practitioner as “a physician, dentist, veterinarian, podiatrist, nurse practitioner, scientific investigator, pharmacist, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in the United States.” IND. CODE § 35-48-7-5.8 (2017).

⁷¹ INSPECT is the Indiana state prescription drug monitoring program (PDMP). IND. CODE § 35-48-7-5.2 (2017). While practitioners or practitioners’ agents certified to receive information from the INSPECT program are authorized to access this information, a “practitioner” under this program “means a physician, dentist, veterinarian, podiatrist, nurse practitioner, scientific investigator, pharmacist, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in the United States.” IND. CODE § 35-48-7-5.8 (2017). *See also* IND. CODE § 35-48-7-11.1 (2017).

inability to locate tapering protocols could potentially overburden the system's clinical pain pharmacists with opioid taper consult requests.

Goal 5: Develop Tools to Identify High-Risk Patients

The system facilitated the use of VHA informatic risk assessment tools to identify high-risk patients although not all PCPs consistently used them.⁷² The OIG found that the system used the STORM, OTRR, and RIOSORD tools for risk assessment. The system provided STORM and OTRR education at the September 12, 2017, medical staff meeting, where attendance records showed 26 of 28 (93 percent) PCPs were present.

Goal 6: Establish Systems for Tapering High-Risk Opioids

Although the system established protocols for tapering high-risk patients on opioids such as sustained action oxycodone, hydromorphone, and methadone, when PCPs were interviewed, seven of 10 (70 percent) were not aware of the protocols or where to find them.⁷³ As noted earlier, PCPs reported they consulted the clinical pain pharmacists when tapering patients on high-risk opioid therapy. Of concern, reliance on the clinical pain pharmacist for opioid tapering protocols does not promote the development of clinical competence of PCPs in pain management, which VHA's Pain Management Directive requires.⁷⁴

In VHA, PCPs provide the bulk of care for patients requiring pain management. The delivery of pain management care consistent with guidelines can be time consuming and when patients receiving such care are prescribed long-term opioids as well, the demands on the provider may be increased considerably compared to the delivery of routine care. The availability of resources such as opioid tapering protocols, when used, enables PCPs to provide more efficient and enhanced care to patients.

Due, at least in part, to VHA's OSI and subsequent changes in providers' prescribing practices, virtually all of the system's PCPs have been involved in the effort to taper opioid regimens in long-term non-cancer pain patients. Data showed that the number of veterans receiving long-term opioids decreased by two percent from FY 2016 to FY 2017. In addition, the OIG team found that when comparing FYs 2016 and 2017, the system had decreased the number of patients on long-term opioid therapy and high-dose opioids each year by four percent.

⁷² Informatics is the VHA infrastructure that supports its EHR and enables providers to review and analyze patient clinical data, order laboratory tests and medications, document care and other data and support clinical decision making.

⁷³ Sustained action is an example of an extended release drug product. A dosage form that allows at least a twofold reduction in dosage frequency as compared to a drug presented as an immediate release form.

⁷⁴ VHA Directive 2009-053.

Goal 7: Identify Patients on Greater than 200 MEDD

The system met the one-time requirement of identifying patients on opioid therapy greater than 200 MEDD and put processes in place to monitor patient MEDD levels.

Updated guidance from the CDC stated that patients on 90 MEDD are considered on high-dose opioid therapy.⁷⁵ According to interviews with one PCP and an Administrative Officer for Primary Care, the system's process identifies patients on greater than 50 MEDD using the OTRR monthly. According to the Administrative Officer for Primary Care, the list of identified patients was emailed each month to PCPs for their attention.

Goal 8: Provide at Least Two CIH Modalities

The system offered at least two different CIH modalities for pain management. The modalities included Battlefield Acupuncture, aqua therapy, traditional acupuncture, massage therapy, tai chi, yoga, taekwondo, and mental health interventions. The Goshen and Muncie CBOCs did not have two CIH therapies available on-site; however, patients were offered CIH therapies through community care.⁷⁶ Twenty-two of 25 (88 percent) current PCPs interviewed at Fort Wayne and Marion campuses, Peru CBOC, and the St. Joseph Clinic reported at least two CIH modalities available for their patients.

