US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Review of VHA's Oversight of Community Care Providers' Opioid Prescribing at the Eastern Kansas Health Care System in Topeka and Leavenworth

Healthcare Inspection | **22-02017-224** | **September 26, 2023**

BE A

VOICE FOR VETERANS

REPORT WRONGDOING

va.gov/oig/hotline | 800.488.8244

OUR MISSION

To serve veterans and the public by conducting meaningful independent oversight of the Department of Veterans Affairs.

CONNECT WITH US

Subscribe to receive updates on reports, press releases, congressional testimony, and more. Follow us at @VetAffairsOIG.

PRIVACY NOTICE

In addition to general privacy laws that govern release of medical information, disclosure of certain veteran health or other private information may be prohibited by various federal statutes including, but not limited to, 38 U.S.C. §§ 5701, 5705, and 7332, absent an exemption or other specified circumstances. As mandated by law, the OIG adheres to privacy and confidentiality laws and regulations protecting veteran health or other private information in this report.

Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess care coordination for patients of the VA Eastern Kansas Health Care System (system) who were receiving care and dually prescribed opioids and benzodiazepines from Community Care Network (CCN) providers. The inspection also reviewed compliance with public law and Veterans Health Administration (VHA) policies and guidelines specific to the oversight of CCN provider opioid prescribing practices.

In 2022, while conducting another project, OIG staff discovered a patient (Patient 1) who received multiple, high-dose opioid and concurrent benzodiazepine prescriptions in 2017 from a VHA contracted community-based pain provider that were filled at a non-VA pharmacy.[1] The patient subsequently experienced a medication overdose, which contributed to the patient's death in early 2018.

Therefore, the OIG initiated the inspection to review

- system and CCN providers' care coordination, documentation, and use of risk-mitigation strategies for patients who are prescribed opioids and benzodiazepines simultaneously by CCN providers or through a combination of system and CCN providers;
- VHA, Veterans Integrated Service Network (VISN), and system oversight of CCN providers' opioid prescribing practices; and
- CCN providers' acknowledgment, review, and application of Opioid Safety Initiative (OSI) Guidelines.[2]

[1] United States Drug Enforcement Administration, "Benzodiazepines," accessed November 15, 2022, https://www.dea.gov/factsheets/benzodiazepines. A benzodiazepine is a medication that depresses (slows down) the central nervous system and can "produce sedation, induce sleep, relieve anxiety, and prevent seizures."; 21 U.S.C. § 812. The Controlled Substances Act divides medications into five schedules with Schedule I consisting of those with the highest likelihood of abuse and dependence, and those with the lowest risk making up Schedule V. Opioids are narcotics regulated under schedule II of the federal Controlled Substances Act because they have a "high potential for abuse," and "may lead to severe psychological or physical dependence."

[2] VA and Department of Defense (DoD), Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0, February 2017. VA and DoD, VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain, ver. 4.0, May 2022. Unless otherwise specified, the VA and DoD guidelines in version 3.0, 2017, contain the same or similar language as the revised 2022 version. The 2017 Clinical Practice Guideline was in effect during the report events until updated in May 2022, during the time of the inspection. VA Health Services Research and Development, "Improving the Safety of Opioid Treatment," July 2017. The OSI Guideline is a framework created jointly by VA and DoD to provide evidence-based recommendations. The OSI is intended to help clinicians "reduce over-reliance on opioid analgesics for pain management and to promote safe and effective use of opioid therapy when clinically indicated." An IVC health systems specialist reported the OSI guidelines refer to VA/DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

During the review, the OIG identified additional issues with the submission of documentation by CCN providers and a lack of CCN provider documentation of OSI risk-mitigation strategies. Additionally, the OIG identified two other patient case examples (Patient 2 and Patient 3) in which patients received multiple controlled substance prescriptions from a combination of system, non-system VHA providers, and CCN providers.[3]

Background

According to the Centers for Disease Control and Prevention, there were more than 75,600 US overdose deaths involving opioids between April 2020 and April 2021.[4] The simultaneous use of benzodiazepines and opioids by individuals is discouraged due to both medications potentially increasing sedation and the risk of overdose. Veterans are at a higher risk of harm associated with concurrent use of opioid and benzodiazepine medication due to the prevalence and severity of chronic pain that is often accompanied by mental health comorbidities compared to the non-veteran population. The system provides consultative services for the management of pain medications such as opioids and benzodiazepines, however, patients who require interventional pain management services are referred to community pain specialists.

The VA/Department of Defense (DoD) Clinical Practice Guideline for Opioid Therapy for Chronic Pain (OSI guidelines) is used by providers as "a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with chronic pain, who are on or being considered for long-term opioid therapy."[5] The OSI guidelines recommend against the "initiation of opioid therapy for the management of chronic non-cancer pain" and "concurrent use of benzodiazepines and opioids for chronic pain," noting " the longer the patient is on opioids, the greater the potential for change in patient status and development of opioid-related harms."[6] These OSI risk-mitigation strategies are also supported by VHA policies, which require patient education about the potential risks, benefits, and alternatives to long-term opioids; written

[3] 21 U.S. Code § 812: Schedules of controlled substances. Two controlled substance prescription classes discussed in this report are opioids and benzodiazepines and are regulated under the federal Controlled Substances Act. The simultaneous use of benzodiazepines and opioids by individuals is discouraged due to both medications potentially increasing sedation and the risk of overdose.

[4] Centers for Disease Control and Prevention (CDC), *Drug Overdose Deaths in the U.S. Top 100,000 Annually*, November 17, 2021, accessed April 6, 2022. https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm.

[5] VA and DoD, *Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* ver. 3.0. The OSI guidelines provide evidence-based recommendations for initiation and continuation of opioids, risk mitigation, type, dose, follow-up, taper of opioids, and opioid therapy for acute pain.

[6] VA and DoD, *VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain,* ver. 4.0. Of note, the corresponding recommendation in version 3.0, regarding initiation of long-term opioid therapy does indicate long-term opioid therapy and does not include "non-cancer." Additionally, regarding the recommendation related to concurrent use of benzodiazepines and opioids does not include "for chronic pain."

informed consent for long-term treatment with opioids; and queries of state prescription drug monitoring program (PDMP) databases.[7]

The VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018 (MISSION Act) established a permanent community care program for eligible veterans to receive hospital care, medical services, and extended care through non-VA providers.[8] Included in the MISSION Act are expectations related to safe opioid prescribing and documentation.[9] In September 2021, VHA's Office for Integrated Veteran Care (IVC) was established to integrate VHA's direct and community care delivery systems by combining the Program Offices of Community Care and Veterans Access to Care.[10] IVC utilizes contracts with third-party administrators (TPAs) as a mechanism to purchase care in the community for veterans throughout five regional networks.[11] VHA awarded the TPA contract to Optum (VA/Optum Contract) to develop and manage the network of providers in region 2 where the system is located.

Inspection Results

The OIG found gaps in care coordination, documentation, and the use of risk-mitigation strategies for system patients receiving community care; similar to those gaps identified in the 2017 OIG report, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*.[12]

[7] VHA Directive 1306(1), *Querying State Prescription Drug Monitoring Programs (PDMP),* October 19, 2016, amended October 21, 2019; VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 13, 2020. The Comprehensive Addiction and Recovery (CARA) Act of 2016, Pub. L. No. 114-198 §130 STAT (2016). Additionally, the Comprehensive Addiction and Recovery Act of 2016 requires VHA to monitor opioid prescribing practices and use risk mitigation strategies.

[8] The Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, Pub. L. No. 115-182 §101 (2018). The MISSION Act established community care eligibility criteria for covered veterans, https://uscode.house.gov/statutes/pl/115/182.pdf.

[9] MISSION Act of 2018, § 131.

[10] VHA Acting Under Secretary for Health memo, "Notification of Program Office Reorganization," September 23, 2021. Due to reorganization of community care program offices to a single, combined program office, the OIG will use IVC when referencing Office of Community Care (OCC) throughout this report, as appropriate. When employees identify OCC within their titles or document titles include OCC, the OIG kept the titles as written.

[11] The TPA contracts with non-VA providers through a separate agreement (Optum/Provider Agreement), creating a network of contracted CCN providers in each region. VA awarded the TPA contract to Optum Public Sector Solutions, Inc (Optum) to develop and manage the network of providers in region 2 where the system is located. The VA/Optum Contract outlines the requirements set forth from VA to Optum regarding the expectations of providers within the community provider network.

[12] VA OIG, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care,* Report No. 17-01846-316, July 31, 2017. In 2017, VA community care was provided under the Veterans Access Choice and Accountability Act of 2014 as the MISSION Act was not in place until 2018.

Community Care Coordination, Documentation, and Risk Mitigation

Sharing health information between providers caring for the same patient is key to care coordination. The 2017 OIG report identified challenges related to health information sharing between VHA and non-VA providers.[13] During this review, the OIG found that VHA has a process to ensure CCN providers receive a patient's medical history and list of active medications at the time of the referral.[14] However, the OIG found continued challenges related to the incomplete and delayed CCN provider documentation, OSI prescribing risk-mitigation strategies, prescriptions dispensed at VHA pharmacies versus non-VA pharmacies, and the lack of medication reconciliation and VHA medication profile updates which place patients at risk.

Incomplete and Delayed CCN Provider Documentation

The MISSION Act requires "each covered health care [CCN] provider to submit medical records of any care or services furnished, including records of any prescriptions for opioids, to the Department in the timeframe and format specified by the Secretary."[15] Optum's Provider Manual and the VHA Office of Community Care Field Guidebook (Field Guidebook) state that CCN providers are required to submit medical records of care, and send all routine/maintenance medications through a VHA pharmacy for fulfillment or processing.[16] According to the VA/Optum contract, CCN providers must include specific data elements in documentation submitted to VHA including encounter notes with descriptions of procedures performed, recommendations for further testing or follow-up, results of imaging, any recommended prescriptions and treatment plans. The Field Guidebook states if CCN providers have not returned medical documentation within 14 days, system staff must verify the appointment occurred and request medical documentation from the CCN provider.[17] The system Chief of Staff told the OIG of challenges in obtaining CCN records. According to the Field Guidebook, CCN providers who automatically submit documentation are "often the exception and not the

[13] VA OIG, Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care.

[14] VHA OCC, "How to Perform Care Coordination," chap. 3 in *VHA OCC Field Guidebook,* accessed April 14, 2022, https://vaww.portal.oig.va.gov/directorates/54/Hotlines/2022-02017-HI-1256/Work%20Papers/Office%20of%20Community%20Care%20Field%20Guidebook%20-%20Chapter%203.pdf. (This website is not publicly accessible.)

[15] MISSION Act of 2018, § 131.

[16] MISSION Act of 2018, § 131; United Healthcare/ Optum, *CCN Provider Manual, v.1.9*; VHA OCC, chap. 3 in *Field Guidebook;* VHA OCC, "Consult Completion and Medical Records Management," chap. 4 in *VHA OCC Field Guidebook*, accessed April 14, 2022, https://vaww.portal.oig.va.gov/directorates/54/Hotlines/2022-02017-HI-1256/Work%20Papers/Office%20of%20Community%20Care%20Field%20Guidebook%20-%20Chapter%204%2C%203-30-2022.pdf. (This website is not publicly accessible.) The field guidebook states CCN provider documentation can be returned to the referring VHA facility through a variety of methods, including the TPA portal, Health Share Referral Manager platform, Veterans Health Information Exchange platform, secure electronic fax, or secure encrypted email.

[17] VHA OCC, *Field Guidebook,* Chapter 4.

rule." [18] During electronic health record (EHR) reviews specific to CCN pain management visits, the OIG found that CCN providers who prescribed controlled substances to patients returned documentation 70 percent of the time (95 percent confidence interval: between 60 and 79 percent).[19] Additionally, the OIG found CCN providers who prescribed opioids and benzodiazepines to patients often failed to provide the system with documentation pertaining to the controlled substances prescribed such as the type of medication prescribed, rationale for the medication, and dosing parameters. Missing or delayed documentation is a gap in care coordination that is a risk to patient safety.

Opioid Prescribing Risk-Mitigation Strategies

Under Section 15.1 of the VA/Optum contract entitled urgent/emergent prescriptions there is a provision which states, "The Contractor must require its CCN providers to check with its state's [PDMP] for any controlled substance utilization prior to writing any prescription for a controlled substance for a Veteran. . . "[20] The contractual language does not expressly limit the requirement to conduct a PDMP query to urgent/emergent prescriptions. Nevertheless, given the location of this text in the contract, it is unclear if the requirement for CCN providers to conduct PDMP queries applies to only urgent/emergent prescriptions or whether it also applies to routine/maintenance controlled substance prescriptions.[21] Optum's Provider Manual contains a requirement for CCN providers to query state PDMP databases before prescribing controlled substances to a veteran. In written correspondence to the OIG, Optum staff confirmed that this requirement applies to routine/maintenance prescriptions, not only to urgent/emergent prescriptions for controlled substances. The OIG conducted an EHR review for patients who were prescribed overlapping opioid and benzodiazepines by both system and CCN providers then filled the prescriptions at a VHA pharmacy; and found CCN providers documented PDMP

[18] VHA OCC, *Field Guidebook,* Chapter 4.

[19] The 95 percent confidence interval indicates that among all possible samples of the same size and design that could have been selected, the true rate would have been included in the computed intervals 95 percent of the time. For visits where CCN providers prescribed controlled substance prescriptions (n=4), the OIG found provider documentation related to the visit scanned into the EHR 8, 15, 63 and 269 days respectively after the completed CCN visit.

[20] VHA OCC, *Field Guidebook*, Chapter 3; VHA OCC, *Field Guidebook*, Chapter 4. The Field Guidebook states CCN providers may send patient prescriptions for emergent/urgent medications (up to a 14-day supply) to local retail in-network pharmacies for fulfillment. Patients who are authorized for non-VA care may have their emergent/urgent prescriptions filled through a CCN retail pharmacy or a VHA pharmacy. Should a patient require continued medications beyond the emergent/urgent, CCN providers must generate a second prescription. Once received, records are scanned into the patient's EHR, and the referring VHA provider is notified the consult is completed.

[21] The pharmacy specific section of the VA/Optum contract requires CCN providers to forward all routine/maintenance prescriptions, including those for controlled substances, to VHA pharmacies for processing and fulfillment, but does not contain a requirement for CCN providers to query state PDMP databases.

queries prior to prescribing controlled substances for seven of the 99 prescriptions (7 percent) reviewed.[22]

As the OSI guidelines recommend initial and ongoing risk-mitigation strategies when caring for individuals prescribed opioids, the OIG utilized the EHR review to determine whether system or CCN providers documented use of recommended key risk-mitigation strategies for care coordination of patients on long-term opioid therapy outlined in the OSI guidelines.[23] In nearly half of all medical charts reviewed the OIG was unable to find documentation showing that system or CCN providers informed patients about the potential risks, benefits, or alternatives to the recommended long-term opioid treatment, ordered a urine drug screen, or provided opioid overdose education or naloxone prior to prescribing an opioid regimen.[24]

VHA Versus Non-VA Pharmacy Filled CCN Prescriptions

The location at which a patient fills a prescription was identified as a vulnerability in the 2017 OIG report because prescriptions written by CCN providers that were filled outside of VA were often unknown to VA providers. To address the concern, the OIG made a recommendation to require CCN providers to submit opioid prescriptions directly to a VHA pharmacy for dispensing and recording in the patient's EHR.[25] The OIG found that unlike VHA pharmacy filled prescriptions, controlled substance prescriptions sent to non-VA pharmacies by CCN providers can lead to potential gaps in VHA provider awareness of the medication. Although

[22] The OIG reviewed routine and urgent prescriptions for documentation of a PDMP query. The 99 opioids prescriptions stemmed from 49 patients within the EHR Review 1. The OIG did not assess the reasons that PDMP checks were not documented and is unable to determine whether CCN providers conducted state PDMP queries in the cases where documentation of a query was not present. State laws regarding PDMP use vary. While the state of Kansas only requires PDMP queries are done for Medicaid patients, CCN providers in Kansas who contract with Optum are to follow expectations regarding PDMP use as outlined in their contract and provider manual.

[23] VA and DoD, *Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* ver. 3.0. The EHR review included 12 co-managed patients who were on long-term opioids, dually prescribed benzodiazepines, and prescribed at least one medication by a CCN provider. The TPA is to provide CCN providers with the OSI guidelines for review which include risk mitigation strategies.

[24] VA and DoD, *Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* ver. 3.0. VHA implemented the Overdose Education and Naloxone Distribution (OEND) program as a component to the OSI guideline's risk mitigation strategies with the aim of reducing patient deaths from opioid overdose. OEND includes "education and training regarding the following topics: opioid overdose prevention, recognition, and rescue response; risk mitigation strategies; and issuing naloxone kits, which can be used as an antidote to opioid overdose." Given CCN providers' failure to submit medical record documentation and the sparse information related to OSI risk mitigation strategies when documentation was submitted to VHA, it is unknown whether risk mitigation strategies were completed but not documented in VHA's EHR. Based on OIG's EHR reviews nearly half of patients on long-term opioid therapy did not have documentation of informed consent (5 of 12 patients), a urine drug screen (5 of 12 patients), and/or naloxone or opioid overdose education (7 of 12 patients).

[25] VA OIG, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*. In December 2019, based on VHA provided status updates, the OIG closed all four recommendations made in the 2017 report.

veterans can fill routine/maintenance prescriptions of all types at little to no cost at VHA pharmacies, they sometimes choose to fill them at non-VA pharmacies at their own expense.[26]

VHA policy requires VHA pharmacies located within a state that has a PDMP to transmit schedule II through V controlled substance prescription data to the PDMP.[27] While not required by VHA for all VA facilities, system policy states that "a PDMP query will be conducted [by VHA pharmacists] on new starts, and [at] three-month intervals for authorized care in the community controlled substance prescriptions presented to the pharmacy before dispensing."[28] System pharmacists must also notify CCN providers of questionable activity (multiple provider or multiple medications) found on a PDMP query.[29] When CCN providers send controlled substance prescriptions to the system's pharmacies for fulfillment, system pharmacists review the prescriptions for appropriateness, query state PDMPs, and add the CCN prescribed medication to the patient's medication profile in the EHR (medication profile).[30]

Patient 2 Case Example

Patient 2 was in their 50s with a history of anxiety and mood disorders, chronic obstructive pulmonary disease, and chronic abdominal and back pain which were treated with opioid therapy.[31] The patient's care was primarily managed through a CCN primary care provider with the exception of a nine-month period starting in the fall of 2020 when a non-system VHA

[26] VHA Reference Sheet, *Veterans Prescription Benefit*, June 7, 2019. Patients can fill *urgent/emergent* prescriptions written by an authorized CCN for 14 days or fewer at a *VHA* pharmacy or any *non-VA* pharmacy.

[27] VHA Directive 1108.07(1), *Pharmacy General Requirements*, March 10, 2017, amended January 26, 2021, rescinded November 28, 2022. This directive defines the Prescription Drug Monitoring Program (PDMP) as "a state-controlled substance monitoring program, including a program approved by the Secretary of Health and Human Services under section 3990 of the Public Health Service Act (42 U.S.C. 280g–3). Generally, these programs require pharmacies registered in their state to enroll and transmit (electronically) records of each dispensing of a controlled substance. States laws vary regarding the definition of controlled substance, requirements for software compatibility, frequency of data transmission, and required patient identifiers."

[28] Pharmacists may select to review surrounding state PDMP while utilizing the Kansas state PDMP.

[29] VA Eastern Kansas Health Care System SOP P-OP-7, *Care in the Community Pharmacy Services*, November 3, 2020.

[30] VHA Directive 1345, *Medication Reconciliation*, March 9, 2022. The Essential Medication List includes "all the medications patients may be taking. In [the EHR], the essential components are [VHA] prescriptions that are pending, not yet furnished to patients, all the medications patients have received from the [VHA] recently or administered in clinic including prescriptions that have recently expired or been discontinued. The Essential Medication List for Review must include Non-VA Medications." VHA Handbook 1108.11(1), *Clinical Pharmacy Services*, July 1, 2015, amended on June 29, 2017. Medication reconciliation includes "updating the medication profile to reflect an accurate, active list of VA and non-VA medications. This may include adding non-VA medications or discontinuing duplicate medications or those the patient is not taking." The OIG uses the term medication profile to describe the active list of VA and non-VA medications in the EHR.

[31] During the course of this review the OIG identified a patient who received two episodes of brief community care coordination from system staff, but who primarily received care from a neighboring VHA facility within VISN 15. While the patient was excluded from EHR Review 1, the OIG had concerns regarding CCN provider opioid prescribing practices with overlapping opioids and benzodiazepines, with a high MEDD.

primary care provider was responsible for the patient's care; including pain management.[32] Non-system VHA staff conducted PDMP queries to review any controlled substance prescribed outside of the VHA. The queries showed the CCN primary care provider prescribed multiple opioids (fentanyl patch and oxycodone) and a benzodiazepine (lorazepam) for the patient that were filled at non-VA pharmacies. These prescriptions included a non-urgent/emergent prescription that was contractually obligated to be filled at a VHA pharmacy. Additionally, the medication profile in the patient's EHR and PDMP queries showed VHA and CCN providers prescribed similar controlled substances simultaneously over the nine-month period during which the patient was cared for by a non-system VHA primary care provider.[33] Upon receiving and reviewing this information, the OIG notified the VISN 15 Chief Medical Officer to convey concern regarding the patient's overlapping controlled substances. The VISN 15 Acting Network Director substantiated the OIG's concern of the patient receiving high-dose opioids from a CCN provider, stated that the CCN provider would be referred to Optum for a review of safe medication practices, and contacted the patient to provide naloxone education and dispense a new naloxone nasal spray kit.

