DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Opioid Safety at the VA Northern California Health Care System in Mather

HEALTHCARE INSPECTION | REPORT #22-00901-78 | MARCH 8, 2023

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to review the Opioid Safety Initiative (OSI) oversight processes at the VA Northern California Health Care System (facility) in Mather.

Opioids are drugs that reduce the feeling of pain by interacting with certain receptors on nerve cells in the body and brain.[1] Use of long-term opioids may increase the risk of opioid use disorder and overdose death.[2] The OIG used the term opioid therapy to describe providers prescribing and managing of long-term opioids (prescriptions greater than 90 days) for chronic pain, excluding opioids used for the treatment of cancer pain or those prescribed for hospice patients.

In an effort to review effectiveness of OSI oversight processes at the Veterans Health Administration (VHA), the OIG reviewed data of several providers across VHA, who based solely on prescribed doses, would have been considered as having "high dose" opioid prescribing practices.[3] During the initial data review, several providers assigned to the facility's Sacramento VA Medical Center were identified as prescribing "high dose" opioids. The initial data review did not identify the prescribing as necessarily inappropriate. In this inspection, the OIG conducted a review of opioid therapy management practices by patient aligned care team (PACT) providers (providers) and supervisors (supervisors) at the Sacramento VA Medical Center, in addition to facility and Veterans Integrated Service Network (VISN) oversight processes for opioid therapy.[4]

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[1] "Commonly Used Terms," Centers for Disease Control and Prevention (CDC), accessed March 15, 2022, https://www.cdc.gov/opioids/basics/terms.html. Legally prescribed opioid drugs include oxycodone, hydrocodone, codeine, morphine, and fentanyl.

[2] "Assessing Benefits and Harms of Opioid Therapy," CDC, accessed March 25, 2022, https://www.cdc.gov/drugoverdose/pdf/assessing_benefits_harms_of_opioid_therapy-a.pdf. "Safe and Responsible Use of Opioids for Chronic Pain: A patient information guide, VHA's PBM Academic Detailing Service," revised October 2018. Opioid use disorder is a brain disease that can develop from long-term use of opioids whereby the person may exhibit a craving for opioids or continue to use the opioids despite having opioid-related problems.

[3] VA and Department of Defense, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* Version 3.0. The guidelines advise "the risk of prescription opioid overdose and overdose death exists even at low opioid dosage levels," as low as 20–50 milligrams morphine equivalent daily dose and continues to increase at higher opioid dosages. A morphine equivalent daily dose equal to or greater than 90 milligrams is considered a "high dose."

[4] VHA Handbook 1101.10(1), *Patient Aligned Care Team (PACT) Handbook*, February 5, 2014, amended May 26, 2017. A PACT consists of a team of primary care health professionals and collaborates with the patient and the patient's support persons(s). The PACT manages and coordinates health care services "consistent with agreed upon goals of care." The providers from Sacramento VA Medical Center were interviewed to gain an understanding of the application of OSI measures. The supervisors, who were also PACT providers, included the chief of primary care, the assistant chief of primary care, and three Sacramento VA Medical Center supervisory physicians. The OIG referred to supervisors as 'providers' in the report when they responded in their capacity as providers.

Brief History of VHA's Response to the Opioid Epidemic

During 2010, in recognition of the growing opioid epidemic and research showing the lack of benefits and severe harm caused by long-term opioid therapy for chronic pain, VA and Department of Defense updated the clinical practice guideline.[5] In 2013, the VA launched the OSI with the goals of safe, effective, judicious opioid prescribing, and the use of alternative pain treatments.[6] As part of the OSI, the VA also launched the Opioid Overdose Education and Naloxone Distribution Program that includes education and training, risk mitigation strategies, and the practice of providing naloxone kits to at-risk patients.[7] In 2016, the President signed into law the Comprehensive Addiction and Recovery Act (CARA) with the goal of addressing the opioid epidemic. The act instructed VA to expand the OSI to include opioid therapy risk reports, pain management education and training for staff, Pain Management teams, and tracking and monitoring of opioid prescriptions and use.[8] In 2017, VA again updated the clinical practice guideline due to increased evidence of the harm of opioids, the absence of long-term benefits, and the safe and effective use of non-pharmacological and non-opioid pharmacological pain therapies.

Provider Opioid Prescribing and Management

The OIG determined that facility providers and supervisors implemented safe opioid therapy prescribing practices including completing informed consents, offering alternative treatments, and reducing opioid therapy when appropriate. When initiating opioid therapy, VHA requires providers to educate patients about the risks, benefits, and alternatives to opioid therapy; discuss a proposed plan with the patient; and complete an informed consent indicating the patient's understanding of the information and agreement to initiate opioid therapy.[9] The providers acknowledged prescribing opioids to patients and reported that an informed consent, documenting the indications, benefits, risks, side effects, and alternative treatments was completed prior to initiating opioid therapy. For calendar year 2021, facility informed consent

[5] VA and Department of Defense, *VA/DoD Clinical Practice Guideline: Management of Opioid Therapy for Chronic Pain*, Version 2.0, May 2010. *VA and DoD, VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0, February 2017.

[6] VA and Department of Defense, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* Version 3.0. "Opioid Safety Initiative Toolkit," Pain Management Internal VA website. "OSI Toolkit," Opioid Safety Internal VA SharePoint site.

[7] VHA Deputy Under Secretary for Health for Operations and Management memorandum, "Rapid Naloxone Availability to Prevent Opioid Related Deaths," September 5, 2018. VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memorandum, "Naloxone Distribution to Veterans Diagnosed with Opioid Use Disorder," February 24, 2021. "Commonly Used Terms," Centers for Disease Control and Prevention (CDC), accessed March 15, 2022, https://www.cdc.gov/opioids/basics/terms.html. Naloxone is a drug used to "reverse the effects of opioid overdose and can be lifesaving." VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0.

[8] The Comprehensive Addiction and Recovery Act of 2016, Pub. L. No.114-198, § 911(2016).

[9] VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 13, 2020.

completion rates for patients prescribed opioid therapy were over 97 percent each month, meeting the VISN performance goal.[10]

VHA recommends against initiating opioid therapy for chronic pain, and instead providing non-opioids or non-pharmacological alternative treatments.[11] The providers reported consulting with pain management pharmacists as needed and prescribed other treatments such as non-opioid pain medications. The facility offered alternatives to opioid therapy including acupuncture, chiropractic, aromatherapy, meditation, yoga, and mental health care; also, several providers reported offering physical therapy.[12]

VHA recommends against prescribing "high dose" opioids for treating chronic pain.[13] Several of the providers at the facility reported not having any patients on high dose opioids, while other providers reported that patients that were on high dose opioids had been transitioned to their care from either other VHA providers or community providers.[14] In these instances, the providers worked with patients to reduce the opioid dose.

Facility providers and supervisors reported implementing VA risk mitigation strategies for patients receiving opioid therapy. Required mitigation strategies include checking state Prescription Drug Monitoring Programs (PDMP), evaluating patients for overdose potential and suicidality, and providing overdose prevention including education and naloxone prescriptions.[15] For calendar year 2021, facility PDMP checks were completed at least every four months for

[10] "Pain Measures and Monitors" (website), Business Intelligence Service Line (BISL) VISN 21, https://vaww.pbi.cdw.va.gov/PBI_RS/report/FRE/D05_VISN21/SSRS/Pain/PainTrendsTable. (This website is not publicly accessible). The informed consent measure is defined as the percentage of all patients prescribed long-term opioid therapy (Schedule II-III) for non-cancer pain with an informed consent note present in the patient's record. The measure excludes patients receiving short-term opioids, long-term opioids for cancer pain, hospice care, palliative care, sublingual buprenorphine for opioid use disorder, or prescriptions from care in the community providers. Cleveland Clinic, "Buprenorphine; Naloxone sublingual tablet," accessed August 31, 2022, https://my.clevelandclinic.org/health/drugs/20384-buprenorphine-naloxone-sublingual-tablet. Buprenorphine is a medication that reduces withdrawal symptoms and the cravings to use opioids.

[11] VA and Department of Defense, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain Clinician Summary*, Version 3.0.

[12] Facility Policy 11-50.

[13] VA and Department of Defense, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* Version 3.0. A morphine equivalent daily dose equal to or greater than 90 milligrams is considered a "high dose."

[14] The OIG was informed that patients transitioned from specialty providers or other primary care providers within VHA or from the community. Several of the providers reported patients on "high dose" opioids had transitioned to care prior to the 2017 clinical practice guideline update.