In interviews with the system's VA Office of Community Care Nurse Manager and PCPs, wait time for CIH therapy in the community was reported to be less than 30 days from the preferred date of appointment.⁷⁷

Goal 9: Develop New Model of Mental Health and Primary Care Collaboration

The system offered mental health support to patients when the PCP was managing veterans prescribed long-term opioids in addition to long-term opioids in conjunction with benzodiazepines. Primary Aligned Care Teams at the Marion Campus, Fort Wayne Campus, and St. Joseph Clinic had Primary Care Mental Health Integration.⁷⁸ Although not integrated in primary care, the remaining sites had mental health staff on-site and accessible. Clinical video telehealth was available for use by mental health professionals at all sites and cognitive

⁷⁵ Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. *JAMA*. 2016; 315(15):1624-1645.

⁷⁶ Community care includes non-VA care such as the Veterans Choice program provided to veterans eligible for VA health care that is paid for by VA when the necessary care is not readily available at VHA.

⁷⁷ The preferred date is the date the patient would like to be seen.

⁷⁸ The purpose of Primary Care Mental Health Integration is to enhance access to mental health services and promote effective treatment of common mental health and substance use problems for patients treated in primary care settings.

behavioral therapy was provided at the Marion Campus, Fort Wayne Campus, Muncie CBOC, and St. Joseph Clinic.⁷⁹ In addition, the system had a pain psychologist who saw patients at the Fort Wayne campus. At the time of the OIG site visit, one pain psychologist position was vacant; as of April 2019, the facility was not pursuing filling the vacant psychology position. Twenty of 25 (80 percent) current PCPs reported that mental health care was available as a support to their patients.

4. Follow-Up to Exit Interviews Recommended by VHA's Office of the Medical Inspector

In response to a request by the Chairperson of the House Committee on Veterans' Affairs, VHA's Office of the Medical Inspector (OMI) conducted a review to assess allegations that abuse of authority by system leaders created a hostile work environment and contributed to physician attrition.⁸⁰ The report did not substantiate allegations of abuse of authority by system leaders or that physicians were leaving the system due to a hostile work environment. However, the OMI found that the system did not conduct exit interviews to identify a physician's reasons for leaving employment. The OMI recommended that the system implement a process of exit reviews for providers and staff leaving employment at the system to identify opportunities for improvement and decrease attrition of staff.

The OIG found that the system was conducting voluntary exit reviews with PCPs who left employment as the 2017 OMI Blue Cover Report recommended.⁸¹ Since November 2017, the system had three PCPs who left employment. The system reported that all three PCPs who left were given the opportunity for an exit interview, and one of the three PCPs participated in the review.

⁷⁹ Cognitive behavioral therapy is "a form of psychotherapy that treats problems and boosts happiness by modifying dysfunctional emotions, behaviors, and thoughts. Unlike traditional Freudian psychoanalysis, which probes childhood wounds to get at the root causes of conflict, cognitive behavioral therapy focuses on solutions, encouraging patients to challenge distorted cognitions and change destructive patterns of behavior." <https://www.psychologytoday.com/us/basics/cognitive-behavioral-therapy>. (The website was accessed January 21, 2019.)

⁸⁰ The Office of the Medical Inspector is an "office within VHA that independently investigates health care issues raised by veterans and other stakeholders to monitor and improve the quality of care provided by VHA." <https://www.va.gov/health/medicalinspector/>. (The website was accessed on January 17, 2019.)

⁸¹ Office of Medical Inspector's November 2017 Blue Cover Report, TRIM 2017-D-2031.