Patient 3 Case Example

Patient 3 was in their 60s with a history of low back pain, lower extremity pain, opioid and benzodiazepine dependence, and mood and anxiety disorders. System providers primarily managed the patient's medical care, including opioid medication until the fall of 2021, when the patient transitioned to CCN primary care services due to VHA's inability to provide timely primary care. The CCN primary care provider prescribed the patient high-dose opioids at levels lower than those previously prescribed by system providers, with a plan to taper the medication. The patient also received benzodiazepine medication from a system psychiatrist who added benzodiazepine dependence to the patient's problem list in early 2022 and made a long-term plan to taper and discontinue the medication. Patient 3 obtained medication from multiple sources, including VHA medical centers in two states and through community emergency departments. While multiple system and non-system VHA staff documented in the EHR awareness of the patient receiving high-dose opioids in the community with a concurrent VHA-prescribed benzodiazepine, the OIG did not find evidence of any additional actions taken to mitigate risk of opioid use. In the spring of 2022, the patient was transported to a non-VA emergency room after

[32] A non-system VHA primary care provider assumed care and pain medication management for nine months of the review period. During this period, the non-system VHA primary care provider referred the patient to pain management and gastrointestinal services; however, the patient was non-compliant with recommendations. The CCN primary care provider consult was not continued due to the previously approved CHOICE eligibility program ending in June 2020, and MISSION Act eligibility was not met. The patient was informed that while continuing care with the CCN primary care provider was an option, it would not be paid for through VHA without an active consult. In summer 2021, a new consult was written allowing the patient to resume care with the CCN primary care provider.

[33] Non-system VHA staff queried the state PDMP 10 times from October 1, 2020, through September 30, 2021.

being found confused with an empty bottle of vodka and an empty prescription bottle with a benzodiazepine label.

Due to the identified lack of CCN provider documentation in the EHR, lack of evidence of VHA staff initiating action to elevate their concerns, and the high dosages of overlapping prescriptions that Patient 3 received, the OIG contacted the VISN 15 Chief Medical Officer in the summer of 2022, and requested a response specific to the care and documentation found in the patient's EHR. The following month, the VISN 15 Network Director told the OIG a system provider was attempting to safely decrease the patient's use of the benzodiazepine to avoid severe withdrawal symptoms.

Lack of Medication Reconciliation and Medication Profile Updates

VHA guidance emphasizes the importance of capturing non-VA medication in the EHR, and OSI guidelines confirm the value of recording all opioids to prevent adverse outcomes and identify concerning prescribing practices.[34] VHA policy requires providers to complete medication reconciliation with patients "at every episode or transition in level of care where medications will be administered, prescribed, modified, or may influence the care given."[35] During EHR reviews, the OIG found that CCN prescribed controlled substances were missing from Patient 1, 2, and 3's medication profile after all three patients filled prescriptions at non-VA pharmacies. In those cases where VHA is made aware of a controlled substance prescription that was filled at a non-VA pharmacy, the OIG found system and non-system VHA providers do not routinely update a patient's patient medication profile to include those medications.

The Chief of Staff told the OIG that VHA providers are to complete a patient's medication reconciliation, including CCN provider prescribed medication at the first opportunity when the patient returns for VHA care. However, the Chief of Staff reported being unaware of any written expectation for VHA providers to complete a medication reconciliation outside of a patient visit. The OIG determined patients receiving their care primarily through CCN providers may not have VHA visits in which medication reconciliation would occur. The system's chief of ambulatory care told the OIG of limited time to address and review incoming CCN documents during routine clinic hours due to workload demands.

Given the multiple sources and high levels of medications noted in the EHR reviews, the OIG found the lack of a formal VHA process to ensure CCN prescribed medications filled by non-VA

[34] VA Office of Information and Technology, *Computerized Patient Record System (CPRS) User Guide: GUI Version*, January 2022. The VHA EHR uses an order checking system that prompts a review of medications, including non-VA medications entered into a patient's medication profile, to check for duplicate drugs, duplicate drug classes, critical and significant drug interactions, allergies and is used to support clinical decisions.VA and DoD, *Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* ver. 3.0.

[35] VHA Directive 2011-012, was rescinded and replaced by VHA Directive 1345, *Medication Reconciliation*, March 9, 2022. The language is similar within both versions of the directive.

pharmacies are identified and added to the EHR medication profile to be a gap in the care coordination and a patient safety issue, which may lead to adverse drug events such as opioid overdose and possible death.[36]

VHA's Oversight of CCN Providers' Opioid Prescribing Practices

The OIG found that VISN and system staff are not conducting oversight of CCN providers opioid prescribing practices as required by the Secretary of Veterans Affairs (Secretary) under the MISSION Act, and as recommended by the OIG in 2019, nor are they reporting concerns of unsafe CCN provider practices to Optum.[37]

The MISSION Act requires the Secretary to monitor the opioid prescribing practices of CCN providers based on OSI guidelines.[38] These reviews are provider focused and use parameters of care outlined in the OSI guidelines. On a national level, the MISSION Act requires the Secretary to submit an annual report to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives to report steps taken by VHA to comply with processes to ensure safe opioid prescribing practices by CCN providers.[39] According to the May 2021 congressionally mandated report, VHA leaders revised a process to review the opioid prescribing practices of CCN providers that aligns with standard patient safety processes.[40] The report indicated VISNs will be "responsible for ensuring that appropriate local [VHA] medical facilities perform a more in-depth review of providers in line with existing safety review procedures."[41]

---

[36] A failure to include the opioids on the medication profile may impact care since VA providers review the medication profile when seeing a patient to see what medications the patient has been prescribed. Failure to include the opioids on the medication profile also impacts the completeness of medication lists sent to CCN providers when patients are referred to them as the medication profile is what is included in the referral packet. The MISSION Act requires VA to ensure non-VA providers submit medical documentation to the VA, including records of all opioid prescriptions, and that this information is recorded in the veterans' EHR; VA OIG, *Oversight Could Be Strengthened for Non-VA Healthcare Providers Who Prescribe Opioids to Veterans*, Report 22-00414-113, September 26, 2023. This recently published Audit report studied this requirement and found the prescription information may be in locations within the EHR other than the medication profile.

[37] VA OIG, *State Prescription Drug Monitoring Programs Need Increased Use and Oversight*. The OIG recommended VHA monitor CCN providers and take appropriate corrective actions if their prescribing practices are inconsistent with the OSI guidelines.

[38] MISSION Act of 2018, § 131.

[39] MISSION Act of 2018, § 131. VA, *Establishment of Processes to Ensure Safe Opioid Prescribing Practices by Non-VA Health Care Providers*, May 2021. This congressionally mandated report outlines the steps taken by VHA to comply with MISSION Act required processes to ensure safe opioid prescribing practices by CCN providers and provides updates from the previous year.

[40] VA indicated reviews were conducted "using opioid prescribing triggers, a chart review of flagged providers by VISN level pain and opioid management committees, and an in-depth review by VA medical [facility's] patient safety leadership of potentially problematic providers."

[41] VA, Establishment of Processes to Ensure Safe Opioid Prescribing Practices by Non-VA Health Care Providers.

The OIG found at the time of this review that although VHA's report to Congress described a process to identify potentially problematic providers had been shared with VHA facilities, VISN 15 leaders failed to ensure the system had the process in place and failed to complete reviews of the opioid prescribing practices of CCN providers. VISN and system staff told the OIG they recognized that their responsibility to monitor CCN provider compliance was not met. The VISN Network Director shared that the system was developing a process to routinely monitor patients who use opioids and receive community care.

The system's Community Care service line manager confirmed that the system has not been monitoring CCN provider compliance with safe opioid prescribing practices. The OIG learned the system has plans to hire a dedicated pain management provider, replace a recently vacated pain pharmacist position, and recruit a Pain Management, Opioid Safety, and Prescription Drug Monitoring Program (PMOP) Coordinator. Staff identified vacancies as a contributing factor for why system staff have not been monitoring CCN provider safe opioid prescribing practices. The OIG found that due to the failure of VISN and system staff to conduct required reviews of CCN providers, the system is unable to fully leverage VHA processes to identify and report CCN provider quality of care concerns to Optum. Further, the OIG found system staff are not aware of, or had differing understanding of, the process to report patient safety concerns involving CCN providers identified outside of system reviews. This was evident when system staff documented patient safety concerns related to CCN provider prescribing in the EHRs of a patient identified earlier in this report.

Through a review of VISN 15 and system committee meeting minutes, the OIG found the members of VISN and system committees are aware of the requirement for the system to conduct reviews of the opioid prescribing practices of CCN providers. However, there is a lack of clarity regarding which committee(s) will be responsible for ensuring that the system completes these reviews. Therefore, clarity regarding the entity assigned to do so is warranted.

TPA's Oversight of CCN Providers' Opioid Prescribing Practices

The OIG found only 1.5 percent of targeted CCN providers associated with both TPAs [Optum and TriWest] had completed the required OSI training. In the 2017 OIG report, the OIG recommended all participating CCN providers receive and review the evidence-based guidelines for prescribing opioids outlined in the OSI guidelines.[42] In response to this recommendation, VHA told the OIG that the IVC would provide the OSI guidelines to CCN providers.[43] To do so, VHA developed a plan to share the OSI guidelines with TPAs and to require TPAs provide and confirm CCN providers receipt *and review* of the guidelines. VHA also created an OSI training module with links to more robust OSI information and tracks provider completion of the module

[42] VA OIG, Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care.

[43] VA OIG, Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care.

through national provider identification numbers.[44] While CCN providers working with Optum are required to acknowledge review of the OSI guidelines and complete the OSI training module, IVC staff told the OIG,

> The CCN contract [for both TPA's] requires [CCN] providers to comply with OSI however there are currently limitations to fully capturing the volume of providers that have acknowledged review of the guidelines and completed training. Contract modification efforts are in play to address these limitations. As of [August 24, 2022], VA has 9,662 [CCN] providers across all CCN regions documented for completion of OSI training, this represents 1.5 % [percent] of active providers [who are] targeted for OSI compliance.[45]

Specific to the TPA serving the system, the OIG determined Optum does not monitor CCN provider compliance with OSI guidelines and found the VA/Optum contract lacks a contractual expectation for Optum to do so.

The OIG made seven recommendations to the Under Secretary for Health related to CCN provider documentation, evidence of CCN provider training and use of OSI risk-mitigation strategies, PDMP queries, and capture of CCN- prescribed medication in the EHR.

The OIG made two recommendations to the Veterans Integrated Service Network Director related to ensuring the system has processes in place to conduct oversight of CCN providers' prescribing practices.

The OIG made four recommendations to the System Director related to documenting use of OSI risk-mitigation strategies, capturing CCN prescribed medication in the EHR, filling vacant positions, and educating staff on processes to report patient safety concerns involving CCN providers.

---

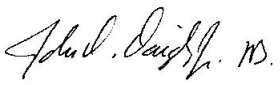
[44] Centers for Medicare and Medicaid Services, *National Provider Identifier Standard (NPI)*, accessed August, 17, 2022, https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProvIdentStand. A national provider identification number is a unique identification number used by some providers in administrative and financial transactions.

[45] IVC leaders told the OIG there are a total of 658,151 CCN providers across all regions [including Optum and Tri-West] with active Drug Enforcement Administration licenses who can prescribe medication, including opioids, and are targeted for OSI training as of August 24, 2022. The OIG did not independently verify CCN provider completion of the OSI training module and was unable to determine how many of the CCN provider completion of the OSI training module and was therefore unable to determine how many of the CCN providers who provide care for EKHCS patients completed OSI training. VA OIG, *Oversight Could Be Strengthened for Non-VA Healthcare Providers Who Prescribe Opioids to Veterans*. This companion Audit report includes information on OSI training completion for a sample of non-VA providers known to have prescribed opioids to veterans.

VA Comments and OIG Response

The OIG publication process includes sharing draft reports with VHA prior to publication. This process is to ensure accuracy of the information intended for publication as well as an opportunity for VHA leaders to seek clarification or discuss concerns with the OIG regarding information presented in the draft report. Accuracy of information is a priority with each publication, and the OIG appreciates the additional details and context that VHA responses can add to each report. Timeliness of publication is also critical to ensuring that findings and recommendations can be implemented and shared across the system. The OIG sent a draft of this report to VHA on June 6, 2023, with a due date for their review to be completed, and the report returned to the OIG by July 6, 2023. The OIG believes that this was more than sufficient time for VHA to review the draft report and provide any comments. VHA requested and received five extensions. The final extension approved a due date of September 1, 2023. Despite multiple attempts by OIG staff to obtain VHA comments, final written comments were not received until September 20, 2023.

The Under Secretary for Health and Veterans Integrated Service Network and Facility Directors concurred with recommendations 2 and 8–13, concurred in principle with recommendations 1, 3, 4, 6, and 7 and nonconcurred with recommendation 5. Acceptable action plans were provided (see appendixes E, F, and G). The OIG will follow-up on the planned actions until they are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
for Healthcare Inspections

Contents

Executive Summary i

Abbreviations xvi

Introduction 1

Scope and Methodology 11

Patient 1 Case Summary 13

Inspection Results 14

Community Care Coordination, Documentation, and Risk Mitigation 14

VHA's Oversight of CCN Providers' Opioid Prescribing Practices 32

TPA's Oversight of CCN Providers' Opioid Prescribing Practices 44

Conclusion 46

Recommendations 1–13 48

Appendix A: VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain Recommendations, ver. 3.0, 2017 50

Appendix B: Opioid Safety Tools 53

Appendix C: Optum's Clinical Quality Management 55

Appendix D: Opioid Safety Initiative (OSI) Department of Veterans Affairs Office of Community Care Training Module 56

Appendix E: Office of the Under Secretary for Health Memorandum 60

Appendix F: VISN Director Memorandum 64

Appendix G: System Director Memorandum 67

OIG Contact and Staff Acknowledgments 70

Report Distribution 71

Abbreviations

CCN	Community Care Network
CHOICE Act	Veterans Access, Choice, and Accountability Act
DoD	Department of Defense
EHR	electronic health record
EKHCS	Eastern Kansas Health Care System
IVC	VHA Office for Integrated Veteran Care
JPSR	joint patient safety report
MEDD	morphine equivalent daily dose
MISSION Act	VA Maintaining Systems and Strengthening Integrated Outside Networks Act
PDMP	prescription drug monitoring program
PMOP	Pain Management, Opioid Safety and Prescription Drug Monitoring Program
STORM	Stratification Tool for Opioid Risk Mitigation
OCC	VHA Office of Community Care
OEND	VA Opioid Overdose Education and Naloxone Distribution Program
OIG	Office of Inspector General
OSI	Opioid Safety Initiative
TPA	third-party administrator
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess care coordination for patients of the VA Eastern Kansas Health Care System (system) who are receiving care from and are dually prescribed opioids or benzodiazepines by Community Care Network (CCN) providers. The inspection also reviewed compliance with public law and Veterans Health Administration (VHA) policies and guidelines specific to the oversight of CCN provider opioid prescribing practices.

Background

The system is comprised of two medical centers, Colmery-O'Neil VA Medical Center located in Topeka, Kansas, and the Dwight D. Eisenhower VA Medical Center located in Leavenworth, Kansas. In addition, the system manages eight outpatient clinics in eastern Kansas and northwestern Missouri. The system is within Veterans Integrated Service Network (VISN) 15, and has a level 2, medium complexity designation.[1] From October 1, 2020, through September 30, 2021, the system served 38,929 patients and system staff placed 4,133 referrals (consults) for patients to receive care in the community. From October 1, 2021, through September 30, 2022, the system served 39,111 patients and system staff placed 32,618 consults for care in the community.[2] System providers told the OIG the system provides consultative services for the management of pain medications; however, patients who require interventional pain management services are referred to community pain specialists.

Care in the Community

In 2014, the VHA implemented the Veterans Access, Choice, and Accountability (CHOICE) Act to improve timely access to health care.[3] The CHOICE Act allowed qualified veterans to utilize care in the community if they were unable to schedule appointments at a VHA facility within 30 days of the veteran's preferred date or the clinically appropriate date or met specific criteria related to the veteran's geographic location and access to VHA health care. To expand access to care, non-VA providers entered into contractual agreements with VHA. In doing so, the providers were required to maintain credentials and licensure equivalent to VHA providers and submit medical records of the care and services provided to the veteran for incorporation into the

[1] VHA Office of Productivity, Efficiency and Staffing. The VHA Facility Complexity Model categorizes medical facility by complexity level based on patient population, clinical services offered, and educational and research missions. Complexity levels include 1a, 1b, 1c, 2 or 3. Level 1a facilities are considered the most complex.

[2] This data was reported by VHA as of November 7, 2022, and was not independently verified by the OIG.

[3] The Veterans Access, Choice, and Accountability (CHOICE) Act of 2014, Pub. L. No. 113-146, §128 (2014); VA Office of Public Affairs Media Relations, "Fact Sheet Veterans Access, Choice, and Accountability Act of 2014," https://www.va.gov/opa/choiceact/documents/Fact-Sheet-Veterans-Choice-Program.pdf.

patient's electronic health record (EHR). CHOICE expired on June 6, 2019, with the implementation of the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018 (MISSION Act).

The MISSION Act established a permanent community care program for eligible veterans to receive hospital care, medical services, and extended care through non-VA providers.[4] Included in the MISSION Act are expectations related to safe opioid prescribing, and documentation.[5]

VHA's Office of Community Care (OCC) established a single, consolidated community care program intended to increase transparency, accountability, quality, and communication between VHA, providers, and veterans. In September 2021, VHA established the Office for Integrated Veteran Care (IVC) to integrate VHA's direct and community care delivery systems by combining the Program Offices of Community Care and Veterans Access to Care.[6] IVC utilizes a contract with third-party administrators (TPA), Optum Public Sector Solutions, Inc., (Optum) and TriWest Health Care Alliance (TriWest), as a mechanism to purchase care in the community for veterans throughout five regional networks.[7] IVC leaders reported the TPA then contracts with non-VA providers (CCN providers) through a separate agreement (TPA/CCN Provider Agreement), creating a network of contracted CCN providers in each region.[8] The TPA/Provider agreement is proprietary in nature; however, an Optum representative provided excerpts of the Provider Agreement indicating the Optum Provider Manual is a binding part of the agreement.[9] VHA awarded the TPA contract to Optum (VA/Optum Contract) to develop and manage the network of providers in region 2 where the system is located.

[4] The Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, Pub. L. No. 115-182 §101 (2018). The MISSION Act established community care eligibility criteria for covered veterans. https://uscode.house.gov/statutes/pl/115/182.pdf.

[5] MISSION Act of 2018, § 131.

[6] VHA Acting Under Secretary for Health memo, "Notification of Program Office Reorganization," September 23, 2021. Due to reorganization of community care program offices to a single, combined program office, the OIG will use IVC when referencing OCC throughout this report, as appropriate. When employees identified OCC within their job titles, or document titles include OCC, the OIG kept the titles as written.

[7] The VA/Optum Contract outlines the requirements set forth from VA to Optum regarding the expectations of providers within the community provider network.

[8] VA Office of Public and Intergovernmental Affairs "VA awards Community Care Network contracts to increase health care access," news release, December 28, 2018. https://www.va.gov/opa/pressrel/includes/viewPDF.cfm?id=5175.

[9] United Healthcare/Optum, *VA Community Care Network VA CCN Provider Manual*, ver. 1.9, July 2021.

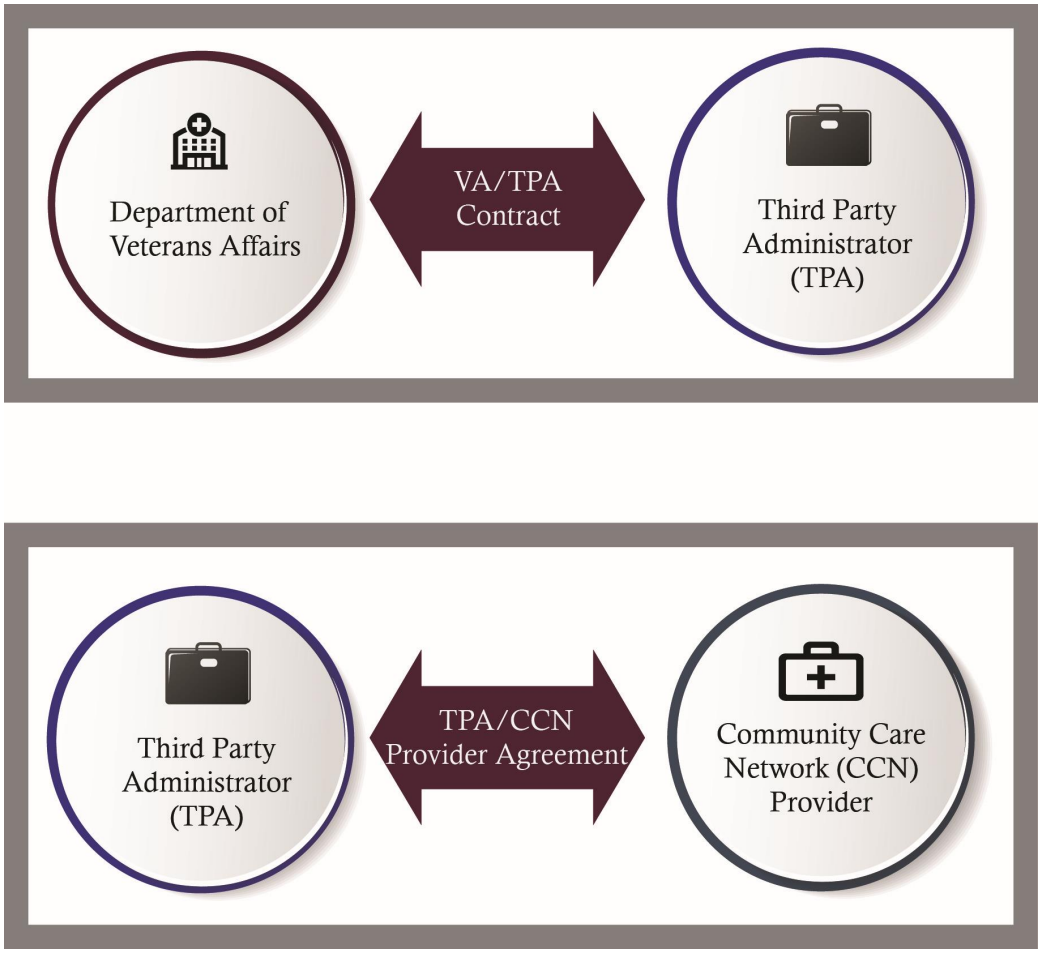


Figure 1. *Contractual relationship between VA, TPAs, and CCN Providers.*
Source: VHA IVC, Contract Management, May 10, 2022.