[15] VHA Directive 1306(1). VA and Department of Defense D, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* Version 3.0. VHA Deputy Under Secretary for Health for Operations and Management memorandum, "Rapid Naloxone Availability to Prevent Opioid related Death." VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memorandum, "Naloxone Distribution to Veterans Diagnosed with Opioid Use Disorder."

over 99 percent of patients on opioid therapy throughout the year.[16] VHA recommends screening through ongoing random urine drug screens (UDS).[17] For calendar year 2021, facility annual UDS completion rates for patients prescribed opioids ranged from 89.8 to 93.9 percent, exceeding the VISN performance goal.[18]

Additionally, the OIG determined that facility providers had knowledge of VHA recommendations for ongoing evaluations of the benefits and risks for opioid therapy. To monitor the effectiveness of a patient's opioid therapy, a provider or a PACT team member completed a pain assessment note every three months. The OIG found that supervisors recognized the facility could improve on completing more assessments within this targeted time frame and implemented changes at the facility to improve timely pain assessments for opioid therapy patients. At the time of the OIG inspection, the VISN dashboard showed that 73.6 percent of facility patients on opioid therapy had a pain assessment completed within the last 100 days.

The OIG also determined that supervisors ensured that providers received mandatory national opioid safety training, in addition to offering informal intermittent education during meetings. Providers' knowledge and implementation of the OSI demonstrated that training was effective.

Facility Oversight

The OIG determined the facility had the required staff to provide oversight and support integration of the OSI into primary care. Opioid safety staff reported consulting on complex patient cases and educating providers about OSI initiatives and resources. The OIG found that the facility established an interdisciplinary pain management committee that met at least quarterly to review the facility's progress toward meeting OSI measures, along with providing education and strategies to increase OSI compliance. The facility also complied with the CARA by having a Pain Management team comprised of interdisciplinary staff who reviewed complex patient cases and supported providers as needed.[19]

[16] "PDMP Trends," VHA National ADS website. The OSI measure is defined as the percentage of patients who had an opioid prescription filled during the fiscal quarter and had a PDMP note entered in the EHR. The measure excludes patients enrolled in hospice or prescriptions with five or less days' supply with no refill.

[17] VA and Department of Defense, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0.

[18] "Pain Measures and Monitors" (website), BISL. The annual urine drug screen measure is defined as the percentage of all patients who received a prescription (an 84-day supply dispensed in the last 120 days) for opioid therapy and completed a urine drug screen in the last year. The measure excludes other methods of drug testing and patients receiving short-term opioids, long-term opioids for cancer pain, hospice care, or sublingual buprenorphine for opioid use disorder.

[19] The Comprehensive Addiction and Recovery Act of 2016, § 911.

The facility did not have a VHA-required policy providing guidance about who is expected to query the PDMP database.[20] Facility directors must ensure facilities have a PDMP policy that outlines training and guidance for providers who are expected to query the PDMP database, and includes any state specific requirements.[21] Through interviews and review of facility PDMP measures, the OIG found that although the facility did not have the required PDMP policy, providers were knowledgeable regarding PDMP database querying requirements. A member of the facility staff stated facility staff referred to VHA recommendations or California state law for guidance. The Facility Director was unaware of the requirement to have a local PDMP policy.

The OIG determined the facility's pain management policy provided guidance on utilizing prohibited opioid pain care agreements rather than informed consents. However, the facility had implemented the practice of using informed consents.[22] In 2020, VHA prohibited the use of opioid pain care agreements or contracts because the documents often used threatening language that could undermine patient-provider trust.[23] The Facility Director is responsible for ensuring that opioid pain care agreements are no longer used.[24] The Facility Director was unaware of the inaccurate pain management policy but stated the need to look into whether the policy needed to be reviewed or rescinded.

VISN Oversight

The VISN provided oversight of the facility's opioid therapy prescribing practices and OSI goals. The OIG determined the VISN had the required opioid safety staff to provide oversight of the facility providers' opioid therapy prescribing practices. VISN opioid safety staff reported attending VISN pain committee meetings, consulting on complex pain cases, and expanding pain services throughout the VISN. The VISN had an established pain committee and provided oversight of OSI measures. The VISN pain committee met at least nine times each fiscal year, discussed progress on OSI measures, and documented actions taken.[25]

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[20] VHA Directive 1306(1).

[21] VHA Directive 1306(1). California Health and Safety Code (CA HLTH & S § 11165.4 (January 1, 2017); CA HLTH & S § 11165.4 (January 1, 2020))

[22] Facility Policy 11-50. VHA Directive 1005. Facility SOP 00Q-04, Medical Center Policy & Standard Operating Procedure Development Guidelines, March 5, 2020. The facility standard operating procedure states that "policies will remain in effect until recertified or rescinded."

[23] VHA Directive 1005.

[24] VHA Directive 1005.

[25] "Budget of the US Government," accessed August 31, 2022, https://www.usa.gov/budget#:~:text=The%20federal%20government%27s%20fiscal%20year,September%2030%20of%20the%20next.The budget office of the US Government defines a fiscal year as October 1 of one calendar year through September 30 of the next. This inspection reviewed fiscal years 2019–2021 (October 1, 2018, through September 30, 2021) in addition to the first four months of fiscal year 2022 (October 1, 2021, through January 31, 2022).

The OIG made two recommendations to the Northern California Health System Director related to the development of a PDMP policy and review of the facility pain management policy to ensure alignment with VHA policy.

Comments

The Veterans Integrated Network and Facility Directors concurred with the recommendations and provided an acceptable action plan (see appendixes A and B). Based on information provided, the OIG considers recommendations 1 and 2 to be closed.

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Assistant Inspector General
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Contents

Abbreviations

CARA	Comprehensive Addiction and Recovery Act
CDC	Center for Disease Control and Prevention
DoD	Department of Defense
EHR	electronic health record
OIG	Office of Inspector General
OSI	Opioid Safety Initiative
PACT	patient aligned care team
PDMP	Prescription Drug Monitoring Program
PMOP	pain management opioid safety
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 to review the Opioid Safety Initiative (OSI) oversight processes at the VA Northern California Health Care System (facility) in Mather.

Background

The facility, part of VA Sierra Pacific Veterans Integrated Service Network (VISN) 21, is an integrated system that consists of two divisions (East Bay and Sacramento Valley), each with a medical center and several community-based outpatient clinics.[1] The facility is a 196-bed 1b-high complexity system that provides comprehensive health care services in medicine, surgery, mental health, and long-term care.[2] The facility has a leadership team consisting of the Facility Director, the Chief of Staff, and the Associate Director for Patient Care Services (Nurse Executive). Additionally, each division has one Associate Director.

Opioids and Opioid Crisis

Opioids are drugs that reduce the feeling of pain by interacting with certain receptors on nerve cells in the body and brain. Legally prescribed opioid drugs include oxycodone, hydrocodone, codeine, morphine, and fentanyl. Prescription opioids can be safe when taken as directed.[3] Taking opioids long-term may increase the risk of an opioid use disorder and overdose death.[4]

[1] The East Bay division medical center is located in Martinez and the Sacramento Valley division medical center is located in Mather, California.

[2] VHA Office of Productivity, Efficiency and Staffing. The VHA Facility Complexity Model categorizes medical facilities by complexity level. Complexity levels include 1a, 1b, 1c, 2, or 3, with 1a being the most complex. Facilities with a Level 1b complexity rating are described as having "medium-high-volume, high-risk patients, many complex clinical programs, and medium-large research and teaching programs."

[3] "Commonly Used Terms," Centers for Disease Control and Prevention (CDC), accessed March 15, 2022, https://www.cdc.gov/opioids/basics/terms.html.

[4] "Assessing Benefits and Harms of Opioid Therapy," CDC, accessed March 25, 2022, https://www.cdc.gov/drugoverdose/pdf/assessing_benefits_harms_of_opioid_therapy-a.pdf. "Safe and Responsible Use of Opioids for Chronic Pain: A patient information guide, VHA's PBM Academic Detailing Service," revised October 2018. Opioid use disorder is a brain disease that can develop from long-term use of opioids whereby the person may exhibit a craving for opioids or continue to use the opioids despite having opioid-related problems.