Conclusion

The OIG substantiated that on four occasions a system leader, the COS, interfered with providers' opioid prescribing practices. The COS told the OIG team "I inserted myself between a patient and provider" when the veteran did not agree with the PCP's treatment recommendations that included the tapering of opioid medications. The OIG reviewed the EHRs with the four specified occasions and found that on Occasion 1 the COS was very clear when instructing the PCP to approve an early opioid medication fill that affected a clinical outcome. On Occasion 2, the COS requested the provider to stop an opioid tapering plan. On Occasions 3 and 4 the COS instructed that current dosages be continued notwithstanding plans of care to the contrary. The OIG reviewed the four occasions and did not identify adverse clinical outcomes, although the continuation of opioids may have prolonged dependence on the opioids.

The OIG also identified three of 29 (10 percent) interviewed providers who reported experiencing pressure from the COS in some manner related to opioid prescribing practices. One of the three identified providers reported feeling an obligation, due to the COS's position, to comply with the COS's request for the patient's opioid refill request despite the patient not having been seen at the visit frequency required by Indiana state law. The provider saw the patient during the lunch hour and prescribed an opioid refill to meet the COS's request.

The OIG substantiated that the system did not follow all requirements specified in VHA Directive 2009-053, *Pain Management*:

- The Pain Management Committee did not provide consistent oversight and monitoring of the pain management activities.
- Leaders did not monitor the quality of pain assessments and effectiveness of pain management interventions.
- Leaders did not annually evaluate their success in meeting the goals of the VHA National Pain Management Strategy.
- The system lacked a formal referral process for a tertiary, interdisciplinary pain rehabilitation program for complex cases.
- The system lacked an ongoing standardized pain management and opioid safety education program for providers.

The OIG evaluated the system's compliance with VHA's requirement for pain management teams as outlined in the May 18, 2017, Deputy Under Secretary for Health for Operations and Management Memorandum. VHA requires pain management teams to be located at each system to comply with CARA requirements. At the time of this report, the system reported the team was active.

The OIG reviewed the system's pain management policy requirement for providers to routinely use opioid risk assessment tools for patients on long-term opioid therapy and determined that not all PCPs used the tools. OIG found that 15 percent of PCPs questioned did not use the risk

assessment tools for opioids and other medications. PCPs reported the following reasons for not using the tools: time required to copy and paste the information into the EHR, burden of time to review the data, and not knowing how to use the tools.

In reviewing the system's pain management policy, the OIG identified that the system was not in policy compliance as it related to patient requests for provider changes. System policy specified a patient request for a PCP change would not be granted if the request was made due to the PCP's opioid prescribing practices. System providers reported that during town hall meetings, the System Director stated that all patient requests for PCP changes should be and were granted. An OSI data analysis conducted for system leaders in fall 2017 recommended that leaders support the clinical decisions of PCPs to taper patients on opioids and not approve change of PCPs to avoid doctor shopping and because PCPs who start a taper should monitor the patient to ensure safety.⁸²

The OIG found the system met six out of nine goals outlined by VHA's OSI Update; three were partially met:

- Goal 3—Partially met. Not all PCPs used the PDMP state databases when opioid medications were prescribed. PDMP reports showed that 26 of 63 (41 percent) providers completed PDMP reports at least yearly greater than or equal to 80 percent of the time.
- Goal 4—Partially met. While the system leadership reported having established VISN tapering protocols for veterans on a combination of opioids and benzodiazepines for PCPs, seven of 10 (70 percent) interviewed providers were unaware of them and did not know how to find them.
- Goal 6—Partially met. While the system had protocols for tapering high-risk patients on opioids such as sustained action oxycodone, hydromorphone, and methadone, seven of 10 (70 percent) providers interviewed were unaware of the protocols or where to find them.

The OIG found that the system was conducting voluntary exit reviews with PCPs who left employment as the OMI Blue Cover Report recommended. Since November 2017, the system had three PCPs who left employment. The system reported that all three PCPs who left were given the opportunity for an exit interview; one of the three PCPs participated in the review.