Controlled Substance Medications

Controlled substances are medications determined by the Drug Enforcement Administration to require heightened regulation due to a risk of abuse and physical or psychological dependence. Opioids are narcotics regulated under schedule II of the federal Controlled Substances Act because they have a "high potential for abuse," and "may lead to severe psychological or physical dependence." Benzodiazepines are depressants regulated under Schedule IV of the Controlled Substances Act as their risk for abuse and addiction is lower.[10]

[10] 21 U.S.C. § 812: The Controlled Substances Act divides medications into five schedules with Schedule I consisting of those with the highest likelihood of abuse and dependence and those with the lowest risk making up Schedule V.

Healthcare providers (providers) prescribe opioids primarily to treat pain. Optum's Provider Manual defines urgent/emergent opioid prescriptions as supplies of less than or equal to seven days, or the state's allowable limit, whichever is less.[11] VHA defines prescriptions as

- urgent/emergent if written for less than or equal to a 14-day supply, opioids may have a shorter supply limit, if required by state law;
- short-term if written for less than a 90-calendar-day supply; and
- long-term if written for greater than or equal to a 90-calendar-day supply.[12]

According to the Centers for Disease Control and Prevention, there were more than 75,600 US overdose deaths between April 2020 and April 2021 involving opioids.[13] Benzodiazepines are used to calm or sedate patients.[14] The simultaneous use of benzodiazepines and opioids by individuals is discouraged due to both medications potentially increasing sedation and the risk of overdose.[15] Veterans are at a higher risk of harm associated with concurrent use of opioid and benzodiazepine medication due to the prevalence and severity of chronic pain that is often accompanied by mental health comorbidities compared to the non-veteran population.[16]

[11] United Healthcare/Optum, VA Community Care Network VA CCN Provider Manual, ver. 1.9.

[12] VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain,* May 13, 2020. VHA OCC, How to Perform Care Coordination," chap. 3 in VHA OCC *Field Guidebook,* accessed April 14, 2022, https://vaww.portal.oig.va.gov/directorates/54/Hotlines/2022-02017-HI-1256/Work%20Papers/Office%20of%20Community%20Care%20Field%20Guidebook%20-%20Chapter%203.pdf, (This link is not publicly accessible.)

[13] Centers for Disease Control and Prevention (CDC), *Drug Overdose Deaths in the U.S. Top 100,000 Annually*, November 17, 2021, accessed April 6, 2022. https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm.

[14] United States Drug Enforcement Administration, "Benzodiazepines," accessed November 15, 2022, https://www.dea.gov/factsheets/benzodiazepines; Deborah Dowell, Tamara M. Haegerich, Roger Chou, "CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016." *Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR)* 65, (March 18, 2016):1–49. http://dx.doi.org/10.15585/mmwr.rr6501e1. A benzodiazepine is a medication that depresses (slows down) the central nervous system and can "produce sedation, induce sleep, relieve anxiety, and prevent seizures."

[15] National Institute for Drug Abuse (NIDA), *Benzodiazepines and Opioids*, February 3, 2021, accessed April 6, 2022, https://nida.nih.gov/drug-topics/opioids/benzodiazepines-opioids. 21 U.S.C. § 812. Two controlled substance prescription classes discussed in this report are opioids and benzodiazepines and both are regulated under the federal Controlled Substances Act.

[16] VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0, February, 2017. VA and DoD, VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain, ver. 4.0, May 2022, https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOpioidsCPG.pdf. Unless otherwise specified, the VA and DoD guidelines in version 3.0, 2017, contain the same or similar language as the revised 2022 version. The 2017 Clinical Practice Guidelines were in effect during the patient events described in this report until updated in May 2022, during the time of the inspection.

VHA Opioid Safety Initiative

In 2013, VHA "launched the Opioid Safety Initiative (OSI), the first of several [enterprise]wide initiatives to address opioid overuse."[17] The goal of the OSI is "to reduce over-reliance on opioid analgesics for pain management and to promote safe and effective use of opioid therapy when clinically indicated." The OSI provided a comprehensive strategy for addressing over-reliance on opioids that included education, pain management, expanded access to non-pharmacologic treatment options, and risk mitigation.[18]

The VA/Department of Defense (DoD) Clinical Practice Guideline for Opioid Therapy for Chronic Pain (OSI guidelines) is used by providers as "a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with chronic pain who are on or being considered for long-term opioid therapy."[19] The OSI guidelines provide evidence-based recommendations for

- initiation and continuation of opioids,
- risk mitigation,
- type, dose, follow-up, and taper of opioids, and
- opioid therapy for acute pain.[20]

See Appendix A for information on OSI guidelines.

The OSI guidelines recommend against the "initiation of opioid therapy for the management of chronic non-cancer pain" and "concurrent use of benzodiazepines and opioids for chronic pain," noting " the longer the patient is on opioids, the greater the potential for change in patient status and development of opioid-related harms."[21] As such, OSI guidelines recommend initial and

[17] VA Health Services Research and Development, "Improving the Safety of Opioid Treatment," July 2017, https://www.hsrd.research.va.gov/news/feature/opioid_safety.cfm.

[18] VA, "The VA Opioid Safety Initiative – how did we get here and what is ahead?" Presentation (February 6, 2018), accessed April 8, 2022. https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/2353-notes.pdf.

[19] VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0. An IVC health systems specialist reported the OSI guidelines refer to VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

[20] VA and DoD, *Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* ver. 3.0. Of note, the corresponding recommendations in version 4.0 are similar; however, "Opioid Therapy for Acute Pain" was removed and "Screening, Assessment, and Evaluation" was added.

[21] VA and DoD, *VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain,* ver. 4.0. Of note, the corresponding recommendation in version 3.0, 2017 against the initiation of long-term opioid therapy for chronic pain does not include the qualifier "non-cancer" chronic pain. Additionally, regarding the recommendation related to concurrent use of benzodiazepines and opioids does not include "for chronic pain."

ongoing risk-mitigation strategies particularly for patients at high-risk of opioid misuse or overdose. Risk-mitigation strategies include

- informed consent,
- urine drug testing,
- state prescription drug monitoring programs (PDMP) queries,
- overdose education and naloxone distribution (OEND), and[22]
- provider follow-up with frequency determined by risk.[23]

These risk-mitigation strategies are also supported by VHA policies, which require patient education about the potential risks, benefits, and alternatives to long-term opioids, written informed consent for long-term treatment with opioids, and queries of state PDMP databases.[24] Additionally, the Comprehensive Addiction and Recovery Act of 2016 requires VHA to monitor opioid prescribing practices and use risk-mitigation strategies.[25]

PDMPs

To improve information sharing with community providers, the MISSION Act permits VHA licensed healthcare providers or their delegates to query the national network of state based PDMPs "in accordance with applicable regulations and policies of the Veterans Health Administration."[26]

---

[22] VA and DoD, *Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* ver. 3.0. VHA implemented the OEND program as a component to the OSI guideline's risk mitigation strategies with the aim of reducing patient deaths from opioid overdose. OEND includes "education and training regarding the following topics: opioid overdose prevention, recognition, and rescue response; risk mitigation strategies; and issuing naloxone kits, which can be used as an antidote to opioid overdose"; U.S. National Library of Medicine, MedlinePlus, "Naloxone Injection," accessed November 25, 2018, https://medlineplus.gov/druginfo/meds/a612022.html. Naloxone is a medication "used along with emergency medical treatment to reverse the life-threatening effects of a known or suspected opiate (narcotic) overdose."

[23] VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0. VA and DoD, VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain, ver. 4.0. The OSI guidelines are "intended to aid practitioners in understanding the state of evidence on the use of opioids for chronic pain. The use of guidelines must always be in the context of a healthcare provider's clinical judgment in the care of a particular patient. Guidelines may be viewed as a tool to aid a practitioner in making evidence-based clinical decisions."

[24] VHA Directive 1306(1), *Querying State Prescription Drug Monitoring Programs (PDMP),* October 19, 2016, amended October 21, 2019. VHA defines a State Prescription Drug Monitoring Program as "a statewide electronic database which collects designated data on controlled substances dispensed in the state. The PDMP is administered by a specified statewide regulatory, administrative or law enforcement agency. The authorized agency distributes data from the database to individuals who are permitted under state law to receive the information for purposes of their profession."; VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain,* May 13, 2020.

[25] The Comprehensive Addiction and Recovery (CARA) Act of 2016, Pub. L. No. 114-198 130 STAT (2016).

[26] MISSION Act of 2018, § 134.

VHA policy recognizes that PDMP searches are crucial to addressing the opioid crisis, enhancing patient safety, and helping to prevent prescription drug abuse and overdose.[27] The OSI guidelines promote timely PDMP queries as they "provide clinicians with a complete and cohesive controlled substance prescription history, across all care locations, to drive more informed decisions."[28] In March 2021, the Centers for Disease Control and Prevention noted that "PDMP information can be used to inform clinical decision-making and prescribing in the following ways:

- Identify clinicians who appear to be prescribing potentially inappropriate amounts of opioids or opioids in combination with other medications (e.g., benzodiazepines)...;
- Identify patients prescribed amounts of opioids or opioids in combination with other medications (e.g., benzodiazepines) at levels that could increase their risk of overdose;
- Equip clinicians with information to assist in reducing overdose risk by providing high-risk patients with education, prescriptions for naloxone or medications for opioid use disorder, or referral to a pain treatment specialist for prescribing as appropriate; [and]
- Inform clinicians that one of their patients has experienced a fatal overdose and provide them with evidence-based solutions to reduce prescribing-related risk."[29]

States have different systems and processes to conduct PDMP queries and the information provided by each system varies. In 2008, Kansas established a PDMP program that provides prescription drug related data for all Kansas patients receiving schedule II–IV controlled substances and "drugs of concern."[30] Missouri, which borders Kansas, passed legislation to

[27] VHA Assistant Under Secretary for Health for Operations Memorandum, "*Compliance with VHA Directive 1306(1)* Querying State Prescription Drug Monitoring Programs*,"* June 15, 2020; VHA Directive 1306(1), *Querying State Prescription Drug Monitoring Programs (PDMP),* October 19, 2016, amended October 21, 2019.

[28] VA and DoD, VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain, ver. 4.0.

[29] Centers for Disease Control and Prevention, *Leveraging Prescription Drug Monitoring Program (PDMP) Data in Overdose Prevention and Response*, March 2021, accessed July 28, 2022, https://www.cdc.gov/drugoverdose/pdf/Leveraging-PDMPs-508.pdf.

[30] Kansas State Law, Pharmacy Practice Act, 65, 16§65-1683.

establish a statewide PDMP in August 2021.[31] Until the program is fully functional, the PDMP process continues to vary by counties within the state.[32]

Prior OIG Reports

A 2017 OIG report, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*, addressed gaps within the VHA and community provider medical documentation exchange as a barrier to care coordination, which could put patients at significant risk of adverse medication interaction and unintentional or intentional overdose.[33]

Table 1 provides the OIG's recommendations from the 2017 *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care* report and lists corresponding requirements published in the MISSION Act of 2018 that address OIG-identified issues.[34]

Table 1. VA OIG 2017 Recommendations and MISSION Act Requirements

VA OIG 2017 Recommendations	MISSION Act Requirements
The Acting Under Secretary for Health require that all participating VA purchased care providers receive and review the evidence-based guidelines outlined in the Opioid Safety Initiative.	The Secretary of Veterans Affairs shall ensure that all covered health care providers are provided a copy of and certify that they have reviewed the evidence-based guidelines for prescribing opioids set forth by the Opioid Safety Initiative of the Department of Veterans Affairs.
The Acting Under Secretary for Health implement a process to ensure all purchased care consults for non-VA care include a complete up-to-date list of medications and medical history until a more permanent electronic record sharing solution can be implemented.	The Secretary shall implement a process to ensure that, if care of a veteran by a covered health care provider is authorized under the laws administered by the Secretary, the document authorizing such care includes the available and relevant medical history of the veteran and a list of all medications prescribed to the veteran as known by the Department.
The Acting Under Secretary for Health require non-VA providers to submit opioid prescriptions directly to a VA pharmacy for dispensing and recording of the prescriptions in the patient's VA EHR.	The Secretary shall... require each covered health care provider to submit medical records of any care or services furnished, including records of any prescriptions for opioids, to the Department in the timeframe and format specified by the Secretary.

[31] Joint Oversight Task Force for Prescription Drug Monitoring, Missouri State Law, 188-215, §195.600 (2021).

[32] Joint Oversight Task Force for Prescription Drug Monitoring, Missouri State Law, 188-215, §195.600 (2021); St. Louis County Prescription Drug Monitoring Program, accessed July 26, 2022, https://pdmp-stlcogis.hub.arcgis.com/.

[33] VA OIG, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*, Report No. 17-01846-316, July 31, 2017.

[34] VA OIG, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*; MISSION Act of 2018, §131.

VA OIG 2017 Recommendations	MISSION Act Requirements
	... upon the receipt by the Department of the medical records... the Secretary shall—ensure the Department is responsible for the recording of the prescription in the [EHR] of the veteran.
The Acting Under Secretary for Health ensure that if facility leaders determine that a non-VA provider's opioid prescribing practices are in conflict with Opioid Safety Initiative guidelines, immediate action is taken to ensure the safety of all veterans receiving care from the non-VA provider.	If the Secretary determines that the opioid prescribing practices of a covered health care provider, when treating covered veterans... the Secretary shall take such action as the Secretary considers appropriate to ensure the safety of all veterans receiving care from that health care provider, including removing or directing the removal of any such health care provider from provider networks or otherwise refusing to authorize care of veterans by such health care provider in any program authorized under the laws administered by the Secretary.

Source: OIG, Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care, Report No. 17-01846-316, July 31, 2017, and the MISSION Act of 2018.

VHA concurred with the four recommendations and provided planned actions specific to each. In June 2018, the MISSION Act was signed into law and included language addressing some of the recommendations in the OIG report.[35] In December 2019, based on VHA-provided status updates, the OIG closed all four recommendations made in the 2017 report.

An OIG Comprehensive Healthcare Inspection Program report for VA Eastern Kansas Health Care System in Topeka, published on June 18, 2020, made three recommendations following the OIG's review of staff's provision of pain management services using long-term opioid therapy.[36] These recommendations addressed urine drug screening, obtaining informed consent, and timely follow-up care for patients on long-term opioid therapy.

Two months later an OIG Comprehensive Healthcare Inspection Program report for VISN 15, published on August 19, 2020, made two recommendations related to establishing a VISN-wide pain committee and submitting an annual implementation and progress report for a pain management strategy.[37]

A 2019 OIG report, *State Prescription Drug Monitoring Programs Need Increased Use and Oversight,* recommended the Under Secretary for Health ensure non-VA providers adhere to the

[35] VHA concurred in principle to Recommendation 3: "The Acting Under Secretary for Health require non-VA providers to submit opioid prescriptions directly to a VA pharmacy for dispensing and recording of the prescriptions in the patient's VA electronic health record."

[36] VA OIG, *Comprehensive Healthcare Inspection of the VA Eastern Kansas Health Care System in Topeka*, Report No. 19-06870-175, June 18, 2020.

[37] VA OIG, *Comprehensive Healthcare Inspection of Veterans Integrated Service Network 15: VA Heartland Network in Kansas City, Missouri*, Report No. 19-06848-209, August 19, 2020.

OSI guidelines, "including guidelines for prescription drug monitoring program queries."[38] The OIG also recommended VHA monitor CCN providers to "ensure appropriate corrective actions are taken if their prescribing practices are found to be inconsistent," with OSI guidelines.[39] In response, VHA leaders told the OIG they validate CCN provider completion of OSI training, and, in the event the training is incomplete, CCN providers are deactivated and can no longer receive referrals from VHA to provide care. VHA's response further indicated each VISN's Community Care Oversight Council would begin reviewing CCN provider opioid prescribing data to include use of data from the OSI dashboard to monitor CCN provider percentage of opioids dispensed. In the event VHA staff found a CCN provider with unsafe prescribing practices, VHA would deactivate the provider, and alert facility community care staff to complete appropriate care coordination activities.[40]

Concerns

In 2022, while conducting another project, OIG staff discovered a patient (Patient 1) who received multiple, high-dose opioid and concurrent benzodiazepine prescriptions in 2017 from a VHA contracted community-based pain provider. The patient subsequently experienced a medication overdose, which contributed to the patient's death in early 2018.[41]

Therefore, the OIG initiated the inspection to review

- system and CCN providers' care coordination, documentation, and use of risk-mitigation strategies for patients who are prescribed opioids and benzodiazepines simultaneously by CCN providers or through a combination of system and CCN providers;
- VHA, Veterans Integrated Service Network (VISN), and system oversight of CCN providers' opioid prescribing practices; and
- CCN providers' acknowledgment, review, and application of OSI Guidelines.

During the review, the OIG identified additional issues with the submission of documentation by CCN providers and a lack of CCN provider documentation of OSI risk-mitigation strategies. Additionally, the OIG identified two similar patient case examples (Patient 2 and Patient 3) in which patients received multiple controlled substance prescriptions from a combination of system, non-system VHA providers, and CCN providers.

[38] VA OIG, *State Prescription Drug Monitoring Programs Need Increased Use and Oversight*, No. 18-02830-164, September 23, 2019.

[39] VA OIG, State Prescription Drug Monitoring Programs Need Increased Use and Oversight.

[40] VA OIG, State Prescription Drug Monitoring Programs Need Increased Use and Oversight.

[41] The OIG uses the singular form of they, "their" in this instance, for privacy purposes.

Scope and Methodology

The OIG initiated the inspection on March 29, 2022, and conducted a virtual site visit May 17–24, 2022.

The OIG interviewed VHA IVC leaders, the VISN 15 Business Implementation Manager, VISN 15 Community Care Network Council members, the VISN 15 Community Care and TPA Lead, the system Chief of Staff, the system Community Care service line manager, system chiefs of Primary and Ambulatory Care, the system chief and associate chief of Pharmacy, system community care pharmacists, and the system patient safety manager.

The OIG reviewed relevant public laws, VHA, VISN, and system policies and procedures, provider training records, OSI dashboard information, CCN contracts, Contracting Officer's Representative delegation letters, and VISN and system committee meeting minutes.

The OIG also conducted independent EHR reviews of VHA patients who had overlapping opioid and benzodiazepine prescriptions filled at a VHA pharmacy with one or more medications prescribed by a CCN provider (EHR Review 1) and patient visits to CCN providers for pain management (EHR Review 2).

Table 2. OIG EHR Reviews of Patient Care from October 1, 2020, through September 30, 2021

	Patient EHR Review Criteria	Total Patients	Number of Patients Excluded from Review	Number of Patients Included in Review
EHR Review 1	Patients with overlapping opioid and benzodiazepine prescriptions Medications filled at a VHA pharmacy At least one opioid or benzodiazepine prescribed by a CCN provider	62	13	49*
EHR Review 2	Patients who visited a CCN provider for pain management	100	4	96

Source: OIG analysis of EHR reviews.

**The OIG reviewed 99 medication prescriptions for the included 49 patients.*

The OIG team reviewed records from October 1, 2020, through September 30, 2021 (fiscal year 2021) to assess care coordination between VHA and CCN providers, the content and availability of community care documentation, and the alignment of CCN providers' practice with components of VHA OSI. Using the Corporate Data Warehouse and Provider Profile

Management System, the OIG identified 62 patients for EHR Review 1, excluding 13 of them, and 100 patients for EHR Review 2, excluding four of them.[42]

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.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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

The OIG did not independently verify VHA data for accuracy or completeness.

[42] The OIG reviewed 62 patient EHRs with 99 overlapping opioid and benzodiazepine prescriptions (EHR Review 1) filled through the system's pharmacy during FY2021. The OIG excluded 13 patient EHRs from the review based on traveling veteran status or if patients primarily received care at a separate facility and received telehealth at the system; patients with a cancer diagnosis, or patients who did not receive an opioid or benzodiazepine prescription from a CCN provider. Multiple CCN prescriptions filled through VHA pharmacies may have been associated with one visit. The OIG reviewed patients' EHRs for documentation related to each prescription. The OIG reviewed 100 patients' EHRs for visits to community care pain management or anesthesiology services (EHR Review 2). The OIG excluded four patients due to patient data inaccuracy or visits for hospice or care not related to pain management.

Patient 1 Case Summary

Patient 1 was in their late 30s with a history of chronic left arm pain treated by VHA providers with oxycodone, with the last VHA-provided prescription in early 2017.[43] In summer 2017, a system primary care provider ordered a community interventional pain management consult for treatment citing opioid seeking behavior with the need for a more permanent pain treatment plan; and a system pain pharmacist consult for non-opioid pain medication recommendations.[44] Mid-year 2017, the community pain specialist submitted four evaluation and treatment notes that included a medication profile with multiple oxycodone and alprazolam entries and treatment plans that included injections for pain but lacked any notation in the summary of care regarding the management of prescribed pain medications or methadone prescriptions prescribed by the provider. The OIG found the provider prescribed methadone through a system pharmacist's PDMP query. Late in 2017, after the patient missed several scheduled appointments, the system pharmacist discontinued the pharmacy pain consult and documented a state PDMP query that showed community pharmacy-filled prescriptions from the community pain specialist including alprazolam as well as oxycodone and methadone at dosages equal to 300 mg morphine equivalent daily dose (MEDD).[45] Further, there was no reference to alprazolam or oxycodone in the VHA EHR medication profile updated by system providers or pharmacists. The system pharmacist noted that the patient was at high-risk for overdose and recommended the system primary care provider facilitate patient education on the risk of continuing the opioid medication and verify the provision of naloxone. However, the primary care nurse left a message with the patient to schedule a follow-up appointment and no further contact was documented.[46] In late 2017, the community pain specialist again provided documentation with the same opioid and benzodiazepine medications in the medication list with a treatment plan that included injections to manage pain, but no mention in the summary of care of provision of prescribed pain medications. According to the death certificate, the patient died in early 2018, from combined alprazolam and methadone intoxication.