Prescription opioid related overdoses since the 1990s, were "driven by dramatic increases in prescribing of opioids for chronic pain."[5] High dose opioid prescribing decreased from 2006 to 2018.[6]

VHA Response to the Opioid Crisis

During 2010, the 2003 VA and Department of Defense (DoD) clinical practice guideline was updated based on recent research and the scope was broadened to include opioid use for cancer pain.[7] The guideline provided recommendations to clinicians on how to safely prescribe long-term opioid therapy for chronic pain.[8]

By 2013, the VA launched the OSI with the goals of safe, effective, and judicious opioid prescribing. The initiative encourages providers to safely prescribe and manage opioids by implementing practices such as patient education about long-term opioid therapy, monitoring benefits and risks, and the use of alternative pain treatments. In addition, VHA provides educational materials to prescribers to assist with clinical decision-making when prescribing opioid therapy.[9] Part of the initiative is the Opioid Overdose Education and Naloxone Distribution Program that includes education and training, risk mitigation strategies, and providing naloxone kits to at-risk patients.[10]

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[5] "2018 Annual Surveillance Report of Drug Related Risks and Outcomes," CDC, accessed March 15, 2022, https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf.

[6] "2019 Annual Surveillance Report of Drug Related Risks and Outcomes," CDC. The CDC rate per 100 persons is adjusted to the U.S. Census population and based on number of patients who filled an opioid prescription. "U.S. Opioid Dispensing Rate Maps," CDC, accessed December 1, 2022, https://www.cdc.gov/drugoverdose/pdf/pubs/2019-cdc-drug-surveillance-report.pdf. VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0. The guidelines advise "the risk of prescription opioid overdose and overdose death exists even at low opioid dosage levels," as low as 20–50 milligrams morphine equivalent daily dose and continues to increase at higher opioid dosages. A morphine equivalent daily dose equal to or greater than 90 milligrams is considered a "high dose."

[7] VA and DoD, *VA/DoD Clinical Practice Guideline: Management of Opioid Therapy for Chronic Pain*, Version 2.0, May 2010. *VA and DoD, VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0, February 2017.

[8] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0.

[9] VA and DOD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0. "Opioid Safety Initiative Toolkit," VHA Pain Management, accessed April 1, 2022, https://www.va.gov/PAINMANAGEMENT/Opioid_Safety/index.asp.

[10] VHA Deputy Under Secretary for Health for Operations and Management memorandum, "Rapid Naloxone Availability to Prevent Opioid Related Deaths," September 5, 2018. VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Naloxone Distribution to Veterans Diagnosed with Opioid Use Disorder," February 24, 2021. "Commonly Used Terms," Centers for Disease Control and Prevention (CDC), accessed March 15, 2022, https://www.cdc.gov/opioids/basics/terms.html. Naloxone is a drug used to "reverse the effects of opioid overdose and can be lifesaving." VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0.

In 2016, the President signed into law the Comprehensive Addiction and Recovery Act (CARA) with the goal of addressing the opioid epidemic. The act instructed VA to expand the OSI to include opioid therapy risk reports, pain management education and training for staff, pain management teams, and tracking and monitoring of opioid prescriptions and use.[11]

In 2017, the updated VA/DoD clinical practice guideline was published due to increased evidence of the harm of opioids, the absence of long-term benefits, and the safe and effective use of non-pharmacological and non-opioid pharmacological pain therapies.[12] The guideline provides recommendations for VA clinicians regarding the use of long-term opioids (prescriptions greater than 90 days) for chronic pain in non-terminal patients.[13] When opioid therapy is prescribed, the guideline recommends

- using the lowest dose required,
- deploying ongoing risk mitigation strategies, and
- reducing high dose prescriptions in patients that are not benefiting from opioid therapy.

Additionally, the guideline recommends using non-opioids, or alternative treatments instead of opioid therapy when possible. Clinical practice guideline recommendations should assist providers in the context of the provider's clinical judgment and patient preferences in caring for an individual and are not intended to be used as a standard of care.[14]

VHA provides numerous educational resources and tools to assist providers in adhering to safe opioid prescribing practices including dashboards with patient specific risk factors and mitigation strategies to prevent overdose.

Concerns

In an effort to review the effectiveness of OSI oversight processes at the Veterans Health Administration (VHA), OIG reviewed data of several providers across VHA, who, based solely on prescribed doses, were considered as having "high dose" opioid prescribing practices. During the initial data review of VHA facilities, several providers assigned to the facility's Sacramento VA Medical Center were identified as prescribing "high dose" opioids The initial data review did not identify the prescribing as necessarily inappropriate. The OIG opened an inspection to review the facility providers' prescribing and managing of long-term opioids for chronic pain (opioid

[11] The Comprehensive Addiction and Recovery Act of 2016, Pub. L. No.114-198, § 911(2016).

[12] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0.

[13] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0. VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 13, 2020. For the purposes of this report, the OIG uses the VHA definition of long-term opioids for chronic pain as prescriptions greater than 90 days excluding opioids used for the treatment of cancer pain or those prescribed for hospice patients.

[14] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0.

therapy).[15] The OIG also reviewed supervisors' and facility and VISN leaders' oversight of providers opioid therapy prescribing and management practices.

Scope and Methodology

The OIG conducted a review of the Sacramento VA Medical Center patient aligned care team (PACT) providers' (providers) opioid therapy management practices, as well as facility supervisors' (supervisors) and VISN 21 oversight processes for opioid therapy from October 2018–January 2022.[16] The OIG initiated the inspection on December 15, 2021 and conducted a virtual site visit January 31–February 3, 2022.[17]

The OIG interviewed facility leaders, supervisors, and staff familiar with the OSI and relevant processes including the Facility Director and Chief of Staff, and department chiefs, supervisors, providers, and pharmacists for Primary Care and Pharmacy Services. The OIG interviewed VISN OSI leaders involved in oversight of the facility's implementation of OSI.[18]

The OIG reviewed relevant VHA policies, clinical practice guidelines, facility policy, and relevant California state law.[19] The OIG reviewed relevant facility credentialing and privileging documents, training documents, patient safety documents, and electronic health record (EHR) progress note templates. The OIG reviewed relevant VISN and facility data trends, as well as committee charters and meeting minutes from the time frame of October 2018–January 2022. The OIG further reviewed relevant documents related to roles and responsibilities of staff involved with opioid safety oversight, both at the VISN and facility. The OIG did not independently verify VHA data for accuracy or completeness.

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[15] VHA Directive 1005.

[16] VHA Handbook 1101.10(1), *Patient Aligned Care Team (PACT) Handbook*, February 5, 2014, amended May 26, 2017. A PACT consists of a team of primary care health professionals who collaborate with the patient and the patient's support persons(s). The PACT manages and coordinates health care services "consistent with agreed upon goals of care." The providers from Sacramento VA Medical Center were interviewed to gain an understanding of the application of OSI measures. The supervisors, who were also PACT providers, included the chief of primary care, the assistant chief of primary care, and three Sacramento VA Medical Center supervisory physicians. The OIG referred to supervisors as 'providers' in the report when they responded in their capacity as providers.

[17] OIG interviews were conducted virtually using online meetings due to the COVID-19 pandemic. World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020*, accessed December 7, 2021, https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. *Merriam-Webster Dictionary*, "pandemic," accessed March 1, 2022, https:/www.merriam-webster.com/dictionary/pandemic. A pandemic is a disease outbreak over a wide geographic area that affects most of the population.

[18] VISN OSI leaders included the VISN Pain Management and Opioid Safety Program coordinator, VISN Primary Care pain champion, VISN pain consultant, and the VISN pharmacy deputy executive for operations.

[19] VHA Directive 1306(1), *Querying State Prescription Drug Monitoring Programs (PDMP)*, October 19, 2016, amended October 21, 2019. VHA providers must conform to state policies and procedures when querying state PDMPs. California Health and Safety Code (CA HLTH & S § 11165.4 (January 1, 2017); CA HLTH & S § 11165.4 (January 1, 2020)).

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).

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, Pub. L. No. 117-286, § 3(b), 136 Stat. 4196, 4206 (2022) (to be codified at 5 U.S.C. §§ 401–24). The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

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

The OIG found that facility providers and supervisors, as well as facility and VISN opioid safety leaders, followed and implemented VHA requirements and recommendations related to safe opioid therapy prescribing. However, the facility did not meet VHA requirements related to facility policies. First, the facility did not have a required Prescription Drug Monitoring Program (PDMP) policy.[20] Second, the facility pain management policy contained outdated guidance on utilizing opioid pain care agreements.[21]

1. Provider Opioid Prescribing and Management

Opioid Therapy Prescribing Practices

The OIG determined that facility providers and supervisors implemented safe opioid therapy prescribing practices including completing informed consents, offering alternative treatments, and reducing or discontinuing opioid therapy.