⁸² Doctor shopping is defined as seeing multiple treatment providers, either during a single illness episode or to procure prescription medicals illicitly.

Recommendations 1–12

1. The Veteran Integrated Service Network 10 Director ensures a case consult is made to Veterans Health Administration's National Center for Ethics to consider whether the Chief of Staff used the position of authority in a manner intended to induce a patient management action which would have otherwise not been taken and, if so, whether the Chief of Staff's conduct comports with a proper ethical standard.
2. The Northern Indiana Health Care Director verifies that the Pain Management Committee is providing oversight and monitoring of pain management activities as required by Veterans Health Administration policy and monitors compliance.
3. The Northern Indiana Health Care Director ensures monitoring of the quality of pain assessments and the effectiveness of pain management interventions and monitors compliance.
4. The Northern Indiana Health Care Director develops and implements a process to evaluate the success of meeting the goals of the Veterans Health Administration National Pain Management Strategy on a regular basis, at least yearly.
5. The Northern Indiana Health Care Director establishes a formal transfer process for tertiary, interdisciplinary pain rehabilitation program referrals as required by Veterans Health Administration's stepped care model for pain management.
6. The Northern Indiana Health Care Director evaluates the educational programs offered to providers related to pain management and opioid safety to determine if the programs meet the intent of the Veterans Health Administration Pain Management Strategy for standardizing training and competencies and ensure that providers attend regularly.
7. The Northern Indiana Health Care Director ensures that the pain management team is operational as required by Veterans Health Administration.
8. The Northern Indiana Health Care Director ensures that the system policy is followed for providers to routinely review an opioid risk assessment for patients on long-term opioid therapy and monitors compliance.
9. The Northern Indiana Health Care Director verifies compliance with the system's pain management policy regarding patients' requests to change providers and monitors compliance.
10. The Northern Indiana Health Care Director makes certain that primary care providers are utilizing the prescription drug monitoring program as required by Veterans Health Administration when prescribing opioid medication and monitors compliance.
11. The Northern Indiana Health Care Director ensures that primary care providers receive education on safe and effective Veterans Integrated Service Network tapering programs for patients using the combination of benzodiazepines and opioids and monitors compliance.

12. The Northern Indiana Health Care Director ensures that providers receive education on tapering programs for patients on high-risk opioids and monitors compliance.

Appendix A: VISN 10 Director Comments

Department of Veterans Affairs Memorandum

Date: May 22, 2019

From: Acting Director, VA Healthcare System Serving Ohio, Indiana, and Michigan
(10N10)

Subj: Healthcare Inspection— Alleged Interference and Failure to Comply with Pain
Management Directives and Opioid Safety Initiatives at the Northern Indiana
Health Care System, Fort Wayne, Indiana

To: Director, Office of Healthcare Inspections, (54HL05)
Director, GAO/OIG Accountability Liaison (GOAL) office (VHA 10EG GOAL)

1. Thank you for the opportunity to review and comment on the draft report, Healthcare Inspection-Alleged Interference and Failure to Comply with Pain Management Directives and Opioid Safety Initiatives at the Northern Indiana Health Care System, Fort Wayne, Indiana.
2. I have reviewed and concur with the findings and recommendations, including Recommendation 1 for the VISN 10 Network Director. As such, a consultation was submitted to VHA's National Center for Ethics by the VISN 10 Acting Quality Management Officer on May 22, 2019.
3. Please find attached the comments and actions to be taken in response to the recommendations in the report.

(Original signed by:)

SANDRA S.
SELVIDGE 213815
Digitally signed by SANDRA
S. SELVIDGE 213815
Date: 2019.05.23 14:49:43 -04'00'

for Shella Stovall, MNA, RN
Acting Network Director, VISN 10

Comments to OIG's Report

Recommendation 1

The Veteran Integrated Service Network 10 Director ensures a case consult is made to Veterans Health Administration's National Center for Ethics to consider whether the Chief of Staff used the position of authority in a manner intended to induce a patient management action which would have otherwise not been taken and, if so, whether the Chief of Staff's conduct comports with a proper ethical standard.