---

[43] The OIG uses the singular form of they, "their" in this instance, for privacy purposes.

[44] U.S. Department of Health and Human Services, *Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations*, May 9, 2019, defines interventional pain management services, or interventional pain medicine, as "a medical subspecialty of pain medicine that diagnoses and treats pain with minimally invasive interventions that can alleviate pain and minimize the use of oral medications. Most interventional pain physicians offer interventional therapies for acute and chronic pain conditions as part of a comprehensive treatment program."

[45] Pallipedia, "Morphine equivalent daily dose (MEDD)" accessed April 8, 2022, https://pallipedia.org/morphine-equivalent-daily-dose-medd/. "MEDD is used to translate the dose and route of each of the opioids the patient has received over the last 24 hours to a parenteral morphine equivalent using a standard conversion table."

[46] The OIG reviewed the patient's complete EHR and was unable to find any further documentation of system staff contacting Patient 1 regarding the follow-up appointment.

Inspection Results

The OIG found gaps in care coordination, documentation, and the use of risk-mitigation strategies for system patients receiving community care that were similar to those gaps identified in the 2017 OIG report, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*.[47]

The case prompting this review included a patient who filled several controlled substances prescriptions at non-VA pharmacies, as identified through a system pharmacist's PDMP query. During EHR Review 1, the OIG identified two additional patients (Patient 2 and Patient 3) who similarly filled multiple controlled substance prescriptions at non-VA pharmacies identified by system and non-system VHA staff through PDMP queries.[48] Other than system and non-system VHA staff documenting contents of the PDMP query, there was no evidence that these prescriptions were documented by system staff in the VHA EHR medication profile, which alerts other providers of the prescribed medications and enables risk-mitigation strategies. Elements within the MISSION Act attempt to mitigate potential gaps in care such as this by ensuring that the provision of opioid medication to veterans is communicated to VHA providers. The OIG determined that actions taken to improve CCN provider documentation of these MISSION Act requirements would enhance coordination of care in these cases.[49]

Community Care Coordination, Documentation, and Risk Mitigation

VHA defines care coordination as a "system-wide approach to the deliberate organization of all Veteran care activities between two or more participants or systems to facilitate the appropriate delivery of health care services."[50] VHA policy requires "that all eligible Veterans cared for within the [VHA] system receive well-coordinated, safe, appropriate, and patient-centered medical care at all levels and transitions of the health care continuum as it pertains to the management of patient medication information."[51]

[47] VA OIG, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*, Report No. 17-01846-316, July 31, 2017. In 2017, VA community care was provided under the Veterans Access, Choice, and Accountability Act of 2014 as the MISSION Act was not in place until 2018.

[48] The OIG excluded these patients from EHR Review 1, because they were assigned primary care at another facility in VISN 15 or did not receive an opioid or benzodiazepine prescription from a CCN provider filled at a VHA pharmacy.

[49] MISSION Act of 2018, § 131.

[50] VHA OCC, *Field Guidebook*, Chapter 3.

[51] VHA Directive 2011-012, *Medication Reconciliation*, March 9, 2011, was rescinded and replaced by VHA Directive 1345, *Medication Reconciliation*, March 9, 2022. The language is similar within both versions of the directive.

The OIG found gaps in care coordination, documentation, and the use of risk-mitigation strategies for system patients receiving community care; similar to those gaps identified in the 2017 OIG report, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*.[52]

Incomplete and Delayed CCN Provider Documentation

The OIG found incomplete and delayed CCN provider documentation throughout the reviewed EHRs. The OIG is concerned that the delay in providing documentation is a gap in care coordination, which poses a risk to patient safety.

Sharing health information between providers caring for the same patient is key to care coordination.[53] In the 2017 OIG report, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*, the OIG identified challenges related to health information sharing between VHA and non-VA providers. The report highlighted the importance of provider access to accurate medication lists and the patient medical history and reported, "without immediate sharing of information, [VHA] providers may also not be aware of treatment plans or new medications prescribed by non-VA providers." Furthermore, the report noted that gaps in care coordination are "particularly risky when treatment plans by either or both groups of providers include opioid therapy."[54] Accordingly, VHA and CCN providers should communicate and record relevant clinical information, including opioids prescribed, to ensure safe and effective care coordination during care transitions.[55]

When VHA staff refer patients to CCN providers, VHA uses an automated system, Referral Documentation Tool, to compile patient EHR documentation. The documentation, which VHA staff send to the CCN provider, includes a comprehensive list of medications prescribed by VHA providers in the previous 12 months and current known medications prescribed by non-VA providers.[56] Once a CCN provider-patient visit occurs, the MISSION Act requires "each covered health care [CCN] provider to submit medical records of any care or services furnished,

[52] VA OIG, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care,* Report No. 17-01846-316, July 31, 2017.

[53] The Joint Commission, *National Patient Safety Goals Effective July 2020 for the Ambulatory Health Care Program*, March 26, 2020. The Joint Commission, Sentinel Event Alert, Issue 58, September 12, 2017. "Inadequate Hand-Off Communication."

[54] VA OIG, Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care.

[55] VA OIG, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care;* The Joint Commission, National Patient Safety Goals Effective July 2020 for the Ambulatory Health Care Program, March 26, 2020. The Joint Commission, Sentinel Event Alert, Issue 58, September 12, 2017. "Inadequate Hand-Off Communication."

[56] VHA OCC, *Field Guidebook*, Chapter 3; VHA OCC, *Referral Documentation Tool (REFDOC)*, Ver. 2.4.3; User Guide, December 2018.

including records of any prescriptions for opioids, to the Department in the timeframe and format specified by the Secretary."[57]

According to the VA/Optum contract and IVC leaders, after patients receive care, CCN providers must send all routine/maintenance prescriptions to a VHA pharmacy for processing and fulfillment and include specific data elements in the medical documentation sent to VHA:

- Encounter notes with descriptions of procedures performed and recommendations for further testing or follow-up
- Results of community radiology testing or imaging
- "Actual results of any ancillary studies/procedures that would impact recommended follow-up...
- *Any recommended prescriptions*, medical devices, supplies or equipment, and treatment plans (emphasis added)
- Other medical documentation based on clinical need"[58]

CCN providers are required to submit medical record documentation to the referring VHA facility within 30 days of the date of service and send all prescriptions for routine/maintenance medications to a VHA pharmacy for fulfillment, or processing.[59]

In an effort to manage compliance of CCN provider documentation within the 30-day time frame, the VHA OCC Field Guidebook (Field Guidebook) states that if CCN providers have not returned medical documentation within 14 days, system staff must verify the appointment

[57] MISSION Act of 2018, § 131.

[58] VA Commodities and Services Acquisition Service and Optum Public Sector Solutions, Inc. Contract No. 36C79119D0005, dated December 28, 2018, amended October 2020.

[59] United Healthcare/Optum, *CCN Provider Manual, v.1.9*; VHA OCC, *Field Guidebook*, Chapter 3; VHA OCC, "Consult Completion and Medical Records Management," chap. 4 in *VHA OCC Field Guidebook*, accessed April 14, 2022 https://vaww.portal.oig.va.gov/directorates/54/Hotlines/2022-02017-HI-1256/Work%20Papers/Office%20of%20Community%20Care%20Field%20Guidebook%20-%20Chapter%204%2C%203-30-2022.pdf. (This link is not publicly accessible.) Optum Provider Manual's specified time frame for submission of CCN provider patient care documentation is within 30 days after completion of care. VHA defines completion of care as determined by the Standard Episode of Care at the beginning of the referral; multiple patient visits may occur within one referral. The OIG learned VHA reimburses CCN provider claims and may close a community care consult even when VHA receives no medical documentation from the CCN provider. The Field Guidebook states CCN provider documentation can be returned to the referring VHA facility through a variety of methods, including the TPA portal, Health Share Referral Manager platform, Veterans Health Information Exchange platforms, secure electronic fax, or secure encrypted email. CCN providers may send patient prescriptions for emergent/urgent medications (up to a 14-day supply) to local retail in-network pharmacies. Patients who are authorized for non-VA care may have their emergent/urgent prescriptions filled through a CCN retail pharmacy or a VHA pharmacy. Should a patient require continued medications beyond the emergent/urgent, CCN providers must generate a second prescription.

occurred and request medical documentation from the CCN provider.[60] Once the CCN provider's medical documentation has been received, facility staff scan or import the medical documents into the patient's EHR and electronically attach the documentation to the relevant consult. This action produces an alert notifying the referring VHA provider that documentation has been received and the consult is completed.

According to the Field Guidebook, CCN providers who "automatically send clinical documentation" after providing care, are "often the exception and not the rule," which requires additional administrative support and contributes to gaps within care coordination.[61] When the OIG asked what barriers limit system staff efforts to coordinate care for patients who receive controlled substances in the community, the Chief of Staff said "the big barrier is getting the records back and knowing what the community provider is doing."

The VISN 15 Business Implementation Manager told the OIG, "I am not aware of any specific guidance on minimally acceptable care documentation for community care. However, if the ordering provider feels additional documentation is required to coordinate care, the ordering provider may request community care follow-up for additional information."[62]

During EHR reviews, the OIG team noted CCN provider documentation often contained limited or no information about the medication prescribed to patients, such as the type of medication prescribed, rationale for the medication, and dosing parameters. As an example, within EHR Review 1, the OIG found one CCN provider who provided 42 controlled substance prescriptions to 21 system patients.[63] The provider prescribed a short-term prescription of both an opioid and a benzodiazepine for the patient to take in relation to a procedure; the prescriptions were sent to and filled at the system's pharmacy.[64] However, the CCN provider documentation routinely did not include information about the controlled substances prescribed to the patient (see example documentation in Figure 2).

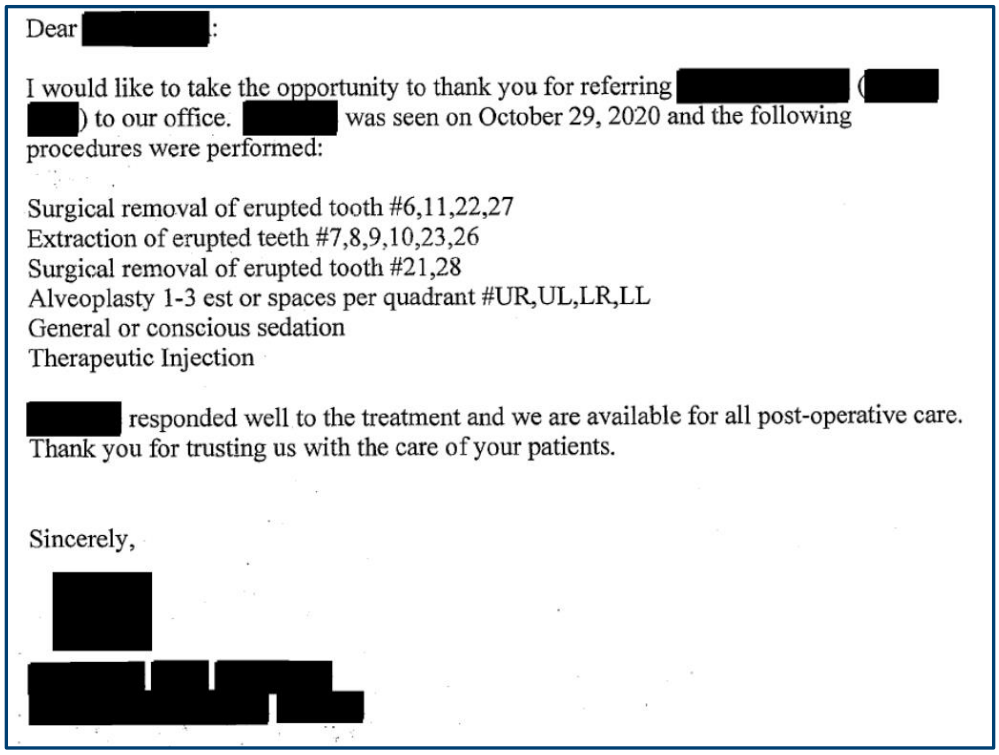
[60] VHA OCC, *Field Guidebook*, Chapter 4; VHA OCC, *Field Guidebook*, Chapter 3. The Field Guidebook provides guidance for VHA staff on managing community care consults, appointment scheduling, and communication between VHA and community providers.

[61] VHA OCC, *Field Guidebook*, Chapter 4.

[62] The OIG uses the singular form of they, "their" in this instance, for privacy purposes.

[63] The provider may have prescribed more than one controlled substance to a system patient related to one visit. The OIG reviewed 21 patients' EHR's for documentation related to each prescription.

[64] This CCN provider prescribed a five day or less supply for 69 percent of the prescriptions provided to the system's patients within EHR Review 1.


Dear [redacted]:

I would like to take the opportunity to thank you for referring [redacted] ([redacted]) to our office. [redacted] was seen on October 29, 2020 and the following procedures were performed:

Surgical removal of erupted tooth #6,11,22,27
Extraction of erupted teeth #7,8,9,10,23,26
Surgical removal of erupted tooth #21,28
Alveoplasty 1-3 est or spaces per quadrant #UR,UL,LR,LL
General or conscious sedation
Therapeutic Injection

[redacted] responded well to the treatment and we are available for all post-operative care. Thank you for trusting us with the care of your patients.

Sincerely,

[redacted]

Figure 2. *CCN provider medical documentation content example.*
Source: System Patient EHR Chart Reviews, retrieved July 19, 2022.

In reviewing documentation specific to CCN pain management visits, the OIG found that CCN providers returned documentation 70 percent of the time (95 percent confidence interval: between 60 and 79 percent).[65] For visits where CCN providers prescribed controlled substance medications (n=4), the OIG found provider documentation related to the visit scanned into the EHR 8, 15, 63, and 269 days, respectively, after the completed CCN visit.

The OIG determined that challenges persist related to the sharing of medical record documentation between CCN providers and VHA. The OIG is concerned that the ongoing delay and absence of CCN provider documentation is a gap in care coordination. Given the risks involved in opioid prescribing, these gaps in care coordination may pose a risk to patient safety.[66]

[65] The 95 percent confidence interval indicates that among all possible samples of the same size and design that could have been selected, the true rate would have been included in the computed intervals 95 percent of the time.

[66] National Institute on Drug Abuse (NIDA), *Benzodiazepines and Opioids*, February 3, 2021, accessed April 6, 2022. https://nida.nih.gov/drug-topics/opioids/benzodiazepines-opioids; VA OIG, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*.

Opioid Prescribing Risk-Mitigation Strategies

The OIG was unable to find critical information related to the use of risk-mitigation strategies for approximately half of the patients included in an EHR review.

As noted in the Background, the 2017 OSI guidelines recommend risk-mitigation strategies specific to patients on long-term opioid therapy who are at increased risk of opioid overdose. These risk-mitigation strategies include

- informed consent,
- urine drug screening,
- OEND, and
- PDMP queries.[67]

OSI guidelines recommend urine drug screens to help identify a substance use disorder or possible diversion prior to initiating or continuing long-term opioid therapy and periodically thereafter. The OSI guidelines further recommended that "overdose education should be provided and naloxone should be offered as an antidote to all patients at-risk for an opioid overdose including those who are in the process of tapering [off opioids]."[68] While the VA/Optum contract specifies Optum must ensure CCN providers submit medical documentation to VHA, it does not explicitly include a requirement for CCN providers to document OSI risk-mitigation strategies.

The OIG conducted EHR Review 1, to examine whether providers documented key OSI risk-mitigation strategies as outlined in the OSI guidelines. The EHR review included co-managed patients who were

- prescribed an opioid,
- dually prescribed benzodiazepines, and

[67] VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0; VA and DoD, VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain, ver. 4.0. At the time of the events reviewed by the OIG in this report, version 3.0 of the guideline was in effect, which strongly recommended providers starting patients on long-term therapy provide the patient with a consent form that included urine drug screening, state PDMP queries, monitoring for overdose and suicidality, and provide OEND. By 2022, version 4.0 no longer emphasized patient consent forms for long-term opioid therapy, risk assessment instruments, and naloxone prescriptions due to a lack of evidence that these measures improved patient safety. The 2022 version does endorse urine drug screening for patients on long-term opioid therapy. Urine drug screens "should be used to screen for the presence of illegal drugs, unreported prescribed medication, or unreported alcohol use prior to starting therapy."

[68] VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0. VA and DoD, VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain, ver. 4.0. The 2022 version contains language that is similar to version 3.0; however, the language does not support OEND as an antidote to all patients at-risk for opioid overdose.

- prescribed at least one medication by a CCN provider.

Of the 49 patients reviewed, 12 were on long-term opioid therapy. The OIG reviewed their EHRs for documentation of the following risk-mitigation strategies:

- patient informed consent for long-term opioids,
- urine drug screening, and
- naloxone or opioid overdose education.[69]

In approximately half of the 12 cases, the OIG was unable to find critical information documenting that the system or CCN provider informed the patient about the potential risks, benefits, or alternatives to long-term opioid treatment; completed a urine drug screen; or provided naloxone or opioid overdose education prior to initiating opioid therapy.[70]

This data suggests an opportunity to improve documentation and care coordination between system and CCN providers. As discussed previously, documentation is a critical component of care coordination, and it is important that system and CCN providers document OSI risk-mitigation strategies for patients receiving long-term opioid therapy and/or a combination of opioid and benzodiazepine therapy to ensure patient safety and decrease opioid overdose.

CCN Provider PDMP Queries

The OIG found the contractual language and framework of the VA/Optum contract is unclear and recommends that VHA consider a contract modification to clarify when CCN providers must conduct PDMP queries, and document completion, prior to prescribing controlled substances.

VHA policy requires VHA providers, or their designee, to conduct a PDMP query when prescribing a new controlled substance, when clinically indicated, and annually.[71] As recommended by OSI guidelines, PDMP queries are a critical tool for patient safety.[72] The Centers for Disease Control and Prevention recommends clinicians query PDMP databases to

[69] VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0.

[70] Given the failure of CCN providers to submit medical record documentation and the sparse information related to OSI risk-mitigation strategies when documentation was provided to VHA, it is unknown whether the risk-mitigation strategies were completed but not documented. The OIG found system or CCN providers often failed to document informed consent (5 of 12 patients), urine drug screens (5 of 12 patients), and naloxone or opioid overdose education (7 of 12 patients) for patients noted to be on long-term opioid therapy.

[71] VHA Directive 1306(1), *Querying State Prescription Drug Monitoring Programs (PDMP)*, October 19, 2016, amended October 21, 2019. This directive outlines VHA's minimum requirements for monitoring PDMPs; in addition, providers may be required to query PDMPs more frequently, as required by state laws, which vary. Patients whose controlled substance prescription is for a five-day supply or less, without refills, and patients enrolled in hospice care, are excluded from PDMP query requirements, unless contrary to applicable state law.

[72] VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0.

"determine whether [a] patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose."[73]

The OIG found in the course of EHR Review 1, that CCN providers documented a state PDMP query prior to prescribing controlled substances for seven of the 99 prescriptions (7 percent).[74] It is unclear whether the VA/Optum contract requires CCN providers to query their state's PDMP prior to writing routine or maintenance prescriptions for controlled substances. The pharmacy specific section of the VA/Optum contract requires CCN providers to forward all routine/maintenance prescriptions, including those for controlled substances, to VHA pharmacies for processing and fulfillment, but does not contain a requirement for CCN providers to query state PDMP databases. However, in the section referring to urgent/emergent prescriptions, the contractual language states, "the Contractor must require its CCN providers to check with its state's [PDMP] for any controlled substance utilization prior to writing any prescription for a controlled substance for a Veteran." The contractual language does not expressly limit the requirement to conduct PDMP queries to urgent/emergent prescriptions. Nevertheless, given the location of this text in the contract, it is unclear if the requirement for CCN providers to conduct PDMP queries applies only to urgent/emergent controlled substance prescriptions, or whether it also applies to routine/maintenance controlled substance prescriptions. Optum's Provider Manual contains a requirement for CCN providers to query state PDMP databases before prescribing controlled substances to a veteran. In written correspondence with the OIG, Optum staff confirmed that this requirement applies to routine/maintenance prescriptions, not only to urgent/emergent prescriptions for controlled substances.

PDMP queries are a critical patient safety tool and risk-mitigation strategy that may help prevent prescription drug abuse and overdose. The querying of state PDMP's by CCN providers, coupled with documentation of the query, prior to prescribing any controlled substances to VHA patients would strengthen care coordination particularly as it relates to opioid prescribing. Given the lack of clarity in the contractual language and framework of the VA/Optum contract, the OIG recommends that VHA consider a contract modification to clarify when CCN providers must conduct state PDMP queries, and document completion, prior to prescribing controlled

[73] Deborah Dowell, Tamara M. Haegerich, Roger Chou, "CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016." *Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR)* 65, (March 18, 2016):1–49. http://dx.doi.org/10.15585/mmwr.rr6501e1.

[74] The OIG reviewed routine and urgent prescriptions for documentation of a PDMP query. The 99 opioids prescriptions stemmed from 49 patients within the EHR Review 1. The OIG did not assess the reasons that PDMP checks were not documented and is unable to determine whether CCN providers conducted state PDMP queries in the cases where documentation of a query was not present. State laws regarding PDMP use vary. While the state of Kansas only requires PDMP queries are done for Medicaid patients, CCN providers in Kansas who contract with Optum are to follow expectations regarding PDMP use as outlined in their contract and provider manual.

substances, whether the prescriptions are urgent, emergent, routine, or maintenance prescriptions.

VHA Versus Non-VA Pharmacy Filled CCN Prescriptions

The OIG found when prescriptions are filled at the system's pharmacy, pharmacists query the state PDMP and add medications to patients' EHRs. However, when CCN prescriptions are not filled at the system pharmacy, the medications are often not added to the patient's EHR. Additionally, the OIG found system staff did not elevate concerns to system leaders after identifying concerning CCN provider prescribing practices.