Informed Consent

When initiating opioid therapy, VHA requires providers to educate patients about the risks, benefits, and alternatives to opioid therapy, discuss a proposed plan with the patient, and complete an informed consent indicating the patient's understanding of the information and agreement to initiate opioid therapy. In addition, providers are required to give patients the information guide titled, "Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide."[22]

[20] VHA Directive 1306(1).

[21] Facility Policy 11-50, *Pain Management*, November 13, 2014. VHA Directive 1005.

[22] VHA Directive 1005.

Providers reported that an informed consent was completed prior to initiating opioid therapy. The facility's informed consent note outlines the reason and goal(s) for opioid therapy, risks and benefits, potential side effects, and alternative treatments. Both patients and providers sign the informed consent confirming discussions about indications, benefits, risks, side effects, alternative treatments, and monitoring compliance of the treatment.[23] The information guide titled, "Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide" was included in the facility's informed consent documentation and providers confirmed a copy was reviewed and provided to patients for reference.

The VISN set performance goals to measure facility compliance with OSI measures. For calendar year 2021, facility informed consent completion rates for patients prescribed opioid therapy were over 97 percent each month, meeting the VISN performance goal.[24]

Alternative Treatments

VHA recommends against initiating opioid therapy for chronic pain, and instead providing non-opioids or non-pharmacological alternative treatments.[25] The providers and supervisors reported that over time, the practice of regularly prescribing opioids for chronic pain has changed. One change is trying alternative treatments prior to initiating opioids. During interviews, providers and supervisors were knowledgeable about and reported use of alternative non-opioid treatments that were available for patients, both at the facility and through community care.[26]

Providers reported consulting with pain management pharmacists as needed and prescribed other treatments such as non-opioid pain medications. The facility offered alternatives to opioid therapy including acupuncture, chiropractic, aromatherapy, meditation, yoga, and mental health care; also, several providers reported offering physical therapy.[27]

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[23] A facility EHR "Consent for Clinical Treatment/Procedure" template indicates informed consents obtained by telephone and signed by witnesses are acceptable at the facility.

[24] "Pain Measures and Monitors" (website), Business Intelligence Service Line (BISL) VISN 21, https://vaww.pbi.cdw.va.gov/PBI_RS/report/FRE/D05_VISN21/SSRS/Pain/PainTrendsTable. (This website is not publicly accessible). The informed consent measure is defined as the percentage of all patients prescribed long-term opioid therapy (Schedule II-III) for non-cancer pain with an informed consent note present in their record. The measure excludes patients receiving short-term opioids, long-term opioids for cancer pain, hospice care, palliative care, sublingual buprenorphine for opioid use disorder, or prescriptions from Care in the Community providers. Cleveland Clinic, "Buprenorphine; Naloxone sublingual tablet," accessed August 31, 2022, https://my.clevelandclinic.org/health/drugs/20384-buprenorphine-naloxone-sublingual-tablet. Buprenorphine is a medication that reduces withdrawal symptoms and the cravings to use opioids.

[25] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain Clinician Summary*, Version 3.0.

[26] Facility Policy 11-50.

[27] Facility Policy 11-50.

Reducing or Discontinuing Opioid Therapy

VHA requires that providers develop personal health plans appropriate to a patient's needs.[28] VHA recommends that clinicians prescribing opioid therapy continually reassess patients and when risks outweigh benefits or patients voice a preference to reduce risk, clinicians should reduce opioids to a lower dose or taper until discontinuation. The pace of the reduction should be reevaluated and adjusted as needed to maximize safety and patient comfort. VHA recommends that when there is evidence of diversion, opioid prescriptions should be discontinued.[29]

During the initial informed consent process for opioid therapy, providers must educate patients on reasons why opioids may be reduced at any point during treatment.[30] The facility's informed consent process included a discussion between patients and providers regarding what circumstances may lead to a reduction or discontinuation of opioid therapy. In OIG interviews, providers reported reducing a patient's opioid dose if

- the patient was on too high a dose or had comorbidities that placed the patient at higher risk for overdose;
- the opioid was interfering with the patient's quality of life by causing depression, sedation, or agitation; or
- there was suspicion that the patient was diverting the medication.[31]

VHA recommends against prescribing "high dose" opioids for treating chronic pain.[32] Several of the providers reported not having any patients on high dose opioids, while other providers reported that patients that were on high dose opioids had been transitioned to their care from either other VHA providers or community providers.[33] In these instances providers reported working with patients to reduce the opioid dose.

Providers advised that a patient's willingness was often a barrier when initially discussing reducing or discontinuing opioid therapy. However, many providers reported that given time to build rapport and trust with a patient, the discussion about initiating a dose reduction was generally met with less resistance. Providers reported that the facility had resources to assist with decreasing a patient's opioid dose, including consulting with the Primary Care pain champion, a

[28] VHA Handbook 1101.10(1).

[29] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0. Diversion is "providing the medication to someone for whom it was not intended."

[30] VHA Directive 1005.

[31] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* Version 3.0.

[32] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* Version 3.0.

[33] The OIG was informed that patients transitioned from specialty providers or other primary care providers within VHA or from the community. Several of the providers reported patients on high dose opioids had transitioned to care prior to the 2017 clinical practice guideline update.

pain pharmacist, and the Pain Management team (pain team) to ensure that reductions were appropriate and safe.

Supervisors did not have concerns with how providers worked with patients to reduce opioid therapy, and shared that providers had been successful in safely reducing patients' opioid therapy doses. The supervisors reported connecting providers with the resources available at the facility when providers needed assistance in reducing opioid doses or discontinuing opioid therapy.

At the time of the OIG inspection, the facility's OSI measures showed a steady reduction in the number of patients who were prescribed opioid therapy (see figure 1).[34] Facility staff reported successful reduction of opioid therapy prescriptions by monitoring the OSI measures and expanding non-opioid therapy alternative treatments such as physical therapy, chiropractic, and acupuncture.

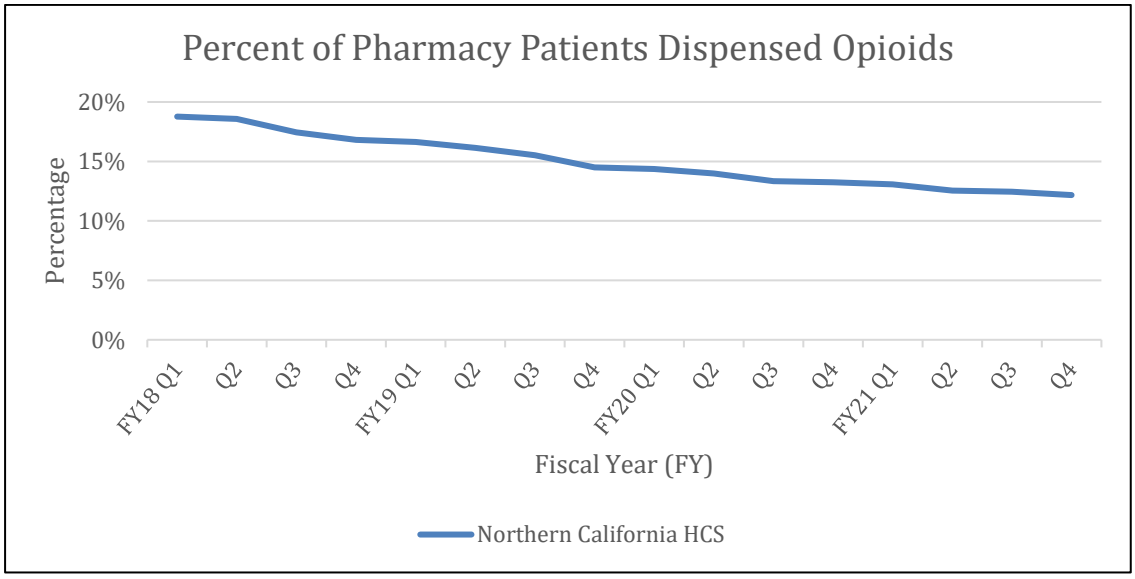

Figure 1. *A line graph that shows the percentage of facility pharmacy patients who were dispensed opioids.*
Source: VHA National Academic Detailing Services "Pain Management Facility Trends."
Note: A fiscal year is a 12-month cycle that spans October 1 through September 30. Fiscal year 2018 began on October 1, 2017, and ended on September 30, 2018, and fiscal year 2021 began on October 1, 2020, and ended on September 30, 2021.