Concur.

Target date for completion: September 30, 2019

Director Comments

A consultation was submitted to VHA's National Center for Ethics by the VISN 10 Acting Quality Management Officer on May 22, 2019.

Appendix B: Northern Indiana Health Care System Director Comments

Department of Veterans Affairs Memorandum

Date: May 21, 2019

From: Director, Northern Indiana Health Care System (610/00)

Subj: Healthcare Inspection—Alleged Interference and Failure to Comply with Pain Management Directives and Opioid Safety Initiatives, Northern Indiana Health Care System, Fort Wayne, Indiana

To: Acting Director, VA Healthcare System Serving Ohio, Indiana, and Michigan (10N10)

I concur with the VA Northern Indiana Health Care System's response and action plans as detailed within this report for Recommendations 2 through 12.

(Original signed by:)

Michael E. Hershman, MHA, FACHE

Comments to OIG's Report

Recommendation 2

The Northern Indiana Health Care Director verifies that the Pain Management Committee is providing oversight and monitoring of pain management activities as required by Veterans Health Administration policy and monitors compliance.

Concur.

Target date for completion: July 31, 2019

Director Comments

VANIHCS Pain Management Committee (PMC) Chair completed a review of Committee oversight and monitoring activities in April and presented the results to the PMC members for discussion and implementation in May 2019. PMC plans to review their membership during their June meeting. PMC will be developing a Dashboard similar to the VISN 10 Dashboard, which will include the nine Opioid Safety Initiative (OSI) goals. This membership review/ discussion will aid in ensuring we have linked OSI and CARA with PMC and that we have also included staff from all applicable areas of VANIHCS (e.g., OSI Committee Chairman, Primary Care, Community Living Center, etc.). Also, during their April 2019 meeting, PMC members initiated a cross-walk of CARA requirements. VANIHCS has requested the VISN 10 Pain Management Team visit VANIHCS by September 30, to assess our Pain Management Program and share best practices with us.

Recommendation 3

The Northern Indiana Health Care Director ensures monitoring of the quality of pain assessments and the effectiveness of pain management interventions and monitors compliance.

Concur.

Target date for completion: June 28, 2019

Director Comments

VANIHCS Pain Management Team (PMT) continues to meet semi-monthly to complete medical record reviews of high-risk Veterans. PMC will monitor monthly the percentage of high-risk reviews using available local data and compare VANIHCS' compliance with both VISN 10 and National percentage rates to validate we are within the targeted range. As noted on the latest VISN 10 Pain Management Dashboard (April 29, 2019), VANIHCS' compliance for 1st Qtr. of FY 2019 was 100% for review of Very High Opioid Risk patients.

Upon VANIHCS' completion of the current revision of our templated Pain Management Note in CPRS, OSI Committee will perform monthly audits of pain management encounters and will be able to assess both the quality of pain assessment and the effectiveness of pain management interventions. The OSI Committee will report these audits to PMC.

Recommendation 4

The Northern Indiana Health Care Director develops and implements a process to evaluate the success of meeting the goals of the Veterans Health Administration National Pain Management Strategy on a regular basis, at least yearly.

Concur.

Target date for completion: September 30, 2019

Director Comments

VANIHCS PMC members will routinely assess the success of VANIHCS in meeting the nine OSI goals of VHA's National Pain Management Strategy and include this in the PMC minutes beginning with the June meeting. As part of our governance structure, PMC provides a quarterly report to Clinical Executive Board (CEB), which in turn reports quarterly to the Executive Council (EC). PMC will also prepare an annual report at the end of each fiscal year which will be shared with CEB and the EC by December 1 of each year.

Recommendation 5

The Northern Indiana Health Care Director establishes a formal transfer process for tertiary, interdisciplinary pain rehabilitation program referrals as required by Veterans Health Administration's stepped care model for pain management.