VHA Filled

The location at which a patient fills a prescription was identified as a vulnerability in the 2017 OIG report because prescriptions written by CCN providers that were filled outside of VA were often unknown to VA providers. To address the concern, the OIG made a recommendation to require CCN providers to submit opioid prescriptions directly to a VHA pharmacy for dispensing and recording in the patient's EHR. [75]

When CCN providers send controlled substance prescriptions to system pharmacies for fulfillment, system pharmacists review the prescription for appropriateness, query state PDMPs, and add the CCN prescribed medication to the patient's medication list for review (medication profile).[76]

[75] VA OIG, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*. In December 2019, based on VHA provided status updates, the OIG closed all four recommendations made in the 2017 report.

[76] VA Eastern Kansas Health Care System SOP P-OP-7, *Care in the Community Pharmacy Services*, November 3, 2020; VHA Directive 1345, *Medication Reconciliation*, March 9, 2022. The Essential Medication List (medication profile) includes "all the medications patients may be taking. In [the EHR], the essential components are [VHA] prescriptions that are pending, not yet furnished to patients, all the medications patients have received from the [VHA] recently or administered in clinic including prescriptions that have recently expired or been discontinued. The Essential Medication List for Review must include Non-VA Medications." VHA Handbook 1108.11(1), *Clinical Pharmacy Services*, July 1, 2015, amended on June 29, 2017. Medication reconciliation includes "updating the medication profile to reflect an accurate, active list of VA and non-VA medications. This may include adding non-VA medications or discontinuing duplicate medications or those the patient is not taking." The OIG uses the term *medication profile* to describe the active list of VA and non-VA medications in the EHR.

VHA policy requires VHA pharmacies to report data to the state PDMP regarding all schedule II through V controlled substances they dispense, including prescription information (i.e., name and Drug Enforcement Agency number of prescriber and quantity of drugs dispensed).[77] Across VHA, providers, or delegated healthcare team members, are required to query PDMPs for patients receiving controlled substance prescriptions prior to "initiating therapy with a controlled substance," when clinically indicated, and at least once a year.[78]

The system has a policy specific to CCN-filled prescriptions that requires system pharmacists to conduct PDMP queries more frequently than what is minimally required by VHA policy. The policy states that "a PDMP query will be conducted on new starts, and [at] three-month intervals for authorized care in the community, controlled substance prescription presented to the pharmacy before dispensing."[79] The policy notes that system pharmacists must notify CCN providers of questionable activity (multiple provider or multiple medications) found on a PDMP query.[80] Additionally, system pharmacy technicians are required to verify that the prescription came from an authorized community care referral and differentiate the prescription written by a CCN provider from VHA-prescribed medications by noting "CCNRX" within the prescription.[81]

Querying state PDMPs identifies patients receiving controlled substance medications, such as opioids and benzodiazepines, from multiple providers and promotes a complete clinical assessment. In interviews with the OIG, the system's pharmacists discussed limitations to PDMP queries. A recurring problem is incomplete data regarding patients' controlled substance filling history due to limited statewide functionality of the PDMP in Missouri, exacerbated by patients traveling to fill prescriptions in those counties that do not have a process to report to the state PDMP. The OIG found the limitations to PDMP queries identified by system pharmacists further

[77] VHA Directive 1108.07(1), *Pharmacy General Requirements*, March 10, 2017, amended January 26, 2021, rescinded November 28, 2022. This directive defines the Prescription Drug Monitoring Program (PDMP) as "a state-controlled substance monitoring program, including a program approved by the Secretary of Health and Human Services under section 3990 of the Public Health Service Act (42 U.S.C. 280g–3). Generally, these programs require pharmacies registered in their state to enroll and transmit (electronically) records of each dispensing of a controlled substance. States laws vary regarding the definition of controlled substance, requirements for software compatibility, frequency of data transmission, and required patient identifiers."

[78] VHA Directive 1306(1).

[79] VA Eastern Kansas Health Care System SOP P-OP-7, *Care in the Community Pharmacy Services*, November 3, 2020. Pharmacists using the Kansas state PDMP may select to review surrounding states prescription drug information. Missouri State Medical Association, "Prescription Drug Monitoring Program: MO HealthNet Policy FAQ," accessed July 19, 2022, https://www.msma.org/resources/SiteAlbums/Practice/PDMP%20FAQs.pdf; Joint Oversight Task Force for Prescription Drug Monitoring, V.A.M.S, §195.600, August 28, 2021. Missouri passed legislation in August 2021 to establish a PDMP and at the time of this review in July 2022, was in the process of implementing the state PDMP; therefore, the process varied across counties.

[80] VA Eastern Kansas Health Care System SOP P-OP-7, *Care in the Community Pharmacy Services*.

[81] VA Eastern Kansas Health Care System SOP P-OP-7, *Care in the Community Pharmacy Services.*

supports the importance of compliance with MISSION Act requirements for CCN providers to send records of all medications, including opioids to VHA.

System pharmacists must follow Drug Enforcement Administration regulations and professional judgment prior to processing a prescription found to be questionable.[82]System pharmacists assigned to fill CCN provider prescribed medications told the OIG they clarify the prescription with the CCN provider or cancel the prescription order if they identify a concern with a prescription. They added that at times, when they determined that CCN provider prescription practices were contrary to VHA OSI guidelines, or if there was questionable controlled substance prescribing activity for a patient or by the provider, they had refused to fill CCN provider prescriptions.

Non-VA Filled

The OIG found that unlike VHA pharmacy filled prescriptions, controlled medication prescriptions sent to non-VA pharmacies by CCN providers lead to potential gaps in VHA provider awareness of the medication. The former VHA Executive Director of Clinical Integration and Field Operations, and IVC told the OIG

> if the veteran wanted to pay for it [opioid prescription] for herself or himself, they could. If they want them to be covered by the [VHA], then they would have to have them filled within [VHA]. But there [is] nothing that stops a veteran from having a script in his or her hand and taking it to a pharmacy. It's legitimately written by a provider who has a DEA [Drug Enforcement Agency] license to... write that script, they can actually get it filled and pay for it... And [VHA] may or may not have visibility into that happening.

CCN providers are contractually required to send routine/maintenance prescriptions to VHA pharmacies where the prescription is filled at little to no cost to the patient. However, patients sometimes choose to fill prescriptions at retail pharmacies at their own expense.[83] Reasons for doing so vary and may include an attempt to hide the amount of controlled substances they are using. While the OIG understands the legitimate need for patients to have access to retail

[82] VA Eastern Kansas Health Care System SOP P-OP-7, *Care in the Community Pharmacy Services;* US Department of Justice, "What We Do," accessed August 4, 2022, https://www.dea.gov/what-we-do. Drug Enforcement Administration is the federal organization in charge of enforcing U.S. Controlled Substance laws.

[83] VHA Reference Sheet, *Veterans Prescription Benefit*, June 7, 2019. Patients can fill urgent/emergent prescriptions written by an authorized CCN for 14 days or fewer at a VHA pharmacy or any non-VA pharmacy. VHA will not reimburse the patient for prescription costs if the patient decides to fill and pay for prescriptions through a non-VA pharmacy, unless the prescription was previously approved by VHA, or the prescription is deemed as urgent/emergent by the CCN provider. VA Health Benefits, Medication Copayments, accessed March 28, 2023, https://www.va.gov/healthbenefits/resources/publications/hbco/hbco_copayments.asp. VHA outpatient medication copayment costs are based on a number of factors including, veteran priority group, and medication type and range from no cost, to 5, 8, and 11 dollars for 30-day or less supplies.

pharmacies, ideally VHA would be made aware of these routine, urgent, emergent controlled substance prescriptions for purposes of care coordination and recording keeping.

VHA could consider leveraging the system's practice of having pharmacists query PDMPs prior to dispensing the medication for all new CCN prescribed controlled substance prescriptions, and every three months thereafter for active controlled substance prescriptions, as the OIG has not uncovered any provision in the MISSION Act, or any other VHA policy, on this issue. Having a complete picture of all controlled substance prescriptions filled at VHA and non-VA pharmacies would greatly aid VHA in reducing adverse opioid-related events and may help stem veteran opioid abuse.

Patient 2 Case Example

During the course of this review, the OIG identified a patient who received two episodes of brief community care coordination from system staff, but who primarily received care from a neighboring VHA facility within VISN 15. While the patient was excluded from EHR Review 1, the OIG had concerns regarding CCN provider opioid prescribing practices with overlapping opioids and benzodiazepines, with a high MEDD. A patient in their 50s (Patient 2) had a history of anxiety and mood disorders, chronic obstructive pulmonary disease, and chronic abdominal and back pain, which were treated with opioid therapy. The patient's care was primarily managed through a CCN primary care provider with the exception of a nine-month period starting late in 2020 when a non-system VHA primary care provider was responsible for the patient's care, including pain management[84] While in the care of the non-system VHA primary care provider, the CCN primary care provider continued to prescribe the patient opioids with evidence of high doses, as noted in system staff PDMP queries. In summer of 2021, a new consult was written that allowed the patient to return to care with the CCN provider.

[84] The CCN primary care provider consult was not continued due to the previously approved CHOICE eligibility program ending in June 2020, and MISSION Act eligibility was not met. The patient was informed that while continuing care with the CCN primary care provider was an option, it would not be paid for through VHA without an active consult. A non-system VHA primary care provider assumed care and pain medication management for nine months of the review period. During this period, the non-system VHA primary care provider referred the patient to pain management and gastrointestinal services; however, the patient was non-compliant with recommendations. In the summer of 2021, a new consult was written allowing the patient to resume care with the CCN primary care provider.

Non-system VHA staff queried the state PDMP 10 times from October 1, 2020, through September 30, 2021. Non-system pharmacy staff PDMP queries noted that the patient received multiple controlled substance prescriptions filled at non-VA pharmacies, including prescriptions for longer than 14 days. The queries showed the previous CCN primary care provider prescribed multiple opioids (fentanyl patch and oxycodone) and a benzodiazepine (lorazepam) for the patient that were filled at non-VA pharmacies. These prescriptions included a non-urgent/emergent prescription that was contractually obligated to be filled at a VHA pharmacy.

In reviewing Patient 2's EHR, the OIG found the following PDMP query showing that the patient filled and assumed the cost personally (private pay) or used other forms of payment to cover the cost of 9 out of 14 controlled substance prescriptions at a non-VA pharmacy (see table 3). The clinical pharmacist who performed this PDMP query stated, "[p]rescription(s) filled outside [VHA] in the last 90 days are noted. However, they do not raise significant safety concerns and do not influence the treatment plan at this time." The patient filled three long-term prescriptions for fentanyl patches, oxycodone, and lorazepam; all were prescribed by the CCN primary care provider. Table 3 shows the results of a single query conducted by the clinical pharmacist in late summer 2021.

Table 3. Patient 2 PDMP Query Dated Late Summer 2021

Medication Fill Date	Day Supply	Medication Name and Dose	Fulfilling Pharmacy
Day 1	30	Oxycodone/Acetaminophen 10/325	Non-VA*
Day 1	30	Fentanyl Patch 100 mcg/hr	Non-VA*
Day 3	30	Lorazepam 1 mg	Non-VA*
Day 22	7	Lorazepam 1 mg	Non-VA*
Day 22	9	Oxycodone/Acetaminophen 10/325 mg	Non-VA*
Day 29	30	Oxycodone/Acetaminophen 10/325 mg	VHA
Day 29	30	Fentanyl Patch 100 mcg/hr	VHA
Day 36	7	Lorazepam 1 mg	Non-VA*
Day 38	30	Lorazepam 1 mg	VHA
Day 59	9	Oxycodone/Acetaminophen 10/325 mg	Non-VA*
Day 60	15	Fentanyl Patch 100 mcg/hr	Non-VA*
Day 66	30	Oxycodone/Acetaminophen 10/325 mg	VHA
Day 67	2	Oxycodone/Acetaminophen 10/325 mg	Non-VA*

Day 72	30	Fentanyl Patch 100 mcg/hr	VHA

Source: Non-system, VHA staff member state PDMP query documented in late summer, 2021.
**Patient may have assumed the cost personally (private pay) or used another form of payment, such as manufacturer's coupons, for these medications at a non-VA pharmacy.*

Due to the OIG's concern about the patient's overlapping controlled substances, totaling more than 300 MEDD, that were prescribed by a CCN provider and filled outside of the non-system VHA pharmacy, the OIG notified the VISN 15 Chief Medical Officer in July 2022, and requested to be informed of any actions taken in response. In written correspondence to the OIG two weeks later, the VISN 15 Acting Network Director substantiated the OIG's concern of the patient receiving high-dose opioids from a CCN provider and stated that the CCN provider would be referred to Optum for a review of safe medication practices. VISN 15 Acting Network Director informed the OIG they also contacted the patient to provide naloxone education and dispense a new naloxone nasal spray kit.

Patient 3 Case Example

Similarly, a patient in their 60s (Patient 3) had a history of low back pain, lower extremity pain, opioid and benzodiazepine dependence, and mood and anxiety disorders. System providers primarily managed the patient's medical care, including opioid medication, until mid- 2021, when the patient transitioned to CCN primary care services due to VHA's inability to provide timely primary care. The CCN primary care provider prescribed the patient opioids at levels lower than those previously prescribed by system providers, with a plan to taper the medication. The patient also received benzodiazepine medication from a system psychiatrist who added benzodiazepine dependence to the patient's problem list in early 2022 and made a long-term plan to taper and discontinue the medication.

Patient 3 obtained medication from multiple sources including VHA medical centers in two different states and through community emergency departments. From October 1, 2020, through July 28, 2022, multiple system and non-system VHA staff documented awareness of the patient receiving high-dose opioids in the community with a concurrently VHA-prescribed benzodiazepine and documented their concerns in the EHR. However, the OIG found no evidence of any additional actions taken to mitigate risk of opioid use. In early spring 2022, the patient was transported to a non-VA emergency room after being found confused, with an empty bottle of vodka and an empty prescription bottle with a benzodiazepine label.

System staff performed multiple PDMP queries for Patient 3 from October 1, 2020, through July 28, 2022, which showed the patient received multiple controlled substance prescriptions from community providers and used private pay to cover the cost of the medication at a non-VA pharmacy.[85] In late summer 2021, a system provider conducted a PDMP query and documented,

[85] VHA staff documented 25 state PDMP queries from October 1, 2020, through July 28, 2022.

"Prescription(s) filled outside [VHA] in the last 90 days are noted. Safety concerns will be discussed with the patient and documented as part of ongoing treatment planning. Pt [Patient] demanding more oxycodone despite being given 160 [tablets] on [summer] in [a different state]."

Three weeks later, a system registered nurse conducted a PDMP query, which documented the patient received three times the recommended MEDD through controlled substance prescriptions filled at both VHA and non-VA pharmacies. This nurse also documented the patient,

> has received controlled substances prescriptions written by 13 prescribers and had them filled at 8 pharmacies during the past 3 months. This equals or exceeds the threshold of 5 prescribers and 3 pharmacies and while there may be a valid reason for this, it also may be indicative of the practice of prescriber and pharmacy shopping.

Table 4 provides a list of the medications found in the PDMP query conducted by a system registered nurse in late summer 2021.

Table 4. Patient 3 PDMP Query Dated Late Summer 2021

Medication Fill Date	Day Supply	Medication Name and Dose	Fulfilling Pharmacy
Day 1	7	Alprazolam 1 mg	VHA
Day 5	5	Oxycodone 5 mg	VHA
Day 5	5	Alprazolam 1 mg	VHA
Day 8	5	Oxycodone 10 mg	VHA
Day 11	30	Alprazolam 0.5 mg	VHA
Day 12	5	Alprazolam 1 mg	VHA
Day 12	5	Oxycodone 5 mg	VHA
Day 15	1	Oxycodone 5 mg	Non-VA*
Day 20	2	Oxycodone 5 mg	Non-VA*
Day 22	3	Oxycodone 10 mg	VHA
Day 29	3	Oxycodone 10 mg	Non-VA*
Day 30	4	Oxycodone 10 mg	Non-VA*
Day 35	1	Oxycodone 10 mg	Non-VA*
Day 36	14	Oxycodone 30 mg	Non-VA*

Source: State PDMP query documented in late summer 2021, by a system registered nurse.
**Patient may have assumed the cost personally or used another form of payment such as manufacturer's coupons, or used private/commercial insurance for these medications at a non-VA pharmacy.*

Another system registered nurse conducted an additional PDMP query in spring 2022, and documented,

> prescription(s) which have been filled outside [VHA] in the last 90 days are noted. [O]xycodone 30 mg [four times a day] from [a] civilian pharmacy on [spring]. [C]linical alerts: exceeds daily active [MEDD] threshold, exceeds opioid consecutive day threshold, exceeds prescriber & dispensary threshold.

Due to the identified lack of CCN provider documentation in the EHR, lack of evidence of VHA staff initiating action to elevate their concerns, and the high dosages of overlapping prescriptions that Patient 3 received, the OIG contacted the VISN 15 Chief Medical Officer in July 2022, and requested a response specific to the care and documentation found in the patient's EHR. Two weeks later, the VISN 15 Network Director told the OIG a system provider is attempting to safely decrease the patient's use of the benzodiazepine to avoid severe withdrawal symptoms. The response reported that a staff member submitted a Joint Patient Safety Report (JPSR) in late summer 2021. The VISN 15 Quality Management Health System Specialist stated the JPSR was due to Patient 3's "disruptive behavior," related to attempting to obtain medication from a system provider.[86] The OIG reviewed the JPSR submitted by system staff and found that it focused on the patient's behavior and did not contain information relating to the prescribing practices of the CCN providers.[87]

The OIG determined that PDMP queries conducted by VHA staff are a critical OSI risk-mitigation tool, particularly for patients receiving controlled substances from non-VA pharmacies. Additionally, the OIG determined non-system VHA staff identified and documented concerning patient opioid seeking behavior and provider opioid prescribing practices through PDMP queries without elevating concerns to system leaders. Given the multiple sources and high levels of medications noted in the EHR reviews, the OIG found the lack of a formal VHA process to ensure CCN prescribed medications filled by non-VA pharmacies are identified and added to the EHR to be a significant gap in the care coordination and risk-mitigation processes.

Lack of Medication Reconciliation and Medication Profile Updates

The OIG found system providers do not routinely update a patient's medication profile when CCN providers supply documentation related to a controlled substance prescription that was not filled at a VHA pharmacy.

VHA policy requires providers to complete medication reconciliation with patients "at every episode or transition in level of care where medications will be administered, prescribed,

[86] VA National Center for Patient Safety, *Joint Patient Safety Reporting (JPSR) System Business Rules*, May 1, 2018. JPSR is a patient safety reporting system that supports a standardized approach for collecting patient safety event information across VHA.

[87] The VISN 15 Network Director also advised the OIG the CCN provider was not elevated to Optum for review, "as there were no community providers mentioned in the JPSR."

modified, or may influence the care given."[88] VHA providers are to conduct medication reconciliation to ensure that patient medication lists are accurate, timely, and complete. Medication reconciliation is completed when providers

- obtain medication information from patients, patient caregivers, and patients' family members;
- identify and address medication information discrepancies through comparing patient, patient caregivers, and patient family members medication information with the medication information available within the EHR;
- assemble, document, and educate the patient, patient caregivers, and patient family members of the updated medication information into the EHR; and
- communicate relevant medication information to and between members of the VHA and non-VA healthcare teams.[89]

VHA's guide for the use of the EHR emphasizes that non-VA medication should be captured in the EHR so that, "providers have a better picture of the medications the patient is taking and that order checks against these medications can occur."[90] OSI guidelines stress the importance of recording all opioids prescribed within the EHR to "identify patients who may be high-risk for adverse outcomes with use of opioids and providers whose prescribing practices do not reflect best evidence."[91]

According to VHA policy, referring providers are responsible for "reviewing and acting on the results of completed consults for clinical services."[92] The system chief of primary care confirmed that the expectation of referring providers is to review records received from CCN providers. It is important for referring providers to review the results of care they order for their patients and complete medication reconciliation when the treatment occurs in the community care setting. Lack of the referring provider review of treatment and medical records places patients at high-risk for an adverse outcome, as may be the case for patients receiving opioids in the community. However, the system chief of primary care also stated for patients receiving CCN primary care,

[88] VHA Directive 2011-012, was rescinded and replaced by VHA Directive 1345, *Medication Reconciliation*, March 9, 2022. The language is similar within both versions of the directive.

[89] VHA Directive 2011-012, was rescinded and replaced by VHA Directive 1345, *Medication Reconciliation*, March 9, 2022. The language is similar within both versions of the directive.

[90] VA Office of Information and Technology, *Computerized Patient Record System (CPRS) User Guide: GUI Version*, January 2022. The order checking system is an EHR process that prompts a review of medications, including non-VA medications entered into a patient's medication profile, to check for duplicate drugs, duplicate drug classes, critical and significant drug interactions, and allergies, and is used to support clinical decisions.

[91] VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0.

[92] VHA Directive 1232(3), *Consult Processes and Procedures*, August 24, 2016, amended April 5, 2021.

VHA primary care providers are removed from patient care and are no longer responsible for the patient.

The Chief of Staff said VHA providers are to complete a patient's medication reconciliation, including CCN provider prescribed medication, at the first opportunity when the patient returns to VHA care; however, the Chief of Staff reported being unaware of any written expectation for VHA providers to complete a medication reconciliation outside of a patient visit. The OIG determined patients receiving their care primarily through CCN providers may not have VHA visits in which medication reconciliation would occur. Some system providers and staff referenced the VA/Optum contract mandate for all routine/maintenance medications prescribed by CCN providers be filled at a VHA pharmacy and therefore, CCN prescriptions are entered into the patients' EHRs by system pharmacists when filling prescriptions.

The former VHA Executive Director of Clinical Integration and Field Operations and IVC and the system Chief of Staff reported they can enter new medications prescribed to patients by CCN providers. The system's Chief of Primary Care stated if the medication is found in documentation provided by the CCN provider, a system provider can manually enter the medication into the patient's EHR, and the medication will be labeled as a non-VA medication. The Chief of Staff told the OIG when non-VA medications are entered by staff, they "[are] just tracking what the med[ication] is, and the dose, and frequency, and route... [it is] just going to be kind of a place holder for the med[ication], dose, route."