The OIG concluded that providers completed informed consents with patients prescribed opioid therapy and were knowledgeable about alternative non-opioid treatments available at the facility to assist in pain management. Providers were able to speak to what factors should be considered when reducing or discontinuing a patient's opioids.

[34] "Pain Management Facility Trends," VHA National Academic Detailing Services (ADS) website. The measure is defined as the percentage of patients who received a VA-issued prescription during the specified fiscal quarter who were also prescribed an opioid prescription excluding buprenorphine sublingual products. The OIG noted the facility is reducing the use of opioids, but the decreased use including the tapering of opioid dosages in patients, was not reviewed as it was beyond the scope of this inspection.

Opioid Therapy Risk Mitigation Strategies

The OIG determined that the providers and supervisors implemented VA risk mitigation strategies for patients receiving opioid therapy. Required mitigation strategies include checking state Prescription Drug Monitoring Programs (PDMP), evaluating patients for risk of suicide or overdose, and providing overdose prevention methods (education and naloxone prescriptions).[35] Additionally, VHA recommends ongoing random urine drug screens (UDS) and reevaluation of pain at least every three months.[36] The OIG found that supervisors identified facility deficiencies in completing timely pain reevaluations and then implemented changes to improve risk mitigation.

Prescription Drug Monitoring Program

PDMP databases allow providers to identify when a patient has received controlled substances from multiple prescribers and can "assist in the prevention of accidental or intentional misuse or diversion of prescribed substances." VHA requires prescribers to query PDMPs at least annually or more frequently when clinically indicated or necessary, and in accordance with respective state law as applicable.[37] From January 1, 2018, through June 30, 2021, California state law required providers to query the PDMP database every four months and starting July 1, 2021, the requirement changed to every six months.[38] The OIG found the facility did not have the required VHA PDMP policy, a detailed discussion of this finding is provided in the Facility Oversight of Safe Opioid Prescribing section of this report.

In interviews, providers confirmed that the PDMP must be checked at least every four months. The OIG learned that facility pharmacists primarily checked the PDMP and entered a note in the EHR documenting results and recommended actions. A pharmacist told the OIG that both providers and pharmacists could enter the PDMP note in the patient's EHR. However, pharmacists entered the majority of the notes and added a provider as an additional signer for awareness and any necessary action. A facility pharmacist reported routinely checking the PDMP dashboard daily, identifying patients whose PDMP checks were over 90 days, and completing the PDMP note.

When a PDMP check showed a discrepancy, providers reported taking action such as having a discussion with the patient about the reason for other opioid prescriptions, and if needed,

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[35] VHA Directive 1306(1). VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* Version 3.0. VHA Deputy Under Secretary for Health for Operations and Management memo, "Rapid Naloxone Availability to Prevent Opioid related Death." VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Naloxone Distribution to Veterans Diagnosed with Opioid Use Disorder."

[36] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0.

[37] VHA Directive 1306(1).

[38] California Health and Safety Code CA HLTH & S § 11165.4 (January 1, 2017); CA HLTH & S § 11165.4 (January 1, 2020)).

discontinuing the opioid prescription. For calendar year 2021, in accordance with state law and VHA directive, facility PDMP queries were completed for over 99 percent of patients on opioid therapy.[39]

Risk Assessment for Suicide or Overdose

VHA recommends assessing patients for suicide risk when considering initiating or continuing opioid therapy.[40] Providers reported completing patient suicide risk assessments and when a patient screened positive, mental health providers were contacted and were responsive in intervening. Supervisors explained that a multidisciplinary team, which included a psychologist, was available to discuss high-risk patients, assist providers in managing patients, and make treatment recommendations.[41]

VHA recommends that providers present overdose education and offer a naloxone prescription to patients who are at risk for opioid overdose.[42] Naloxone is a medication that reverses the effect of opioids, and "can save lives when administered quickly following an intentional or unintentional overdose" of opioids.[43] Providers described prescribing naloxone to patients on opioid therapy. Providers were knowledgeable about the ordering and education process for naloxone and reported PACT pharmacists also provide patient education.

Urine Drug Screen

VHA recommends ongoing random UDS when patients are prescribed opioid therapy. UDS result assist providers in monitoring whether a patient is taking opioids as prescribed and whether the patient is taking other drugs.[44] Supervisors reported that patients who are prescribed opioid therapy should have a UDS completed annually, however, encouraged providers to complete a patient UDS every six months. When a UDS showed unexpected results, providers described actions that were taken such as having a discussion with the patient, repeating the

[39] "PDMP Trends," VHA National ADS website. The OSI measure is defined as the percentage of patients who had an opioid prescription filled during a fiscal quarter and had a PDMP note entered in the EHR. The measure excludes patients enrolled in hospice or prescriptions with five or less days' supply with no refill.

[40] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0.

[41] VHA Notice 2021-21, "Conduct of Data-Based reviews of Opioid-Exposed or Overdose Patients with Risk Factors," December 1, 2021. High-risk patients are those that may be at an elevated risk of experiencing an adverse event related to an opioid prescription.

[42] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0. VHA Deputy Under Secretary for Health for Operations and Management memo, "Rapid Naloxone Availability to Prevent Opioid related Death." VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Naloxone Distribution to Veterans Diagnosed with Opioid Use Disorder."

[43] VHA Deputy Under Secretary for Health for Operations and Management memorandum, "Rapid Naloxone Availability to Prevent Opioid related Death." VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memorandum, "Naloxone Distribution to Veterans Diagnosed with Opioid Use Disorder."

[44] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0.

UDS, and if needed, discontinuing the opioid prescription. For calendar year 2021, facility annual UDS completion rates for patients prescribed opioids ranged from 89.8 to 93.9 percent, exceeding the VISN performance goal.[45]

Reevaluation for Opioid Therapy

The OIG determined that providers had knowledge of VHA recommendations for ongoing patient evaluations of the benefits and risks of opioid therapy.

VHA risk mitigation strategies outline that frequent follow-up visits contribute to the appropriate use and adjustment of opioid therapy. VHA recommends that, at least every three months, providers evaluate a patient's benefits of continued opioid therapy and the risk for opioid related adverse events including substance use disorder, overdose, and death.[46]

In order to monitor the effectiveness of a patient's opioid therapy, a provider or a PACT team member completed a templated EHR pain assessment note every three months. Providers confirmed assessing a patient's pain every six months with an in-between assessment completed by a PACT team member.[47] To determine whether the patient's pain improved, worsened, or remained unchanged since the last assessment, the providers or PACT team members reevaluated several factors including: level of pain, interference of pain with enjoyment of life, and interference of pain in general activity. Providers further evaluated if the patient was experiencing any side effects or had new health factors that contradicted opioid therapy.[48]

Supervisors acknowledged that patient pain assessments were to be completed quarterly; however, historically the facility did not meet this metric. Barriers to meeting the metric included providers completing the pain assessment outside of the clinical reminder, as well as limitations when scheduling face-to-face visits during COVID.[49] The OIG learned that providers were aware that every six-month pain assessments are to be done face-to-face, however, due to the COVID-

[45] "Pain Measures and Monitors" (website), BISL. The annual urine drug screen measure is defined as the percentage of all patients who received a prescription (an 84-day supply dispensed in the last 120 days) for opioid therapy and completed a urine drug screen in the last year. The measure excludes other methods of drug testing and patients receiving short-term opioids, long-term opioids for cancer pain, hospice care, or sublingual buprenorphine for opioid use disorder.

[46] VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0.

[47] Facility Policy 11-50. Facility policy states that the inter-disciplinary team, which includes nurses, pharmacists, and support staff, is responsible for assessing and documenting a plan of care and treatment for pain. The plan must also be re-assessed for effectiveness.

[48] A facility EHR "Chronic Opioid Therapy" template prompts providers to evaluate for side effects including sedation, mental status changes, trouble breathing, nausea or vomiting, and decreased libido. Providers further evaluate changes in health factors that may affect the risk of prescribing opioid therapy including severe respiratory issues, active substance use disorder, and new prescriptions of sedative drugs.

[49] VA Office of Information and Technology, *Clinical Reminders Manager's Manual*, March 2005, revised May 2021. A clinical reminder displays in the EHR to assist providers with tracking, documenting, and directing patient care. Reminders "can direct providers to perform certain tests or other evaluations," which can assist providers in responding to needed clinical activities.