Concur.

Target date for completion: July 22, 2019

Director Comments

As per VANIHCS Pain Management policy (11-41-18), the Stepped-Care approach is listed as: Step 1 – Primary Care; Step 2 – Secondary Consultation; and Step 3 – Tertiary Interdisciplinary Care. VANIHCS acknowledges that this is the only reference to the Stepped-Care approach in our System policies, and an enhanced, formal transfer process on the use of the Stepped-Care model will be developed.

Recommendation 6

The Northern Indiana Health Care Director evaluates the educational programs offered to providers related to pain management and opioid safety to determine if the programs meet the

intent of the Veterans Health Administration Pain Management Strategy for standardizing training and competencies, and that providers attend regularly.

Target date for completion: July 1, 2019

Director Comments

VANIHCS has evaluated the educational programs offered to Providers related to pain management and opioid safety. It was determined that the education provided is sufficient; however, no clear or consistent process could be found to ensure applicable Providers receive the necessary education.

Moving forward, Providers will be required to review the following materials during their New Employee Orientation, and then annually thereafter: 1) TMS Module: Pain Management and Opioid Safety (VA 31108); 2) Applicable VANIHCS opioid and pain management policy(ies) (currently under revision); and 3) Pain Management Opioid Safety: VA Educational Guide. Additionally, an Academic Detailing encounter with a clinical pharmacist related to opioid use will be required.

To ensure compliance, this annual requirement will be added to forthcoming, annual Physician Performance Pay Plans, and will be considered in the assessment of the annual Proficiency Report for non-physician Providers.

Recommendation 7

The Northern Indiana Health Care Director ensures that the pain management team is operational as required by Veterans Health Administration.

Concur.

Target date for completion: Complete

Director Comments

VANIHCS Pain Management Team (PMT) has been in place since July 9, 2018. PMT continues to meet twice a month to review cases of Veterans referred to the Team. Reports from PMT are presented to PMC, which reports quarterly to CEB. PMT meeting minutes are posted on the OIG SharePoint site, and available for review. We are asking this Recommendation be considered closed.

OIG Comment

Based on information provided, the OIG considers this recommendation closed.

Recommendation 8

The Northern Indiana Health Care Director ensures that the system policy is followed for providers to routinely review an opioid risk assessment for veterans on long-term opioid therapy and monitors compliance.

Concur.

Target date for completion: May 23, 2019

Director Comments

Veterans who are receiving long-term opioid therapy are assessed for risks by their Providers. Our templated Pain Management Note, currently under revision, has an embedded link prompting the provider to perform a risk mitigation assessment with the Stratification Tool for Opioid Risk Management (STORM). Among the elements abstracted from CPRS by the OSI Committee as part of their reviews of 20 charts per Provider each year, is the use of either the STORM or the OSI Opioid Therapy Risk Report (OTRR). Results of the OSI data analysis is shared with Leadership on a quarterly basis. Current analysis of OSI data reflects a substantial decline of the number of Veterans at VANIHCS who are on a long-term opioid therapy regimen (November 2017: 4455, versus January 2019: 2936). In addition, OSI information is reported monthly to VANIHCS Executive Council (EC).

Recommendation 9

The Northern Indiana Health Care Director verifies compliance with the system's pain management policy regarding patients' requests to change providers and monitors compliance.

Concur.

Target date for completion: July 22, 2019

Director Comments

The matter of a Veteran seeking a change in provider is referenced in the VANIHCS policy "Long-Term Opioid Use for Chronic Pain Management" (11-89-17), which has been under revision and is approaching finalization. This current language will be removed, noting that any pain management care plan will follow the Veteran seeking to find a Provider who best meets their needs. The policy will further explain that if a Veteran has any concerns regarding their opioid management, they may be referred to the Pain Management Team (PMT).