During interviews with the OIG, system providers expressed concerns related to

- intermittent EHR alerts indicating when newly scanned medical documentation had been uploaded,
- CCN provider documentation missing from the EHR, and
- workload demands limiting the time system providers have to review incoming CCN provider documentation to assess for controlled substance prescriptions prescribed to patients.

The system's Chief of Ambulatory Care told the OIG of limited time to address and review CCN documents during routine clinic hours due to workload demands. The provider acknowledged they receive alerts when community consults are completed and available within the EHR; however, said they may or may not look at the documents telling the OIG, "[I will] be honest with you, the results that come back from the [CCN], if [there is] a note [that has] been scanned into [the EHR], and again depending on the seriousness of the disease, is whether or not I go look at it."

During EHR reviews, the OIG found that CCN prescribed controlled substances were missing from the medication profiles of patients 1, 2, and 3, after all three patients filled prescriptions at non-VA pharmacies. Additionally, the OIG found that when system and

non- system VHA staff became aware of the medications through PDMP queries, the medications were not added to the patients' medication profiles. System providers told the OIG of being unaware of requirements to capture non-VA medications in patient medication profiles outside of a clinic visit, and cited barriers with the EHR alert system, and workload demands.

The OIG determined that the system lacks a standardized process to review and include medications made known to the system but filled at non-VA pharmacies into the patient medication profile. In conjunction with the identified care coordination and documentation deficiencies identified in this report, VHA providers, pharmacists, and CCN providers may lack awareness of all medications prescribed to a patient when the medication profile is not accurate. Additionally, they may lack awareness of completed or missed OSI risk-mitigation efforts. The OIG determined these gaps are a patient safety issue, which may lead to adverse drug events such as opioid overdose death.[93]

VHA's Oversight of CCN Providers' Opioid Prescribing Practices

The OIG found that VISN and system staff are not conducting oversight of CCN providers' opioid prescribing practices as required by the Secretary under the MISSION Act, and as recommended by the OIG in 2019, nor are they reporting concerns of unsafe CCN provider opioid prescribing practices to the TPA.[94]

"The purpose of oversight should be to ensure that proper structures in health care delivery are in place, as well as processes that ensure good quality and measure patient outcomes in ways that enhance improvement efforts."[95] The Joint Commission states the purpose of healthcare oversight is to "make sure that care, treatment, and services provided directly are safe and

[93] The MISSION Act 2018, § 131 requires VA to ensure non-VA providers submit medical documentation to the VA, including records of all opioid prescriptions, and record this information in the veterans' EHR. A failure to include the opioids on the active medication profile may impact care since VA providers review the active medication profile when seeing a patient to see what medications the patient has been prescribed. Failure to include the opioids on the active medication list also impacts the completeness of medication lists sent to CCN providers when patients are referred to them as the active medication list is what is included in the referral packet. VA OIG, *Oversight Could Be Strengthened for Non-VA Healthcare Providers Who Prescribe Opioids to Veterans*, Report 22-00414-113, September 26, 2023. This recent companion OIG Audit report studied this requirement and found the prescription information may be in locations within the EHR other than the non-VA medication list within the medication profile.

[94] MISSION Act of 2018, § 131; VHA OCC, *Field Guidebook*, Chapter 4; VA OIG, State Prescription Drug Monitoring Programs Need Increased Use and Oversight.

[95] Burney, Richard. "Oversight of Medical Care Quality: Origins and Evolution," *Journal of Medical Regulation* 101, no. 4 (December 2015): 8-15.

effective" and that the quality of care should be the same regardless of whether the care is provided at the facility or in the community through a contract.[96]

VHA has opioid safety tools such as the OSI dashboard, the Stratification Tool for Opioid Risk Mitigation (STORM), Opioid Therapy Risk Report, OEND Patient Risk dashboard and Opioid Use Disorder dashboard that provide clinicians and administrators with data related to opioid prescribing practices recommended in the OSI guidelines. These tools provide VHA with data to render oversight and assess the care provided by, and prescribing practices of, VHA and CCN providers, and identify patients who would benefit from mitigation efforts associated with opioid use. The tools include information such as patient and prescriber name, opioid dispensing location, medication strength, number of days supply, MEDD, patients on opioid therapy with a concurrent prescription for benzodiazepines, urine drug screen use, PDMP use and patients at high-risk for overdose. See Appendix B for information on each tool.

VHA Review of CCN Providers

The OIG found that VISN and system staff lack a process to conduct reviews of opioid prescribing practices by CCN providers.

The MISSION Act requires the Secretary to ensure that CCN providers receive "a copy of and certify that they have reviewed the" OSI guidelines. To ensure safe opioid prescribing practices, the MISSION Act requires the Secretary to enable VHA staff to monitor the opioid prescribing practices of CCN providers. The Field Guidebook states that "[VHA] will review [CCN] providers based on these [OSI] guidelines."[97] These reviews are provider focused and use the OSI parameters of overall opioid use, opioid and benzodiazepine co-prescribing, MEDD, urine drug screening, informed consent, PDMP queries, naloxone distribution, and timeliness of follow-up with prescribers.[98]

In the 2019 VA OIG report, *State Prescription Drug Monitoring Programs Need Increased Use and Oversight*, the OIG recommended VHA monitor CCN providers and take appropriate corrective actions if their prescribing practices are inconsistent with the OSI guidelines.[99] VHA concurred and told the OIG they developed a monthly process to review CCN provider opioid prescribing data within each VISN. VHA stated the "review will be managed by each VISN's Community Care Oversight Council," which will "review the VHA OSI dashboard to monitor [CCN] providers percentage of opioids dispensed." Additionally, the council is to "review

[96] The Joint Commission, *Standards Manual*, LD.04.03.09, July 2021. "Care, treatment, or services provided through contractual agreement are provided safely and effectively."

[97] MISSION Act of 2018, § 131; VHA OCC, *Field Guidebook,* Chapter 4.

[98] VA, *The VA Opioid Safety Initiative – how did we get here and what is ahead?*, accessed April 8, 2022, https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/2353-notes.pdf.

[99] VA OIG, *State Prescription Drug Monitoring Programs Need Increased Use and Oversight*.

concerns raised from other sources."[100] The OIG agreed to close this recommendation on February 11, 2020, after VHA leaders issued a memo on November 18, 2019, to VISN Directors requiring the new mandatory review of opioid prescribing practices of CCN providers.

During an April 2021 VHA Opioid Safety and Risk Mitigation Community of Practice call, the Senior Advisor to Acting Assistant Under Secretary for Health for Community Care shared that the process for conducting the reviews was undergoing revisions and information regarding the roll out would be forthcoming. The response to an attendee asking who was responsible for conducting the reviews was "there is not a specific designation and that's because the [community care and pain] committees are set up differently in different VISNs" and "it's been left to the VISNs and VAMCs [VA Medical Centers] to determine which is the appropriate committee to be doing the review." The same group met in June 2022 and received a process update from the Acting Chief Medical Officer and Executive Director of the Office of Integrated Field Operations, within IVC, who indicated ongoing work to refine the prescriber review process and reiterated that different VISNs have different processes for completing the reviews and that there are no requirements for the numbers of reviews to perform.

An IVC guidance document states that reviews of community care opioid prescribing practices can be done through "one of these approaches:

1. Embed regular reviews into interdisciplinary VISN and/or facility oversight committees.
2. Monitor community provider opioid prescribing trends and obtain direct feedback from staff or Veterans to identify concerns through facility oversight committees.
3. Use data trends, direct feedback, and proactive sampling of patients treated by community providers to complete a structured review of concerns, through existing facility quality reviews... "[101]

The Field Guidebook outlines the procedure for VHA staff to assess CCN provider practice, assigning primary responsibility for the process to the VISN [Pain Management or equivalent] Committee, VISN Patient Safety Officer and system patient safety manager. The quarterly process begins with the reviewer accessing the OSI dashboard to identify CCN providers with concerning opioid prescribing practices and completing the checklist guidance shown in Figure 3. Once completed, the reviewer uploads the checklist to a centralized repository for inclusion in an annual report from VHA to Congress.

[100] VA OIG, *State Prescription Drug Monitoring Programs Need Increased Use and Oversight*.
[101] *VA Guidance for Community Provider Opioid Prescribing Practices Review,* March 26, 2020

Yes	No	N/A	Guidance
☐	☐	☐	1. Has the provider conducted a urine drug screen prior to starting a new opioid or within the last 365 days for a patient taking long-term opioid therapy?
☐	☐	☐	2. Has the provider prescribed opioids to a Veteran with a concurrent benzodiazepine prescription?
☐	☐	☐	3. Has the provider noted if the Veteran's opioids dosage has been tapered or ended completely (i.e., is the Veteran on less than or equal to 100 MEDD)
☐	☐	☐	4. Has the provider issued Naloxone kits to Veterans at risk?
☐	☐	☐	5. Was informed consent for opioid therapy obtained by the provider?
☐	☐	☐	6. Is there evidence [VHA] sent a list of [VHA] prescribed (including remote) and non-VA medications?
☐	☐	☐	7. Is there any medical documentation from the provider to review?

Figure 3. *VA Guidance for Community Provider Opioid Prescribing Practices Review, March 26, 2020*.

In written correspondence to the OIG, the system's Community Care service line manager reported that the system "has not been monitoring compliance of opiate prescribing practices by [CCN] providers." The system patient safety manager reported being unfamiliar with CCN provider opioid prescription review processes and a pain committee co-chair reported a general awareness that the need to conduct reviews may be forthcoming. The system patient safety manager told the OIG that in April of 2020, the VISN Patient Safety Officer sent a memo about reviewing community care opioid prescriptions and stated there would be more to come but received no further communication on the topic. Therefore, system staff were unaware of the logistics for conducting a review, whether it is a VISN or system guided review, or if the responsibility to conduct the review was included in a specific job description.

The VISN Business Implementation Manager shared that some facilities within the VISN have completed the required reviews but acknowledged a lack of structure to ensure all facilities within the VISN were doing so. In written correspondence with the OIG dated August 11, 2022, the VISN Network Director shared that the system is developing a process to routinely monitor the population of community care patients using opioids. The plan will include chart reviews, discussions by a multidisciplinary committee, and reporting to the Community Care Oversight Council, and is expected to be in place by the beginning of fiscal year 2023.

Staffing Vacancies

System leaders and a VISN manager told the OIG they recognized their responsibility to monitor CCN provider safe opioid prescribing practices was not met and reported having a lack of staff to conduct reviews.

System staff and the VISN 15 Pain Management, Opioid Safety and Prescription Drug Monitoring Program (PMOP) coordinator identified vacancies in pain management, including lack of a system PMOP, pain provider, and pain pharmacist, as contributing factors to system staff failing to conduct the required CCN provider reviews. The OIG interviewed system Pain Steering Committee co-chairs who said they do not have the staffing necessary to conduct reviews of opioid prescribing practices of CCN providers. They said there have been discussions of conducting reviews, however, the system does not have a pain management provider or a PMOP coordinator. Similarly, the VISN 15 PMOP coordinator identified that system staff conduct reviews of very high-risk patients identified in STORM, however, reported being unaware that similar reviews are conducted for patients receiving community care. Further, according to the VISN 15 PMOP coordinator, the reviews conducted focused on VHA care only, with no community care component. The VISN 15 PMOP coordinator identified the system's lack of a pain management team and a PMOP coordinator as contributing reasons why the system has not been monitoring CCN provider opioid prescribing practices.

The OIG confirmed from an information request that the system has no dedicated pain management providers. System staff told the OIG they planned to hire a dedicated pain management provider, replace a recently vacated pain pharmacist position, and as of August 22, 2022, were recruiting a system PMOP coordinator. The OIG learned the system has two pain champions, both of whom are primary care providers and co-chairs of the system's Pain Steering Committee.[102] When asked how the system provides a stepped-level of pain care, a system pain champion said the system provides consultative services to primary care physicians for help managing pain medications, and patients who require interventional pain management services are referred to CCN providers.

The OIG found that although required by the MISSION Act, VHA policy, and identified as a concern in a 2019 OIG report, system and VISN staff lack a process to monitor CCN provider opioid prescribing practices. [103] The OIG determined neither system nor VISN staff are conducting these required reviews. Staff identified vacancies as a contributing factor for why system staff have not been monitoring CCN provider opioid prescribing practices.

[102] VHA Pain Management, *For Providers - Team-Based Pain Care,* accessed August 25, 2022, https://www.va.gov/PAINMANAGEMENT/Providers/IntegratedTeambasedPainCare.asp. "The VA [Primary Care] Pain Champions Initiative is a program designed to improve pain care options in primary care." Pain champions participate in monthly community of practice calls to "share ideas and innovations."

[103] MISSION Act of 2018, § 131; VHA OCC, *Field Guidebook*, Chapter 4; VA OIG, *State Prescription Drug Monitoring Programs Need Increased Use and Oversight*.

VHA's Review Limitations

The OIG found gaps in the tools provided by VHA to review CCN provider prescribing practices, which may impact identification of both patients at risk of adverse opioid-related events and concerning CCN opioid prescribing practices.

The reviews required by the Secretary under the MISSION Act are designed to look at concerning trends associated with the actions of CCN providers.[104]

The tools created by VHA rely on outpatient prescription data found in the EHR to assist in identifying these providers and the patients at risk for opioid abuse or overdose (see Appendix B**)**. Reviewing the records of these patients, in addition to the prescribing providers, may better identify patients in need of intervention and providers with quality of care issues that may not otherwise trigger inclusion on the OSI dashboard.

The OIG learned that due to the challenges with the documentation of prescriptions filled in the community described earlier, VHA does not always capture prescriptions written by CCN providers in the VHA databases used to populate the OSI dashboard. Unrelated to this system but of note, the new EHR, in use at a small number of facilities, is not capable of capturing all pertinent risk factors, resulting in incomplete OSI dashboard metrics for VA medical facilities who utilize the new EHR, which may impact national roll-ups. Therefore, it is possible that some CCN provider prescribing patterns as well as patients at risk for opioid-related adverse events are not known to VISN or system staff, preventing staff from providing oversight and interventions.

A recommendation made, and concurred with, in the 2019 OIG report directed VHA to "ensure non-VA care providers are in good standing and have a current state medical license that requires adherence to their state's PDMP review requirements; [and adherence] to the Veterans Affairs Opioid Safety Initiative Guidelines, including guidelines for PDMP reviews... "[105] Several of the recommendations made in the OSI guidelines are reflected in the data collected by VHA in the OSI tools and are included on the CCN provider review checklist. However, the elements for review on the CCN provider review guidance checklist do not include a step to verify if the CCN

[104] MISSION Act of 2018, § 131

[105] VA OIG, *State Prescription Drug Monitoring Programs Need Increased Use and Oversight*.

provider documented that a PDMP query was done when opioids were prescribed. [106] PDMP queries may be the only way a provider discovers a patient is receiving controlled substances elsewhere. The OIG is concerned that not including a review of whether a CCN provider documented completing a PDMP query is a gap in oversight. This concern is elevated given the gaps in OSI risk-mitigation strategies mentioned previously and the lack of clarity in the VA/Optum contract regarding PDMP queries. Therefore, inclusion of this element in VHA's review of CCN providers may be an opportunity to identify providers who are prescribing controlled substances without documenting evidence of PDMP queries. Checking for PDMP documentation as part of the reviews would also allow VHA to identify patients who received an opioid prescription from a CCN provider without a documented PDMP check who may benefit from a VHA pharmacist completing a PDMP query.

Reporting and Reviewing Quality of Care Concerns

VHA has processes in place to report CCN provider quality of care concerns identified through review of CCN providers' opioid prescribing practices or raised by VHA staff. However, the OIG found the system is not fully leveraging the reporting process due to the failure of VISN and system staff to conduct these reviews, as required.

The Secretary, under the MISSION Act, is to take action including removal of a provider from the network, if the opioid prescribing practices of a CCN provider are determined to be in "conflict with, or are otherwise inconsistent with, the standards of appropriate and safe care" or "may place at risk the veterans receiving health care from the [CCN] provider."[107]

VHA leaders concurred with a recommendation in the 2019 OIG report for VHA to monitor CCN providers and take appropriate corrective actions if their prescribing practices were found to be inconsistent with OSI guidelines. VHA's written response to OIG's recommendation indicated VISN Community Care Oversight Councils would conduct the reviews described previously and would also "review concerns raised from other sources including," VHA managers, patients, family members, state agencies, and other providers. VHA also indicated in its response that if a VISN Community Care Oversight Council finds a CCN provider with

[106] VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0; VA and DoD, VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain, ver. 4.0. At the time of the events reviewed by the OIG in this report, version 3.0 of the guideline was in effect, which strongly recommended providers starting patients on long-term opioid therapy monitor for overdose potential and suicidality, and provide the patient with a consent form and informed consent conversation that included urine drug screening, state PDMP queries, and provide OEND. By 2022, version 4.0 no longer emphasized patient consent forms for long-term opioid therapy, risk assessment instruments, and naloxone prescriptions due to a lack of evidence that these measures improved patient safety. The 2022 version does endorse urine drug screening for patients on long-term opioid therapy. Urine drug screens "should be used to screen for the presence of illegal drugs, unreported prescribed medication, or unreported alcohol use prior to starting therapy."

[107] MISSION Act of 2018, § 131

concerning prescribing practices, an "in-depth review based on the OSI guidelines will be completed." Further, VHA stated that, "if the in-depth review validates a concern, the council will report the findings to the existing VISN and VAMC [VA Medical Center] Patient Safety Manager and notify the contractor's [TPA's] quality management office."[108]

VHA Reporting and Patient Safety Processes

The OIG found system staff are not aware of a uniform process to report patient safety concerns involving the prescribing practices of CCN providers. VHA (system and non-system) staff documented patient safety concerns in Patient 2's and Patient 3's EHRs related to CCN provider opioid prescribing practices and the patients being prescribed large dosages of opioids from a variety of sources. However, system staff failed to initiate established patient safety processes.

According to the Field Guidebook, "if a potential deviation or concern" about a CCN provider's opioid prescribing practice is identified through the VHA review process, the reviewer notifies the VISN Patient Safety Officer and the system patient safety manager. The VISN Patient Safety Officer then notifies the IVC VAMC Oversight Council and Optum of any providers in need of more formal review.[109] The VA/Optum contract outlines expectations for the monitoring of clinical quality, including resolution of quality issues reported by VHA, a patient, or a provider (see Appendix C).

VHA's *Patient Safety Events in Community Care: Reporting, Investigation, and Improvement Guidebook* states that VHA staff can report patient safety events involving community care through the JPSR system.[110] In addition to using JPSR, VHA's guidance directs VHA staff to report community care safety concerns, as appropriate, through the Optum's quality and safety reporting channels using a Potential Quality Issue form.[111]

To understand the degree to which JPSRs and Potential Quality Issue forms are used, the OIG reached out to the VISN Patient Safety Officer. The written response indicated that system staff had not entered concerns specific to CCN provider opioid prescribing into JPSR from October 1, 2020, through June 22, 2022, nor had they submitted any CCN provider opioid prescribing patient safety related Potential Quality Issues to Optum from October 1, 2020, through June 27, 2022.

VHA, VISN, and system staff confirmed that community care quality of care concerns can be reported through JPSR and that once entered, the system quality management or patient safety

---

[108] VA OIG, *State Prescription Drug Monitoring Programs Need Increased Use and Oversight*.

[109] VHA OCC, *Field Guidebook,* Chapter 4; VHA OCC, "Review of Community Provider Opioid Prescription Practices," June 6, 2020.

[110] VHA OCC, Patient Safety Events in Community Care: Reporting, Investigation, and Improvement Guidebook, December 2020.

[111] VHA OCC, Patient Safety Events in Community Care: Reporting, Investigation, and Improvement Guidebook.

staff are expected to send them directly to Optum for review.[112] However, the OIG received varying responses from some system leaders and staff about how they would elevate patient safety concerns involving CCN providers. Some staff reported the belief that concerns should be reported to a supervisor, reported to the community care office, or entered as a JPSR. The system patient safety manager told the OIG many CCN provider concerns are not entered into JPSR. The system chief of primary care said system providers have not received education about how to report concerns about CCN providers.

The OIG found non-system VHA staff conducted PDMP queries documenting that Patient 2 filled multiple overlapping controlled substance prescriptions at community pharmacies. System staff documented concerns related to CCN provider prescribing practices and patient prescriptions for controlled substance found on PDMP queries within Patient 3's EHR. However, for Patient 3, the OIG learned from a VISN leader that prior to the OIG's inquiry described above, system staff did not enter these patient safety concerns within the patients' EHRs into the JPSR system and did not elevate their concerns with the CCN provider prescribing practices to Optum. For Patient 3, system staff entered a JPSR to report the patient's behavior in an attempt to obtain additional opioids, but did not include discussion of their concern with the CCN provider's opioid prescribing practices or the patient obtaining multiple controlled substance prescriptions from a variety of VHA and community providers throughout two states.[113]

The OIG determined system staff failed to fully report patient safety concerns. Additionally, the OIG found that some system staff were unaware of the process to elevate patient safety concerns about CCN provider opioid prescribing practices through entry into the JPSR system, and to Optum.

Committee Review of Opioid Prescribing Practices

While not specific to CCN provider opioid prescribing practices, the OIG learned about VISN and system committees that review opioid-related data and are part of VHA's oversight process.

VISN and System Pain Committees

VHA policy requires that each facility have an interdisciplinary team to complete and document risk reviews for patients identified as being in the very high-risk category for overdose or a suicide-related event by the STORM tool (see Appendix B**).** Patients who are not "up to date on

[112] CCN providers work directly for Optum, rather than VHA. Only Optum has the authority to conduct reviews of CCN providers that could, when appropriate, result in the removal of a CCN provider from the network.