19 pandemic, appointment scheduling was a challenge. During the pandemic, VHA allowed the use of video appointments to complete the pain assessment. Providers acknowledged using technology to meet the recommended pain assessments.[50]

The VISN set a goal for facilities to complete 65 percent of pain assessments every 100 days for patients on opioid therapy.[51] In calendar year 2021, the facility's completion rate ranged from 43.6 to 68.7 percent. Supervisors and providers reported that the facility implemented interventions to meet the VISN goal. These changes included having clerical staff run reports to identify and schedule patients who did not have a pain assessment completed in the last 90 days, and adding pharmacists to assist nurses with completing the in-between assessments. Supervisors reported monitoring the VISN dashboard for how these interventions affected the timely completion of pain assessments. At the time of the OIG inspection, the VISN dashboard showed that 73.6 percent of the facility patients receiving opioid therapy had a pain assessment completed within the last 100 days.

The OIG concluded the providers and supervisors implemented risk mitigation strategies for patients receiving opioid therapy and took actions when needed. The OIG found that supervisors recognized the facility could improve on completing pain assessments and implemented changes to improve monitoring of patients' pain.

Provider OSI Training

The OIG determined that supervisors ensured that providers received the required opioid safety and pain management training.

VHA requires that providers prescribing opioid therapy take national online training regarding opioid safety and pain management.[52] Facility policy specifically requires that providers are educated on pain assessment and management.[53]

Supervisors were knowledgeable that providers were required to take training related to opioid therapy. At the time of inspection, all of the providers had completed the training. Additionally, supervisors reported that during new employee orientation providers received a binder that included opioid safety training and information about the facility's pain management dashboards. Footnote 7

[50] VHA Deputy Under Secretary for Health for Operations and Management memo, "COVID-19: Controlled Substance Prescribing Through Telehealth During the COVID-19 Public Health Emergency," March 21, 2020.

[51] "Pain Measures and Monitors" (website), BISL. The Pain Trends Table pain assessment measure is defined as the percentage of chronic opioid patients (Schedule II-III) with "'Pain Assessment' health factor entered in the last 3 months (100 days) or [an] oncology/hospice health factor entered." The measure excludes patients receiving short-term opioids, sublingual buprenorphine, and prescriptions filled under the Mission Act.

[52] VHA Deputy Under Secretary for Health for Organizational Excellence memo, "Opioid and Pain Management Training Compliance," February 27, 2017.

[53] VHA Handbook 1101.10(1). Facility Policy, 11-50.

Supervisors shared that other training was informal, largely through educational meetings held throughout the year on various opioid safety updates including but not limited to pain management, PDMP, and UDS in the context of safe opioid prescribing. Providers reported receiving OSI related education during intermittent trainings and meetings. Providers reported that primary care pharmacists and the Primary Care pain champion were resources available for questions related to opioid therapy. In July 2018, the facility held a pain conference for providers, and at the time of the OIG inspection, the facility reported another pain conference for further education was being developed.

The OIG concluded that supervisors provided training and educational offerings to providers. Based on providers' knowledge about and implementation of OSI, the OIG determined that trainings were effective.

2. Facility Oversight of Safe Opioid Prescribing

The OIG determined the facility's OSI support staff, pain committee, and pain team provided general oversight of opioid therapy prescribing practices and monitored OSI goals. However, the facility lacked a PDMP policy, and the pain management policy information was outdated.

Facility OSI Support Staff

The OIG determined the facility had the VHA-required staff to provide oversight and support integration of the OSI into primary care. VHA requires that facilities have a Pain Management, Opioid Safety and Prescription Drug Monitoring Program coordinator (PMOP coordinator), Primary Care pain champion, Pain Management point of contact, and an Academic Detailing Program manager.[54]

PMOP Coordinator

In April 2021, VHA established a requirement that each facility have a PMOP coordinator for the purpose of monitoring policy compliance and facilitating implementation of best practices related to pain management and opioid safety.[55] The facility's PMOP coordinator reported starting the role in December 2021, just prior to the opening of this inspection. During interviews with the OIG, the PMOP coordinator was able to discuss and provide examples of

- coordinating care to meet and improve the facility OSI measures,

[54] VHA Assistant Under Secretary for Health for Clinical Services memo, "Fiscal Year 2021 Pain Management, Opioid Safety, and the Prescription Drug Monitoring Programs (PMOP-11SPEC20) Field Funding," April 8, 2021. VHA Deputy Under Secretary for Health for Operations and Management memo, "Required Implementation of Academic Detailing and Designation of Primary Care Pain Champions," October 2, 2018.

[55] VHA Manual, "VA Pain Management, Opioid Safety, and Prescription Drug Monitoring Program (PMOP) National Program Field Roles and Responsibilities Manual," October 2021.

- working with key stakeholders to address any deficiencies or areas of concern,
- collaborating with other facility and VISN OSI staff, and
- updating opioid safety committee charters and policies.

Primary Care Pain Champion

In 2018, VHA established the Primary Care pain champion role to serve as a consultative pain care resource and liaison for PACT providers.[56] This champion is also responsible for representing PACT on opioid safety committees, and "serving as the pain and opioid safety subject matter expert on PACT case presentations and staff meetings."[57] The facility Primary Care pain champion had been in the role for seven years and discussed leading committees that evaluated patients with pain, establishing a high risk pain clinic to treat patients in a group setting, and supporting other providers who had complex patient cases.

Pain Management Point of Contact

In 2009, VHA established the facility level Pain Management point of contact role to serve as the primary subject matter expert for pain management and to provide consultation regarding policy, practice, and services.[58] Two facility Pain Management & Rehabilitative Service providers facility's held the Pain Management point of contact role . During interviews, the facility pain management points of contact reported attending the VISN monthly PMOP meetings, collaborating with the facility PMOP coordinator, attending the monthly pain team meetings, and serving as a resource for providers. The facility PMOP coordinator confirmed the pain management points of contact were active members of the facility's pain team.

Academic Detailing Program

In 2018, VHA required implementation of the Academic Detailing Program to improve patient safety and to foster more program initiatives to ensure safe prescribing of medications.[59] The facility Academic Detailing Program manager is responsible for developing OSI patient care

[56] VHA Manual, "VA Pain Management, Opioid Safety." VHA Deputy Under Secretary for Health for Operations and Management memorandum, "Required Implementation of Academic Detailing and Designation of Primary Care Pain Champions."

[57] VHA Manual, "VA Pain Management, Opioid Safety.""

[58] VHA Manual, "VA Pain Management, Opioid Safety, and Prescription Drug Monitoring Program (PMOP) National Program Field Roles and Responsibilities Manual," October 2021. VHA Assistant Under Secretary for Health for Clinical Services memo, "Fiscal Year 2021 Pain Management, Opioid Safety, and the Prescription Drug Monitoring Programs (PMOP-11SPEC20) Field Funding."

[59] VHA Deputy Under Secretary for Health for Operations and Management memo, "Required Implementation of Academic Detailing and Designation of Primary Care Pain Champions."

tools and staff trainings.[60] During an OIG interview, the Academic Detailing Program manager was able to discuss,

- educating providers about OSI initiatives and resources,
- consulting with providers about patient cases and ways to improve care, and
- working to unite outpatient and specialty clinics.

Additionally, the Academic Detailing Program manager reported assisting with the development of interdisciplinary team meetings to identify and discuss patients at high risk for overdose and provide suggestions for treatment planning. Meetings occurred at most facility outpatient clinics.

Several of the providers, supervisors, and the Chief of Staff acknowledged receiving assistance and education from the OSI support team members. The OIG concluded the facility's PMOP coordinator, Primary Care pain champion, Pain Management points of contact, and Academic Detailing Program manager are active in their roles to support the OSI.

Facility Pain Committee

The OIG found that per VHA requirement, the facility established an interdisciplinary pain management committee (facility pain committee). The OIG confirmed that the facility pain committee met quarterly as required by the committee charter.[61]

Chartered in 2016, the facility pain committee was charged with overseeing implementation and compliance with OSI measures and education to front-line staff; developing and reviewing documentation tools such as templates or protocols; and providing revisions to the facility's pain management programs.[62] In the 12 months prior to the inspection, meeting minutes confirmed the committee met at least quarterly and reviewed the facility's progress toward meeting OSI measures, educating front-line staff and assessing strategies to increase compliance.[63]

In addition, the committee's charter requires pain committee members to apprise facility leaders of the committees' activities.[64] In interviews, facility OSI support staff and facility leaders confirmed that information such as performance on the OSI measures and new OSI developments flowed up through the facility reporting structure. The OIG concluded the facility pain committee provided necessary oversight of the facility OSI measures.

[60] Facility Functional Description, Academic Detailing Program Manager Pharmacy Service, signed February 25, 2022.