Recommendation 10

The Northern Indiana Health Care Director makes certain that primary care providers are utilizing the prescription drug monitoring program as required by Veterans Health Administration when prescribing opioid medication and monitors for compliance.

Concur.

Target date for completion: July 1, 2019

Director Comments

As of May 17, 2019, a designated Advanced Medical Support Assistant (AMSA) within the Primary Care Service Line has been assigned the responsibility of generating a monthly report of Provider compliance with queries of the Indiana State Prescription Drug Monitoring Program (SPDMP) through the use of the OTRR, to determine which Veterans on chronic opioids may not have had an INSPECT query within the past 12 months. We recognize that the STORM data base reviews for Veterans who have been newly prescribed opioids is lacking at VANIHCS and we have added a prompt to the encounter note in CPRS to complete the STORM assessment as well as INSPECT query as the providers complete the progress note. These reports, identifying delinquent providers, are given to the respective Providers, as well as the RN Care Managers.

Recommendation 11

The Northern Indiana Health Care Director ensures that primary care providers receive education on safe and effective Veterans Integrated Service Network tapering programs for patients using the combination of benzodiazepines and opioids, and monitors compliance.

Concur.

Target date for completion: July 31, 2019

Director Comments

VANIHCS has reviewed the education Providers have received on safe and effective VISN tapering programs for patients on the combination of benzodiazepines and opioids. Providers will be required to review the applicable educational materials during their New Employee Orientation and then every other year. To ensure compliance, this annual requirement will be added to forthcoming, annual Physician Performance Pay Plans, and will be considered in the assessment of the annual Proficiency Report for non-physician Providers.

Further instruction and assistance with opioid tapering is available in our current policy, "Long-Term Opioid Use for Chronic Pain Management," as well as through academic detailing, provided by our clinical pharmacists. In addition, VANIHCS plans to expand education to Providers on how to easily and quickly obtain the tools at the point of care. This information is

easily accessible to the Providers thru the Computerized Patient Record System (CPRS) under the Tools option. The plan is also to educate all Providers on how to access the tools for chronic pain/opioid management at the point of care. This information is easily accessible to the providers thru CPRS under the tools option. The plan is also to educate all Providers on how to access the tools for chronic pain/opioid management at the point of care.

Further, Providers have been provided with the Stratification Tool for Opioid Risk Mitigation (STORM) tool and Tapering Tools in CPRS. The Opioid Therapy Risk Report (OTRR) is available to Providers for their review of Veterans receiving Opioid therapy. VANIHCS plans to educate Providers on how to obtain the tools at the point of care. This information will be easily accessible to the Providers.

PMC has added this to the standing agenda items and will be reviewing and discussing the data monthly. The data will be vetted thru the Clinical Executive Board (CEB) and to the Executive Council (EC).

Recommendation 12

The Northern Indiana Health Care Director ensures that providers receive education on tapering programs for patients on high-risk opioids and monitors compliance.

Concur.

Target date for completion: July 31, 2019

Director Comments

VANIHCS has reviewed the education Providers have received on tapering programs for patients on high risk opioids. Providers will be required to review the applicable educational materials during their New Employee Orientation and then every other year.

To ensure compliance, this annual requirement will be added to forthcoming, annual Physician Performance Pay Plans, and will be considered in the assessment of the annual Proficiency Report for non-physician Providers. In addition, VANIHCS plans to expand education to Providers on how to quickly obtain the tools at the point patient of care with one to two clicks of the mouse. This information is easily accessible to the Providers thru CPRS under the Tools option. The plan is also to educate all Providers on how to access the tools for chronic pain/opioid management at the point of care.

Providers may use one of the four tapering recommendations available in Opioid Taper Decision Tool in CPRS in consultation with Clinical Pharmacist and academic detailing. VANIHCS has added this to the standing agenda items of the PMT and will be reviewing and discussing the data monthly. The data will be vetted thru the Clinical Executive Board (CEB) and to the Executive Council (EC).

OIG Contact and Staff Acknowledgments

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