[113] The OIG was unable to determine if all of Patient 3's prescriptions were provided by CCN providers or other community providers not contracted with VHA through Optum.

standard risk-mitigation criteria must be reviewed by an interdisciplinary team focused on controlled substance risk review."[114]

The VISN 15 Pain Management Committee is responsible for oversight of the system's pain management program. Oversight includes VISN monitoring of opioid prescribing practices to ensure they are safe. According to the VISN 15 Pain Management Committee's charter, the committee reviews facility performance, and as reported by the VISN PMOP coordinator, monitors several OSI dashboard goals. According to the committee's charter, these goals include reducing the percentage of patients

- provided opioids,
- taking 90 MEDD of opioids or more,
- provided opioids and benzodiazepines together,

and increasing

- the percentage of "patients on long-term opioid therapy with urine drug screen[ing],"
- the "patients on long-term opioid therapy with informed consent,"
- the percentage of patients on long-term opioid therapy with PDMP queries performed within the past year, and
- "distribution of naloxone rescue kits to patients with a diagnosis of opioid use disorder."[115]

The VISN 15 PMOP coordinator reported that OSI information is reported through VISN 15 Pain Management Committee quarterly meetings and is sent to system contacts who report on it through their local pain committee meetings. The VISN 15 PMOP coordinator told the OIG that while some CCN provider prescription information is available in the OSI dashboard, the information reviewed is predominantly focused on VHA providers.

The OIG reviewed VISN 15 Pain Committee meeting minutes from October 2020 through September 2021 and found in March 2021 the committee added "community care opioid reviews," as a standing agenda item to their quarterly meetings. According to the VISN 15 Pharmacy program manager, community care opioid reviews, which do not include individual

[114] VHA Notice 2021-21, "Conduct of Data-Based Reviews of Opioid-Exposed or Overdose Patients with Risk Factors," December 1, 2021.

[115] VISN 15 Pain Committee Charter, June 12, 2020.

patient or provider reviews, were added to the agenda to share best practices "in an open forum among VISN 15 Pain Committee Members," across VISN 15 facilities.[116]

The OIG learned the system has a Pain Steering Committee, which works to guide and lead pain management and opioid safety, and a Pain Steering Review Subcommittee, a multidisciplinary group that meets to review high-risk patients identified in STORM. According to a presentation by the VHA Acting National Program Director for Pain Management and a pharmacist from VA's Pharmacy Benefits Management Services, these reviews help staff allocate resources and identify patients who need closer follow-up or care coordination according to their risk level.

VISN and System Community Care Oversight

The VISN 15 Community Care Council serves as the "executive decision-making body that links the administrative processes, clinical oversight, and budget management in the VISN community care program."[117] The OIG reviewed VISN 15 Community Care meeting presentations and found during a May 2022 meeting the committee reviewed MISSION Act requirements to review CCN provider opioid prescribing practices.[118] According to the meeting presentation, information reviewed included, "sites should have a process to review opioids prescriptions," and summaries of "community opioid prescription reviews should be reported through facility[system] Community Care Oversight Council[s].[119]

Similarly, the system has a Community Care Oversight Committee, which serves to "monitor clinical, quality, and safety aspects of care coordination with non-VA providers," and "provide oversight for the balance of internal and community-based services."[120] The committee reports results, risks, and resource needs to the aligning VISN 15 Community Care Council. During interviews the Chief of Staff told the OIG the system's Community Care Oversight Committee has not been conducting opioid-related reviews of CCN providers, which they identified as a "gap."

Through a review of the VISN and system committees, the OIG found the VISN and system have committees that are aware of the requirement for the system to conduct reviews of the opioid prescribing practices for CCN providers. However, there is a lack of clarity regarding

[116] The VISN 15 Pharmacy Program Manager told the OIG, "community care opioid reviews," was added as an informational standing agenda item to "allow the topic to be discussed in an open forum among VISN 15 Pain Committee members."

[117] VA Heartland Network, VISN 15 Community Care (CC) Council Charter.

[118] MISSION Act of 2018, § 131.

[119] VISN 15 Community Care Steering Group, Meeting Presentation, May 11, 2022.

[120] VA Eastern Kansas Health Care System, Community Care Oversight Committee (CCOC), [Fiscal Year] 2021 Charter.

which committee (s) will be responsible for ensuring that the system completes these reviews. Therefore, clarity regarding the entity assigned to do so is warranted.

Congressional Reporting

Congressional reporting is another form of oversight. The MISSION Act requires the Secretary to submit an annual report to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives.[121] The congressionally mandated report outlines the steps taken by VHA to comply with processes required by the MISSION Act to ensure safe opioid prescribing practices by CCN providers and provides updates from the previous year.[122]

The May 2021 congressionally mandated report included information related to CCN providers' review of OSI guidelines, the status of VHA's review of CCN provider opioid prescribing practices, and information on the sharing of medical record documentation between VHA and CCN providers.

According to the May 2021 report, based on feedback from end users, VHA leaders recently revised the process, which aligns with standard patient safety processes, to review the opioid prescribing practices of CCN providers using

- "opioid prescribing triggers,
- a chart review of flagged providers by VISN level pain and opioid management committees, and
- an in-depth review by VA medical [facility's]patient safety leadership of potentially problematic providers."

Additionally, the report said "[VHA] has provided guidelines to VISN and medical facility staff to assist in the identification of potentially problematic providers." The report indicated VISNs will be "responsible for ensuring that appropriate local [VHA] medical facilities perform a more in-depth review of providers in line with existing safety review procedures."[123]

The OIG found at the time of this review that although VHA's report to Congress described a process to identify potentially problematic providers that had been shared with VHA facilities, VISN 15 leaders failed to ensure the system had the process in place and failed to complete reviews of the opioid prescribing practices of CCN providers.

[121] MISSION Act of 2018, § 131.

[122] MISSION Act of 2018, § 131; VA, Establishment of Processes to Ensure Safe Opioid Prescribing Practices by Non-VA Health Care Providers, May 2021.

[123] VA, Establishment of Processes to Ensure Safe Opioid Prescribing Practices by Non-VA Health Care Providers.

TPA's Oversight of CCN Providers' Opioid Prescribing Practices

VA as the contracting entity, relies on Optum as the administrator of the network of community care providers, to provide oversight of some components required by the MISSION Act. The OIG found 1.5 percent of CCN providers associated with both TPAs [Optum and TriWest] who held active Drug Enforcement Administration licenses who can prescribe medication, including opioids, had completed required OSI training documentation. Specific to the TPA serving the system, the OIG determined Optum does not monitor CCN provider compliance with OSI guidelines and found the VA/Optum contract lacks a contractual expectation for Optum to do so.

CCN Provider OSI Education

In the 2017 OIG report, the OIG recommended all participating CCN providers receive and review the evidence-based guidelines for prescribing opioids outlined in the OSI guidelines.[124] In response to this recommendation, VHA told the OIG the IVC would provide the OSI guidelines to CCN providers.[125] To do so, VHA developed a plan to share the OSI guidelines with TPAs and to require TPAs provide and confirm CCN providers receipt of *and review* of the guidelines. VHA also created an OSI training module with links to more robust OSI information and tracks provider completion of the module through national provider identification numbers **(**see Appendix D)**.**[126]

VHA's OSI training module was developed with the intent to "educate and ensure a greater awareness of the evidence-based guidelines for prescribing opioids as outlined in the [OSI] to all participating non-VA purchased care providers."[127] On November 29, 2017, the VHA Deputy Under Secretary for Health for Operations and Management issued a memorandum to all VHA network directors outlining the request for CCN providers to complete an online OSI training module.[128] In 2018, the MISSION Act required that the Secretary ensure all CCN providers receive a copy of and certify that they have reviewed the OSI guidelines.[129] The Field Guidebook

[124] VA OIG, Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care.

[125] VA OIG, Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care.

[126] Centers for Medicare and Medicaid Services, *National Provider Identifier Standard (NPI)*, accessed August, 17, 2022, https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProvIdentStand. A national provider identification number is a unique identification number used by some providers in administrative and financial transactions.

[127] VHA, IVC, Opioid Safety Initiative Training Module.

[128] CHOICE Act of 2014, §128. VHA Deputy Under Secretary for Health for Operations and Management memo, "Opioid Safety Initiative and Prescribing Guidance for Community Providers," November 29, 2017. The issuance of the letter containing information related to the Community Provider Opioid Safety Initiative online training module was completed under the CHOICE Act. The memorandum required each VA medical center to disseminate the same letter to, "all community providers with whom they have a direct relationship."

[129] MISSION Act of 2018, § 131.

reiterates the requirement for CCN providers to review the OSI guidelines and states that VHA will review CCN provider's opioid prescribing practices based on these guidelines.[130]

The 2020 VA/Optum contract includes expectations that CCN providers complete education on specific topics, to include the OSI guidelines. According to an Optum representative, they provide CCN providers with the OSI guidelines via an OSI Factsheet.[131] The OSI Factsheet describes a requirement for CCN providers to complete the OSI training module, and states, "[i]f opioid-prescribing providers do not complete the [OSI] training course within the allotted timeframe, they will not receive any new referrals for Veteran care until they complete the training course."[132]

The OIG requested IVC provide the percentage of active CCN providers who acknowledged review of the OSI guidelines and completed the OSI training module as of August 24, 2022. IVC staff responded,

> The CCN contract [Optum and TriWest] requires [CCN] providers to comply with OSI however there are currently limitations to fully capturing the volume of providers that have acknowledged review of the guidelines and completed training. Contract modification efforts are in play to address these limitations. As of [August 24, 2022], VA has 9,662 [CCN] providers across all CCN regions documented for completion of OSI training, this represents 1.5 [percent] of active providers [who are] targeted for OSI compliance.[133]

Although described as a requirement in the OSI Fact Sheet provided by Optum to the CCN providers, the OIG determined few CCN providers completed training.

---

[130] VHA OCC, *Field Guidebook*, Chapter 4.

[131] VHA OCC, *Veteran Community Care,* Fact Sheet, *Opioid Safety Initiative*, accessed February 13, 2023, https://vacommunitycare.com/doc/ccnCCToolKit/ccnFSOpiodSafe. The Optum representative indicated they provide the OSI Fact Sheet to CCN providers via a link on a provider portal. According to the CCN Provider Manual the Optum VA CCN Provider Portal is a website that includes information about claim and referral status, veteran eligibility, training, and guides.

[132] VHA OCC, *Veteran Community Care,* Fact Sheet, *Opioid Safety Initiative*, accessed February 13, 2023, https://vacommunitycare.com/doc/ccnCCToolKit/ccnFSOpiodSafe. According to the OSI Factsheet, CCN providers must complete the OSI training module within 180 days of enrolling in the VA network.

[133] IVC staff told the OIG there are a total of 658,151 CCN providers across all regions [Optum and TriWest] with active Drug Enforcement Administration licenses who can prescribe medication, including opioids, who are targeted for OSI training. The OIG did not independently verify CCN provider completion of the OSI training module and was therefore unable to determine how many of the CCN providers who provide care for VAEKHCS patients completed OSI training. A companion OIG Audit report, *Oversight Could Be Strengthened for Non-VA Healthcare Providers Who Prescribe Opioids to Veterans*, includes information on OSI training completion for a sample of non-VA providers known to have prescribed opioids to veterans.

Optum's Monitoring of CCN Providers' Opioid Prescribing Practices

The Optum contract does not state a requirement to monitor CCN provider compliance with the OSI. To gain an understanding of whether Optum does so, the OIG reviewed copies of correspondence sent from IVC leaders to Optum, which asked how Optum confirms that CCN providers are complying with the OSI. An Optum representative responded, "our responsibility is to educate providers on the participation requirements but does not (currently) extend to monitoring [CCN] provider compliance. Monitoring this would fall under the incomplete [contract] Opioid mod[ification]." On July 18, 2022, an IVC leader informed the OIG, "as of now, there are no contractual processes on how VA wants the TPAs to enforce OSI guidelines. However, there are numerous monitoring activities that are in place with both [TPAs] to support safe Opioid prescribing practices."[134] The OIG contacted IVC leaders and asked for information about the referenced contract modification. IVC leaders informed the OIG

> VA has been working with Optum for a period of time and has not been able to reach a technically acceptable solution that is determined to have Fair and Reasonable pricing. IVC, Integrated External Network Executive Director is involved as well as the Acting ADUSH. . . on a solution for all parties. It is anticipated that this solution will be available to present to. . . Optum in the Fall, 2022. Targeted implementation date is FY [Fiscal Year] [2023] Q [Quarter] 2.[135]

The OIG determined Optum does not monitor CCN provider compliance with OSI guidelines and found the VA/Optum contract lacks a contractual expectation for Optum to do so.

Conclusion

The OIG found concerns related to care coordination, documentation, and use of risk-mitigation strategies for patients prescribed controlled substances from CCN providers. The OIG found challenges persist related to the sharing of medical record documentation between CCN providers and VHA. The OIG is concerned that the ongoing delay and absence of CCN provider documentation is a gap in care coordination. Given the risks involved in opioid prescribing, these gaps in care coordination pose a risk to patient safety. The OIG found CCN and VHA providers failed to document OSI risk-mitigation strategies for approximately half of the co-managed

[134] VHA, "Community Care Network," accessed August 17, 2022, https://www.va.gov/COMMUNITYCARE/programs/veterans/CCN-Veterans.asp. At the time of this report, VHA contracts with two TPA's; Optum and TriWest Health Care Alliance.

[135] A fiscal year in VHA begins on October 1 and ends the following September 30. The year given to the fiscal year is associated with the year on the September 30 date.

patients reviewed receiving long-term opioid therapy and/or a combination of opioid and benzodiazepine therapy to ensure patient safety and decrease opioid overdose.

The OIG determined the VA/Optum contract contains unclear language, which makes it uncertain whether CCN providers are required to query state PDMP's prior to prescribing routine/maintenance controlled substances. The OIG recommends VHA consider a contract modification to clarify when CCN providers must conduct state PDMP queries and document completion prior to prescribing controlled substances, regardless whether the prescriptions are urgent, emergent, routine, or maintenance prescriptions.

The OIG found when prescriptions are filled at the system's pharmacy, pharmacists query the state PDMP and add medications to the patient's medication profile in the EHR. However, when CCN prescriptions are not filled at the system pharmacy, the medications are often not added to the patient's medication profile, and there is often no documented evidence that CCN providers completed key OSI risk-mitigation strategies, like state PDMP queries. Additionally, during an EHR review, the OIG found system staff did not elevate patient safety concerns after identifying questionable provider prescribing practices.

The OIG found the system lacks a standardized process to review and include medications made known to the system, but filled at a non-VA pharmacy, into the patient medication profile. System providers told the OIG of being unaware of requirements to capture non-VA medications in patient medication profile outside of a clinic visit, and cited barriers with the EHR alert system, and workload demands.

The OIG found that VISN and system staff are not conducting oversight of CCN providers' opioid prescribing practices and their adherence to OSI guidelines, as required by the MISSION Act, and as recommended by the OIG in 2019. VISN and system staff identified the lack of a PMOP coordinator and pain management providers as contributing factors for why required reviews were not conducted.

System staff are not consistently aware of steps to report concerns related to CCN provider quality of care, including making entries into JPSR and completion of Optum's Potential Quality Issue form.

The OIG found that although the 2021 VA congressionally mandated report indicated review processes would be in place to identify potentially problematic providers, both VISN and system leaders failed to ensure the system had a process in place to review CCN providers.

Although described as a requirement in the OSI Fact Sheet provided by Optum to the CCN providers, the OIG determined few CCN providers completed OSI training.

Finally, the OIG determined Optum does not monitor CCN provider compliance with OSI guidelines and that the VA/Optum contract lacks a contractual expectation for Optum to do so.

Recommendations 1–13

1. The Under Secretary for Health collaborates with the region 2 third-party administrator to ensure that community care providers submit documentation of care to the Veterans Health Administration including treatments provided specific to opioid risk mitigation (urine drug screening, prescription drug monitoring program checks) and all prescriptions, to include urgently/emergently prescribed opioids and routine/maintenance opioid prescriptions.

2. The VA Eastern Kansas Health Care System Director ensures system providers document evidence of Opioid Safety Initiative risk-mitigation strategies for patients who are on long-term opioids, as required by Veterans Health Administration policy.

3. The Under Secretary for Health develops and implements action requiring community care network providers to document evidence of application of Opioid Safety Initiative risk mitigation strategies when treating a veteran to whom they have prescribed opioids, and monitor compliance as part of their Community Provider Opioid Prescribing Practice reviews.

4. The Under Secretary for Health develops and implements action requiring community care network providers to conduct and document completion of state prescription drug monitoring program queries consistent with VHA policy, prior to prescribing controlled substances, regardless of whether the prescriptions are urgent, emergent, routine or maintenance prescriptions and monitor compliance as part of their Community Provider Opioid Prescribing Practice reviews.

5. The Under Secretary for Health considers issuing formal guidance to all Veterans Health Administration pharmacy staff regarding best practices for conducting state prescription drug monitoring program queries upon receipt of controlled substance prescriptions from community care network providers.

6. The Under Secretary for Health develops and implements a process to oversee compliance of VHA's medication reconciliation process for patients receiving care in the community who are prescribed opioids to include recording of the prescriptions in the non-VA medication section of the medication profile.

7. The Under Secretary for Health considers options and implements a process for including non-VA medications prescribed by community care providers in the data populating the opioid safety tools.

8. The VA Eastern Kansas Health Care System Director ensures that medications known to system staff are entered into the patient's medication profile in the electronic health record.

9. The VA Heartland Network Director ensures the Veterans Integrated Service Network Community Care Oversight Council conducts oversight of community care network providers'

opioid prescribing practices and reports results through the Opioid Prescribing Community Providers' SharePoint site.

10. The VA Heartland Network Director confirms that the VA Eastern Kansas Health Care System has a local process outlining expectations, roles, and responsibilities for completing reviews of community care network provider's opioid prescribing practices and that the process is shared with system staff, initiated, and monitored.

11. The VA Eastern Kansas Health Care System Director continues efforts to recruit and hire staff to fill vacant pain management positions.

12. The Under Secretary for Health consults with the Office for Integrated Veteran Care to determine the value of including a review of community care network provider documentation for evidence of prescription drug monitoring program queries as a required element in VA's Guidance for Community Provider Opioid Prescribing Practices Review.

13. The VA Eastern Kansas Health Care System Director ensures system staff and leaders are educated on the processes to report patient safety concerns involving community care network providers.

Appendix A: VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain Recommendations, ver. 3.0, 2017[136]

#	Recommendations
	Initiation and Continuation of Opioids
1.	a) We recommend against initiation of long-term opioid therapy for chronic pain. b) We recommend alternatives to opioid therapy such as self-management strategies and other non-pharmacological treatments. c) When pharmacologic therapies are used, we recommend non-opioids over opioids.
2.	If prescribing opioid therapy for patients with chronic pain, we recommend a short duration. Note: Consideration of opioid therapy beyond 90 days requires re-evaluation and discussion with patient of risks and benefits
3.	For patients currently on long-term opioid therapy, we recommend ongoing risk mitigation strategies (see Recommendations 7-9), assessment for opioid use disorder, and consideration for tapering when risks exceed benefits (see Recommendation 14)
4.	a) We recommend against long-term opioid therapy for pain in patients with untreated substance use disorder. b) For patients currently on long-term opioid therapy with evidence of untreated substance use disorder, we recommend close monitoring, including engagement in substance use disorder treatment, and discontinuation of opioid therapy for pain with appropriate tapering (see Recommendation 14 and Recommendation 17).
5.	We recommend against the concurrent use of benzodiazepines and opioids. Note: For patients currently on long-term opioid therapy and benzodiazepines, consider tapering one or both when risks exceed benefits and obtaining specialty consultation as appropriate (see Recommendation 14 and the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders).
6.	a) We recommend against long-term opioid therapy for patients less than 30 years of age secondary to higher risk of opioid use disorder and overdose. b) For patients less than 30 years of age currently on long-term opioid therapy, we recommend close monitoring and consideration for tapering when risks exceed benefits (see Recommendation 14 and Recommendation 17)

[136] VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver. 3.0; VA and DoD, VA/DoD Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain, ver. 4.0. At the time of the events reviewed by the OIG in this report, version 3.0 of the guideline was in effect which strongly recommended providers starting patients on long-term therapy monitor for overdose and suicidality and provide the patient with a consent form that included urine drug screening, state PDMP queries, and provide OEND. By 2022, version 4.0 no longer emphasized patient consent forms for long-term opioid therapy, risk assessment instruments, and naloxone prescriptions due to a lack of evidence that these measures improved patient safety. The 2022 version does endorse urine drug screening for patients on long-term opioid therapy.

#	Recommendations
	Risk Mitigation
7.	We recommend implementing risk mitigation strategies upon initiation of long-term opioid therapy, starting with an informed consent conversation covering the risks and benefits of opioid therapy as well as alternative therapies. The strategies and their frequency should be commensurate with risk factors and include: • Ongoing, random urine drug testing (including appropriate confirmatory testing) • Checking state prescription drug monitoring programs • Monitoring for overdose potential and suicidality • Providing overdose education • Prescribing of naloxone rescue and accompanying education
8.	We recommend assessing suicide risk when considering initiating or continuing long-term opioid therapy and intervening when necessary.
9.	We recommend evaluating benefits of continued opioid therapy and risk for opioid-related adverse events at least every three months.
	Type, Dose, Follow-up, and Taper of Opioids
10.	If prescribing opioids, we recommend prescribing the lowest dose of opioids as indicated by patient-specific risks and benefits. Note: There is no absolutely safe dose of opioids.
11.	As opioid dosage and risk increase, we recommend more frequent monitoring for adverse events including opioid use disorder and overdose. Note: • Risks for opioid use disorder start at any dose and increase in a dose dependent manner. • Risks for overdose and death significantly increase at a range of 20-50 mg morphine equivalent daily dose.
12.	We recommend against opioid doses over 90 mg morphine equivalent daily dose for treating chronic pain. Note: For patients who are currently prescribed doses over 90 mg morphine equivalent daily dose, evaluate for tapering to reduced dose or to discontinuation (see Recommendations 14 and 15).
13.	We recommend against prescribing long-acting opioids for acute pain, as an as-needed medication, or on initiation of long-term opioid therapy.
14.	We recommend tapering to reduced dose or to discontinuation of long-term opioid therapy when risks of long-term opioid therapy outweigh benefits. Note: Abrupt discontinuation should be avoided unless required for immediate safety concerns.
15.	We recommend individualizing opioid tapering based on risk assessment and patient needs and characteristics. Note: There is insufficient evidence to recommend for or against specific tapering strategies and schedules.
16.	We recommend interdisciplinary care that addresses pain, substance use disorders, and/or mental health problems for patients presenting with high-risk and/or aberrant behavior.
17.	We recommend offering medication assisted treatment for opioid use disorder to patients with chronic pain and opioid use disorder.