[61] Facility Charter, *Pain Subcommittee Charter*, April 25, 2016.

[62] Facility Charter, *Pain Subcommittee Charter*.

[63] The OIG reviewed January 2021–January 2022 committee meeting minutes.

[64] Facility Policy Statement 00-11, *Pain Subcommittee Charter*, April 25, 2016. The Chief of Staff gave the reporting structure for the pain committee as follows: pain committee, Provision of Care Committee, Medical Executive Committee, and the Executive Management Board.

Facility's Pain Management Team

The OIG determined the facility was compliant with the CARA requirements regarding a pain team. Specifically, the facility pain team consisted of interdisciplinary staff who reviewed complex patient cases and supported treating providers as needed.[65]

VHA requires facilities to comply with CARA by having a designated interdisciplinary pain team that is "responsible for coordinating and overseeing pain management therapy." At a minimum, the composition of a pain team must include healthcare providers with expertise in pain management, addiction medicine, behavioral medicine, and rehabilitation medicine. Functions of the pain team include: "evaluation and follow up, as needed, of patients with complex pain conditions, pain consultation for medication management, and review of patients with high risk opioid prescriptions with recommendations to clinical providers."[66]

Members of this team included the facility's Pain Management point of contact and PMOP Coordinator, mental health and addiction and recovery treatment providers, and pain pharmacists. According to providers, the pain team reviewed complex patient cases. During an OIG interview, the facility PMOP coordinator stated that complex patient cases were brought to the pain team through consults placed by providers or pain pharmacists. Additionally, the pain team discussed interventions and medication management, completed chart reviews, approved community care referrals, and supported treating providers by documenting recommendations in patients' EHRs.

The OIG concluded the facility's pain team included required staff who provided coordination and oversight of pain management therapy.

Facility Prescription Drug Monitoring Program Policy

The OIG determined the facility did not have a VHA-required policy providing guidance about who is expected to query the PDMP database.[67]

VHA requires facility directors to ensure each facility has a PDMP policy that outlines training and guidance for providers who query the PDMP database.[68] VHA requires querying the database, at a minimum, annually; however, local policy may require more frequent querying of PDMP databases due to state laws.[69] At the time of inspection, California state law required

[65] The Comprehensive Addiction and Recovery Act of 2016, § 911.

[66] VHA Deputy Under Secretary for Health for Operations and Management memo, "Comprehensive Addiction and Recovery Act Requirements from Section 911(c) Pain Management Team Facility Report (VAIQ# 7791174)." The Comprehensive Addiction and Recovery Act of 2016, § 911.

[67] VHA Directive 1306(1).

[68] VHA Directive 1306(1).

[69] VHA Directive 1306(1). California Health and Safety Code (CA HLTH & S § 11165.4 (January 1, 2017); CA HLTH & S § 11165.4 (January 1, 2020)).

providers to query the PDMP more often than the VHA requirement.[70] Additionally, the facility policy states the Chief of Staff is responsible for ensuring that all queries are documented in the facility PDMP progress note.[71]

Through interviews and review of the facility's PDMP measures, the OIG found that although the facility did not have the required PDMP policy, providers were knowledgeable regarding PDMP database querying requirements.[72] The facility PMOP coordinator stated the facility referred to VHA recommendations or California state law for guidance. The Facility Director was unaware of the requirement to have a local PDMP policy. The OIG concluded that the facility lacked a PDMP policy; however, the VHA PDMP database was queried as required.

Facility Pain Management Policy

The OIG determined the facility's pain management policy was not updated to reflect VHA's requirement regarding informed consent for opioid therapy. The OIG found that the facility's pain management policy provided guidance on utilizing prohibited opioid pain care agreements rather than informed consents. However, the facility had implemented the practice of using informed consent.[73]

Starting in 2020, VHA prohibited the use of opioid pain care agreements or contracts because the documents often used threatening language that could undermine patient-provider trust. Facility directors are responsible for ensuring that opioid pain care agreements are no longer used.[74]

The facility's pain management policy, which was issued in 2014, contained outdated guidance to use opioid pain care agreements instead of informed consent.[75] The Facility Director was unaware of the inaccurate pain management policy but stated the need to look into whether the policy needed to be reviewed or rescinded.

The OIG concluded that although the facility policy was not consistent with VHA requirements, facility providers' informed consent practices were in alignment with VHA requirements.

[70] California Health and Safety Code (CA HLTH & S § 11165.4 (January 1, 2017); CA HLTH & S § 11165.4 (January 1, 2020))

[71] VHA Directive 1306(1).

[72] VHA Directive 1306(1).

[73] Facility Policy 11-50. VHA Directive 1005. Facility SOP 00Q-04, *Medical Center Policy & Standard Operating Procedure Development Guidelines*, March 5, 2020. The facility standard operating procedure states that "policies will remain in effect until recertified or rescinded."

[74] VHA Directive 1005.

[75] Facility Policy 11-50. VHA Directive 1005.

3. VISN Oversight of Safe Opioid Therapy Prescribing

The OIG determined that VISN 21 provided oversight of the facility's opioid therapy prescribing practices and OSI goals. The OIG evaluated VISN oversight through interviews with VISN OSI support staff and review of VISN pain committee minutes.

VISN OSI Support Staff

The OIG determined the VISN had the required opioid safety staff to provide oversight of facility providers' opioid therapy prescribing practices.

VHA requires that VISNs have a PMOP coordinator, Primary Care pain champion, and Pain Management point of contact to support facility level implementation and maintenance of the OSI.[76]

VISN PMOP Coordinator

VHA established the VISN PMOP coordinator role to monitor and evaluate pain management programs and OSI, and to collaborate with other OSI leaders to ensure the implementation of PMOP initiatives across the VISN.[77] During an OIG interview, the VISN PMOP coordinator discussed starting the role in November 2021, collaborating with facility and VISN OSI staff, chairing the VISN pain committee, and monitoring OSI measures. The VISN PMOP coordinator also established monthly meetings with the facility PMOP coordinators and participated in the national PMOP planning team.

VISN Primary Care Pain Champion

VHA established the VISN Primary Care pain champion (VISN pain champion) to support initiatives related to pain management and opioid safety and to collaborate with VISN-level partners.[78] The VISN pain champion reported being a facility pain champion and was concurrently assigned as the VISN pain champion. Duties included co-leading the VISN pain

[76] VHA Assistant Under Secretary for Health for Clinical Services memo, "Fiscal Year 2021 Pain Management, Opioid Safety, and the Prescription Drug Monitoring Programs (PMOP- 11SPEC20) Field Funding." VHA Deputy Under Secretary for Health for Operations and Management memo, "Required Implementation of Academic Detailing and Designation of Primary Care Pain Champions."

[77] VHA Assistant Under Secretary for Health for Clinical Services memo, "Fiscal Year 2021 Pain Management, Opioid Safety, and the Prescription Drug Monitoring Program Field Funding." VHA Manual, VA Pain Management, Opioid Safety, and Prescription Drug Monitoring Programs (PMOP) *National Program Field Roles and Responsibilities Manual*, October 2021.

[78] VHA Deputy Under Secretary for Health for Operations and Management memo, "Required Implementation of Academic Detailing and Designation of Primary Care Pain Champions." VHA Assistant Under Secretary for Health for Clinical Services memo, "Fiscal Year 2021 Pain Management, Opioid Safety, and the Prescription Drug Monitoring Programs Field Funding." VHA, *VA Pain Management, Opioid Safety, and Prescription Drug Monitoring Program (PMOP) National Program Field Roles and Responsibilities Manual*, October 2021.

committee and collaborating with VISN OSI staff. In 2021, this position was split between two primary care physicians.

VISN Pain Management Point of Contact

VHA established the VISN Pain Management point of contact to serve as a clinical pain consultant to VISN leaders and to collaborate with VISN and facility OSI support staff to coordinate pain-related resources across the VISN.[79] During OIG interviews, the VISN Deputy Pharmacy Executive for Operations reported the original responsibility of the VISN Pain Management point of contact was to establish and lead the VISN pain committee and set up resources such as the VISN OSI dashboard. Additionally, the OIG learned that the VISN Deputy Pharmacy Executive for Operations served as the VISN point of contact until late 2021 when a new point of contact was appointed to the position. The VISN Pain Management point of contact reported attending the VISN pain committee meetings, consulting on pain cases, and expanding pain services throughout the VISN. Additionally, the VISN Pain Management point of contact shared that the role and oversight is still developing.

The OIG determined the VISN had the required opioid safety staff to support VISN facilities in safe opioid therapy prescribing.

VISN OSI Oversight

The OIG found that the VISN had an established pain committee and provided oversight of OSI measures. VHA requires VISNs to establish an interdisciplinary VISN pain committee to provide oversight, coordination, and monitoring of pain management programs and the OSI within the VISN.[80] VHA also requires VISNs to evaluate the VHA pain management strategy through performance measures that are established by the National Pain Management Program Office.[81]

VISN OSI leaders reported the VISN pain committee provides oversight of OSI practices and measures (such as initial PDMP checks and Stratification Tool for Opioid Risk Mitigation reviews), and serves as a venue for sharing ideas and standardizing practices across VISN

[79] VHA Assistant Under Secretary for Health for Clinical Services memo, "Fiscal Year 2021 Pain Management, Opioid Safety, and the Prescription Drug Monitoring Programs Field Funding." VHA, *VA Pain Management, Opioid Safety, and Prescription Drug Monitoring Program (PMOP) National Program Field Roles and Responsibilities Manual*, October 2021.

[80] VHA Directive 2009-053. VHA Deputy Under Secretary for Health for Operations and Management memo, "Opioid Safety Initiative," December 7, 2016.

[81] VHA Directive 2009-053. VHA Deputy Under Secretary for Health for Operations and Management memo, "Opioid Safety Initiative."

facilities.[82] The VISN pain committee met at least nine times each fiscal year 2019–2021, and discussed progress on OSI measures, documented actions taken, and provided reports to the VISN healthcare delivery committee.[83] A VISN OSI leader told the OIG there is an expectation that information from the VISN's pain committee be incorporated at the VISN facilities. The facility had at least one representative attend all but one VISN pain committee meetings in the two years prior to the inspection.[84]

VISN OSI leaders reported establishing a dashboard to assist the VISN pain committee and facility supervisors and providers in monitoring risk mitigation strategies when prescribing opioid therapy. VISN OSI leaders told the OIG that the VISN real-time dashboard was created in 2010, prior to the establishment of national dashboards, and has been adjusted over time with input from the VISN pain committee. The dashboard was customized to accommodate providers, whereby, providers can review a list of patients with appointments and identify those that have actions to be taken. Additionally, the VISN dashboard contains links to national dashboards, such as Stratification Tool for Opioid Risk Mitigation, for providers to quickly identify high-risk patients.

VISN OSI leaders told the OIG that the facility was initially a high prescriber in the VISN, however, facility staff made efforts to improve and were trending in the right direction. The OIG concluded that VISN 21 had an established VISN pain committee and was providing effective oversight of safe opioid therapy prescribing practices.

Conclusion

Facility providers and supervisors, as well as facility and VISN opioid safety leaders followed and implemented VHA requirements and recommendations related to safe opioid therapy prescribing. However, the facility did not meet all of the VHA requirements related to facility policies; specifically, the facility did not have a required PDMP policy, and the pain management policy contained outdated guidance about utilizing opioid pain care agreements.

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[82] VISN OSI leaders include the VISN PMOP coordinator, the VISN Primary Care pain champion, VISN pain consultant, and the VISN pharmacy deputy executive for operations. "Stratification Tool for Opioid Risk Mitigation User Guides," VHA Program Evaluation and Resource Center (PERC). VHA utilizes a dashboard tool called Stratification Tool for Opioid Risk Mitigation, which predicts the risk of overdose or suicide-related health care events or death. Based on an overdose risk score, categories include very high risk, high risk, medium risk, and low risk.

[83] VISN 21 Healthcare Delivery Committee Charter, February 15, 2022. The committee provides oversight of the "development, coordination, and implementation of clinical policy, plans, and practices." "Budget of the US Government," accessed August 31, 2022, https://www.usa.gov/budget#:~:text=The%20federal%20government%27s%20fiscal%20year,September%2030%20of%20the%20next. The budget office of the US Government defines a fiscal year as October 1 of one calendar year through September 30 of the next. The OIG reviewed the VISN meeting minutes for three fiscal years, from October 1, 2018, through September 30, 2021.

[84] The OIG found that the attendance for one meeting was not recorded.

Providers and supervisors implemented safe prescribing practices including completing informed consents and offering alternative treatments. Providers and supervisors were aware of what factors should be considered when reducing or discontinuing a patient's opioids, and the resources available at the facility to assist in decreasing or discontinuing opioids when needed. Providers confirmed that PDMP queries were completed for patients on opioid therapy. Providers were knowledgeable about the ordering and education process for naloxone and were able to speak to the importance of UDS to monitor patients. Providers had knowledge of the need to reevaluate patients on opioid therapy, and supervisors recognized areas for improvement and implemented changes to better monitor patients' pain. Supervisors ensured that the providers received the required training about opioid safety and pain management and that trainings were effective.

OSI support staff, pain committee, and pain team provided general oversight of opioid therapy prescribing practices and OSI goals. Required staff were in place to provide oversight and support integration of the OSI into primary care. The facility interdisciplinary pain management committee met regularly and provided necessary oversight of OSI measures. The CARA requirements regarding a pain team was met; specifically, the facility pain team was compromised of interdisciplinary staff who reviewed complex patient cases, and supported treating providers as needed.

The VISN provided oversight of OSI measures, had an established pain committee, and had the required opioid safety staff to provide oversight of facility providers' opioid therapy prescribing practices.

Recommendations 1–2

1. The VA Northern California Health Care System Director will ensure development and implementation of a VA Northern California Health Care System prescription drug monitoring program policy as required by Veterans Health Administration Directive 1306(1), *Querying State Prescription Drug Monitoring Programs (PDMP)*.

2. The VA Northern California Health Care System Director verifies the VA Northern California Health Care System pain management policy is in alignment with Veterans Health Administration Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: February 8, 2023

From: Director, VA Sierra Pacific Veterans Integrated Service Network (10N21)

Subj: Healthcare Inspection—Opioid Safety at the VA Northern California Health Care System

To: Director, Office of Healthcare Inspections (54HL10)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. I have reviewed and concur with the responses provided by the VA Northern California Health Care System.

2. If you have any additional questions or need further information, please contact the VISN 21 Quality Management Officer.

(*Original signed by:*)

Ada Clark, FACHE, MPH
Interim Network Director
VA Sierra Pacific Network (VISN 21)

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: January 27, 2023

From: Director, VA Northern California Health Care System (612/A4)

Subj: Healthcare Inspection—Opioid Safety at the VA Northern California Health Care System

To: Director, VA Sierra Pacific Veterans Integrated Service Network (10N21)

1. We appreciate the opportunity to review the draft report of recommendations from the OIG Health Care virtual inspections conducted at the VA Northern California Healthcare System from January 31 – February 3, 2022.
2. Please find the attached response to each recommendation included in the report. We have completed, or in the process of completing, actions to resolve these issues.

(*Original signed by*:)

David Stockwell, MHA
Medical Center Director
VA Northern California Healthcare System

Facility Director Response

Recommendation 1

The VA Northern California Health Care System Director will ensure development and implementation of a Northern California Health Care System Prescription Drug Monitoring Program policy as required by Veterans Health Administration Directive 1306(1) *Querying State Prescription Drug Monitoring Programs (PDMP)*.

Concur.

Target date for completion: January 27, 2023

Director Comments

To ensure development and implementation of a Northern California Health Care System (NCHCS) Prescription Drug Monitoring Program policy, as required by VHA Directive 1306(1), NCHCS developed and implemented the NCHCS Querying State Prescription Drug Monitoring Programs (PDMP), (MCP) 119-01. The Querying State Prescription Drug Monitoring Programs (PDMP), (MCP) 119-01 was completed January 26, 2023. NCHCS is exceeding both the minimum goals and National VA averages for PDMP monitoring requirements.

OIG Comments

The Facility Director provided sufficient supporting documentation, and the OIG considers this recommendation closed.

Recommendation 2

The VA Northern California Health Care System Director verifies the Northern California Health Care System pain management policy is in alignment with Veterans Health Administration Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*.

Concur.

Target date for completion: January 27, 2023

Director Comments

NCHCS updated the NCHCS Pain and Opioid Safety MCP 11-50 to include language from VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain and the Comprehensive Addiction and Recovery Act (CARA) mandated data-based risk reviews for opioid initiation. The revised Pain and Opioid Safety MCP 11-50, with updated terminology, was completed January 26, 2023.

OIG Comments

The Facility Director provided sufficient supporting documentation, and the OIG considers this recommendation closed.

OIG Contact and Staff Acknowledgments

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