#	Recommendations
	Note: See the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders.
	Opioid Therapy for Acute Pain
18.	a) We recommend alternatives to opioids for mild-to-moderate acute pain. b) We suggest use of multimodal pain care including non-opioid medications as indicated when opioids are used for acute pain. c) If take-home opioids are prescribed, we recommend that immediate-release opioids are used at the lowest effective dose with opioid therapy reassessment no later than 3-5 days to determine if adjustments or continuing opioid therapy is indicated. Note: Patient education about opioid risks and alternatives to opioid therapy should be offered.

Source: Statements are verbatim from VA and DoD, Clinical Practice Guideline for Opioid Therapy for Chronic Pain, ver.3.0.

Appendix B: Opioid Safety Tools

Opioid Safety Initiative Dashboard

VHA's Pharmacy Benefits Management Services manages an OSI dashboard, updated quarterly, to "provide trending reports of outpatient opioid utilization at the National, VISN, and Medical Center level," which includes provider- and patient-specific information related to opioid prescriptions. While the intended audience is healthcare administrators, all VHA staff with permission to access protected health information may request access to the dashboard. The OSI dashboard identifies VHA and CCN providers with patients who

- are on opioid therapy, to include long-term opioid use;
- are prescribed opioids equal to or greater than 90 MEDD; and
- are on opioid therapy with a concurrent prescription for benzodiazepines.

Stratification Tool for Opioid Risk Mitigation

STORM is a predictive tool accessible through a tools menu within the EHR that uses administrative data from across VHA daily to generate a set of reports with the goal of improving opioid safety in the provision of care. STORM can be used by VHA clinicians to identify patients with current or recent opioid prescriptions who are at "risk of overdose or suicide-related health care events or death," or elevated risk for adverse opioid-related events. STORM provides clinicians with risk-mitigation strategies to consider, and upcoming appointments that a patient has scheduled.[137] The OIG learned from IVC staff that CCN providers are excluded from accessing STORM because it requires access to VHA systems.

Opioid Therapy Risk Report

The Opioid Therapy Risk Report is accessed by VHA clinicians through the EHR. The report is designed to identify patients receiving long-term opioid therapy. Report data updates daily and includes opioid and benzodiazepine medication histories, including the prescriber name, dispensing location, strength, number of day's supply, and MEDD. The report also notes patient diagnoses of posttraumatic stress disorder, depression, Substance Use Disorder, Obstructive Sleep Apnea that may increase opioid use risk; recent primary care or mental health appointments; status of a patient's consent forms for opioid therapy, most recent urine drug screen results, timeline of the last PDMP query; and patient pain scores.

[137] VA Stratification Tool for Opioid Risk Mitigation (STORM), accessed April 7, 2022, https://dvagov.sharepoint.com/sites/VHAPERC/Reports/SitePages/STORM_home.aspx. (This link is not publicly accessible.)

Opioid Overdose Education and Naloxone Distribution Patient Risk Dashboard

VA's OEND program is intended to help reduce patient deaths from opioid overdoses. The OEND Patient Risk dashboard can be accessed by VHA clinicians and administrators on VHA's Academic Detailing Service's site. The dashboard provides patient-level data on the distribution and reported use of naloxone. In addition to data, the website provides naloxone education for providers, guides for managing opioid use disorder, and PDMP enrollment and monitoring. The OIG learned from a leader in the Academic Detailing Service that CCN providers are excluded from accessing OEND as it requires access to VHA systems.

Opioid Use Disorder Dashboard

The opioid use disorder dashboard is designed to generate reports that assist in the identification of patients at high-risk for opioid use disorder. The tool also allows clinicians to review patient-specific opioid use disorder treatment with the goal of identifying patients who may benefit from an opioid use disorder treatment that the patient is not currently receiving. The dashboard is available to individuals with a VA login and not accessible to CCN providers.

Appendix C: Optum's Clinical Quality Management

The VA/Optum contract outlines expectations for monitoring clinical quality. The Optum Provider Manual states that CCN providers are required to participate in Optum's Clinical Quality Management program which includes monitoring clinical performance, assessing quality of care, and resolving quality issues reported by VHA, a patient, or a provider.[138] Concerns brought to the attention of Optum are handled through the peer review process outlined in the contract. [139]

Optum incorporates Potential Quality Issue referrals into their Clinical Quality Management process with the purpose of reducing medical errors, increasing patient safety and improving patient outcomes. Once Optum has reviewed the concern reported in the Potential Quality Issue, they must send the referral for peer review to determine if the provider's actions deviated from expected practice standards. Optum has a Peer Review Committee that, according to IVC leaders, is comprised of staff from Optum, VHA IVC Program Office, and CCN providers. The VISN BIM told the OIG the committee reviews the outcome of the reported quality of care issues and determines whether a corrective action plan is warranted or if the care provided by a CCN provider justifies removal from the network. IVC staff sit as non-voting members on the committee. According to the VISN BIM, Optum does not provide the system with information from the Peer Review Committee, or any actions taken.

[138] United Healthcare/ Optum, *VA CCN Provider Manual, v.1.9,* July 2021. United Healthcare/Optum, the terms of the provider manual are incorporated into Participating Provider Agreements signed by each CCN provider and are binding parts of the Optum/CCN provider contract. The VA/Optum contract uses the term Clinical Quality Monitoring while the Provider Manual refers to these same activities as Clinical Quality Management.

[139] United Healthcare/Optum, *VA CCN Provider Manual*, ver. 1.9.

Appendix D: Opioid Safety Initiative (OSI) Department of Veterans Affairs Office of Community Care Training Module[140]

Objective

The intent of [IVC] is to educate and ensure a greater awareness of the evidence-based guidelines for prescribing opioids as outlined in the Opioid Safety Initiative (OSI) to all participating non-VA purchased care providers. To build a collaborative effort between the [VHA] and non-VA purchased care providers promoting evidence-based management of Veterans with chronic pain, improve patient outcomes, and decrease incidence of complications in regards to opioid prescribing.

Introduction

In 2013, a national system-wide effort mandated by Congress, the Department of Veterans Affairs (VA) and the Department of Defense (DoD), developed and implemented the Opioid Safety Initiative (OSI), a multi-faceted, comprehensive effort to improve Veteran quality of life suffering from chronic pain, to assist in decreasing opioid prescribing practices associated with adverse outcomes, and to promote safer opioid related prescribing for Veterans. The guidelines were published in February 2017. The OSI addresses the challenge of opioid dependency with an innovative, comprehensive plan that closely monitors [VHA's] dispensing practices system-wide and coordinates pain management to include patient and provider education, testing and tapering programs, and use of complementary integrated health modalities. Ref: www.va.gov/opa/pressrel/pressrelease.cfm?id=2529

Opioid Safety Initiative (OSI)

Management of Opioid Therapy (OT) for Chronic Pain (2017) - VA/DoD Clinical Practice Guidelines

There is a mounting body of research detailing the lack of benefit and potentially severe harm of long-term opioid therapy. Since the publication of the Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain in 2010, there has been a growing epidemic of opioid misuse and opioid use disorder in America. The 2017 updated guideline is based on a systematic review of both the clinical and epidemiological evidence available as of December 2016.

[140] This content is printed verbatim from a CCN provider training document.

The guideline was developed by a panel of multidisciplinary experts and it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation. This guideline is intended to provide healthcare providers with a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with chronic pain, who are currently on or are being considered for long-term opioid therapy (LOT).

Link to VA/DoD Clinical Practice Guidelines:
http://www.healthquality.va.gov/guidelines/Pain/cot/

Clinical Practice Guidelines

Clinical practice guidelines are used in health care to improve patient care as a potential solution to reduce inappropriate variations in care. Guidelines should be evidence-based, incorporate patient input, as well as explicit criteria to ensure internal validity. The use of guidelines must always be in the context of a health care provider's clinical judgment(sic) in the care of a particular patient. For this reason, the guidelines may be viewed as an educational tool to provide information in shared decision-making.
https://www.healthquality.va.gov/index.asp

Key Clinical Information

- **Veterans are twice as likely to die from accidental overdose compared to the non-Veteran population.** Assessment of risk factors is important in our Veteran population especially in returning combat Veterans. Often they present to primary care seeking relief from both physical and psychological pain.
- **Psychological distress may lead to inappropriate use of opioid medications in patients with mental health disorders. Caution should be used in this high risk population.**
- Veterans with Posttraumatic Stress Disorder are more likely to:
    - Be prescribed opioids at higher doses
    - Receive opioids and sedative hypnotics (including benzodiazepines) concurrently
    - Combinations lead to increased risk of unintentional overdose

Chronic Pain Treatment Strategies

- Assessment
- Set Expectations for Pain Management
- Offer Non-pharmacological and Non-opioid treatment options
- Proceed with opioid treatment with caution

- Assess treatment at every visit
- Stop and reassess if you have any concerns
- Refer to Substance abuse treatment teams when necessary

More details to be reviewed in the Opioid Safety-Educational Guide found in the OSI Toolkit

Requirements for the Non-VA community Provider

- Review and sign the receipt of the evidence-based guidelines outlined in the Opioid Safety Initiative (OSI) included within this module.
- With respect to clinical judgement and or contractual requirements, submit all prescribed [routine/maintenance] medications in accordance with the VHA National Formulary Handbook to VA for dispensing and as part of the health care treatment authorized by the VA.

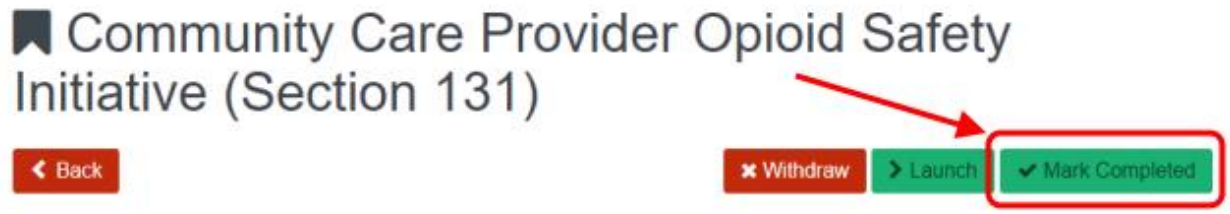
Resource Section:

The OSI Toolkit can be found here, each element is listed for your convenience
https://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_OSI.asp

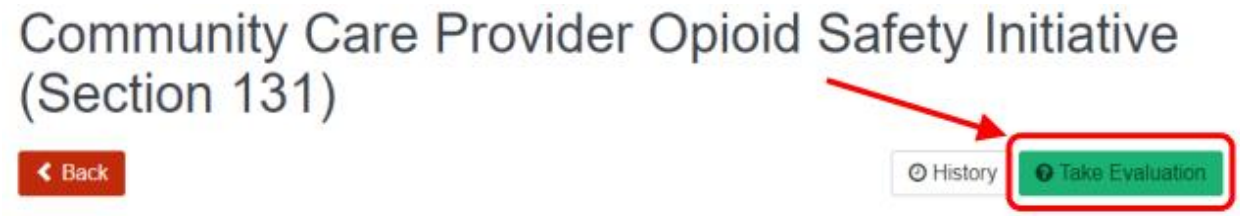
The Opioid Therapy pocket guide
https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPGPocketCard022817.pdf
created 08/24/17 mwb

Completion Instructions

Once you've read through this pdf, return to the course details page and click the "Mark Completed" button.



To finish out the course, click the "? Take Evaluation" button and follow the prompts through the completion of the evaluation.


Community Care Provider Opioid Safety Initiative (Section 131)
Back
History
Take Evaluation

Appendix E: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: September 18, 2023

From: Under Secretary for Health (10)

Subj: Office of Inspector General (OIG) Draft Report, Review of Veterans Health Administration's (VHA) Oversight of Community Care Providers' Opioid Prescribing at the Eastern Kansas Health Care System in Topeka and Leavenworth (Project # 2022-02017-HI-1256) (VIEWS 10455733)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the OIG draft report on opioid prescribing at the Eastern Kansas Health Care System in Topeka and Leavenworth. VHA concurs in principle with recommendations 1, 3, 4, 6, 7 and 12. VHA provides an action plan in the attachment.
2. VHA appreciates OIG's thoughts and recommendation to shift responsibility for querying state prescription drug monitoring programs to pharmacists, however, information garnered from such a query is to be used by the prescriber when making clinical decisions about providing opioids to an individual for health care and treatment. VHA finds its policy appropriately places the responsibility for conducting such queries with the controlled substance prescriber when prescribing the medication. VHA does not agree with delegating prescribers' responsibilities to pharmacy staff. Thus, VHA does not concur with recommendation 5.
3. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

(Original signed by:)

Shereef Elnahal M.D., MBA

Office of the Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan
Review of VHA's Oversight of Community Care Providers' Opioid Prescribing at the Eastern Kansas Health Care System in Topeka and Leavenworth
(2022-02017-HI-1256)

Recommendation 1. The Under Secretary for Health collaborates with the region 2 third-party administrator to ensure that community care providers submit documentation of care to the Veterans Health Administration including treatments provided specific to opioid risk mitigation (urine drug screening, prescription drug monitoring program checks) and all prescriptions, to include urgently/emergently prescribed opioids and routine/maintenance opioid prescriptions.

VHA Comments: Concur in principle

The Veterans Health Administration (VHA) Office of Integrated Veterans Care (IVC) agrees that medical documentation should be submitted from Community Care Network (CCN) providers to VHA when treating a Veteran with opioids. VHA currently requires CCN providers to broadly meet elements of documentation consistent with the care provided, such as urine drug screening, but does not specify individual elements. VHA currently does not require community care providers to submit copies of all prescriptions for opioids. VHA appreciates this recommendation from the Office of Inspector General (OIG) and also acknowledges the associated requirements in the VA MISSION Act. As other health insurance companies do not have this requirement, adding it may deviate from community standards of practice and may have negative impacts on the adequacy of the CCN provider network. As a result, IVC concurs in principle and, in order to further address and evaluate the feasibility of implementing this recommendation and the associated requirements under the VA MISSION Act, IVC has established an Integrated Project Team (IPT).

Status: In Progress Target Completion Date: December 2023

Recommendation 3. The Under Secretary for Health develops and implements action requiring community care network providers to document evidence of application of Opioid Safety Initiative risk mitigation strategies when treating a veteran to whom they have prescribed opioids, and monitor compliance as part of their Community Provider Opioid Prescribing Practice reviews.

VHA Comments: Concur in principle

There are no statutory requirements that covered providers document evidence of application of OSI risk mitigation strategies when treating Veterans or that VHA monitor compliance with the OSI as part of its Community Provider Opioid Prescribing Practice Reviews.
VA uses industry standards for documentation by providers. VHA requires community care providers broadly meet elements of documentation consistent with the care provided, but does not specify individual elements. However, to document compliance, VA is developing processes to review documentation for a subset of community care providers who prescribe opioids. Therefore, IVC concurs in principle. To determine feasibility of more stringent documentation requirements, IVC has established an IPT.

Additionally, provider education and training efforts by VA and State and Federal entities may address concerns related to documentation. For example: the CCN contract requires the Third Party Administrator (TPA) to educate providers on requirements such as the OSI. Many State and Federal initiatives require training in opioid safety, including the Consolidated Appropriations Act of 2023 eight-hour training requirement for all Drug Enforcement Administration (DEA)-registered practitioners on the treatment and management of patients with opioid or other substance use disorders.

Status: In Progress Target Completion Date: December 2023

Recommendation 4. The Under Secretary for Health develops and implements action requiring community care network providers to conduct and document completion of state prescription drug monitoring program queries consistent with VHA policy, prior to prescribing controlled substances, regardless of whether the prescriptions are urgent, emergent, routine or maintenance prescriptions and monitor compliance as part of their Community Provider Opioid Prescribing Practice reviews.

VHA Comments: Concur in principle

Responsible opioid prescribing practices are essential to Veteran safety and high-quality care. The CCN contract states, *"The Contractor must require its CCN providers to check with its state's prescription monitoring program for any controlled substance utilization prior to writing any prescription for a controlled substance for a Veteran to ensure appropriate opioid/controlled substance use."* While the contract has this requirement, the ability to monitor and ensure compliance from individual providers has been challenging. To further address this and evaluate other elements of the recommendation, IVC has established an IPT.

Status: In Progress Target Completion Date: December 2023

Recommendation 5. The Under Secretary for Health considers issuing formal guidance to all Veterans Health Administration pharmacy staff regarding best practices for conducting state prescription drug monitoring program queries upon receipt of controlled substance prescriptions from community care network providers.

VHA Comments: Non-concur

This recommendation is based on review in one state. State requirements for private sector prescriber PDMP reporting vary significantly, and specific geographical nuances do not necessarily indicate a perpetual challenge across the enterprise. Kansas PDMP reporting regulations only require a private sector provider to report controlled substance prescribing to their PDMP for Medicaid patients. This could explain the low compliance rate observed by OIG relative to the community care prescribers PDMP reporting. Because of these local concerns, Eastern Kansas HCS has instituted local policies. However, the same concerns do not exist in all places. From a national perspective it makes more sense to have the responsibility for querying PDMPs rest with the prescriber, rather than with the pharmacy staff. VHA Directive 1306(1), Querying State Prescription Drug Monitoring Programs (PDMP), clearly states it is the responsibility of the controlled substance prescriber to maintain access to appropriate State PDMPs and interpret the PDMP data to make safe and appropriate care decisions. VHA Directive 1306(1) has this responsibility appropriately tied to the controlled substance prescriber by design, as checking the PDMP and should be accomplished by the prescriber at the time the prescription therapy is being considered to permit any necessary discussion with the patient. To address concerns with the oversight of CCN providers prescribing opioids, IVC has established an IPT as described in recommendations 1, 3 and 4.

Status: In Progress Target Completion Date: December 2023

OIG Comments: The OIG is disappointed that the Under Secretary for Health non-concurred with Recommendation 5. This recommendation directs the Under Secretary for Health to ***consider*** issuing formal guidance to all Veterans Health Administration pharmacy staff regarding best practices for conducting state prescription drug monitoring program queries upon receipt of controlled substance prescriptions from community care network providers. This report highlights significant risk to veterans prescribed controlled substances by community providers which are then filled and dispensed by *VHA pharmacists who often do not have evidence that the community care network provider queried the prescription drug monitoring program*. An Eastern Kansas Health Care System practice detailed in this report ***may*** provide an option for VHA staff to better ensure the safety of veterans participating in community care until VHA can ensure community care network providers are compliant with querying prescription drug monitoring programs. Assuming a position that refuses to consider all options and supporting that position with a directive that is not applicable to community care network providers, fails to

mitigate the significant risk to patients when evidence of a prescription drug monitoring program query is lacking.

Recommendation 6. The Under Secretary for Health develops and implements a process to oversee compliance of VHA's medication reconciliation process for patients receiving care in the community who are prescribed opioids to include recording of the prescriptions in the non-VA medication section of the medication profile.

VHA Comments: Concur in principle

VA currently captures information regarding opioids prescribed by community care providers if the prescription is filled by VHA. This recommendation requires VHA to record prescriptions if they are prescribed by CCN providers but not filled by VHA. There are significant limitations of the non-VA medication section of the health record. This section of the health record was not designed to capture, and does not capture, the important elements, such as dose, frequency, and duration of prescription, for opioid prescriptions that a provider would need to know for safe clinical decision making; therefore, VHA concurs in principle. To address this recommendation, VHA will establish an IPT of relevant subject matter experts to evaluate opportunities for CCN providers to record opioid prescriptions into the Electronic Health Record (EHR) system.

Status: In Progress Target Completion Date: February 2024

Recommendation 7. The Under Secretary for Health ensures that all opioid prescriptions recorded in the non-VA medication section of the medication profile are included in the data populating the opioid safety tools.

VHA Comments: Concur in principle

VHA agrees with the important role of the opioid safety tools in supporting VHA clinicians when making clinical decisions regarding opioid prescribing. Inclusion of reliable and up-to-date data of non-VA opioid prescriptions would be ideal to further enhance the OSI and improve clinicians' ability to do risk assessments of Veterans under their care. VHA will form an IPT to consider available options to incorporate this information into the data populating the opioid safety tools.

Status: In Progress Target Completion Date: December 2023

Recommendation 12. The Under Secretary for Health consults with the Office of Integrated Veteran Care to determine the value of including a review of community care network provider documentation for evidence of prescription drug monitoring program queries as a required element in VA's Guidance for Community Provider Opioid Prescribing Practices Review.

VHA Comments: Concur

To further address and evaluate the feasibility of this recommendation, IVC has established an IPT to determine the value of including a review of community care network provider documentation for evidence of PDMP queries as a required element in VA's Guidance for Community Provider Opioid Prescribing Practices Review.

Status: In Progress Target Completion Date: December 2023

Appendix F: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 14, 2023

From: Director, VA Heartland Network (10N15)

Subj: Healthcare Inspection—Review of VHA's Oversight of Community Care Providers' Opioid Prescribing at the VA Eastern Kansas Health Care System in Topeka and Leavenworth

To: Director, Office of Healthcare Inspections (54HL05)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. Attached is the facility's response to the OIG Draft Report - Review of VHA's Oversight of Community Care Providers and Opioid Prescribing Practices at the Eastern Kansas Health Care System in Topeka and Leavenworth.

2. I concur with the facility's action plan. No technical or general comments were made.

(*Original signed by:*)

Patricia L. Hall, PhD, FACHE
Network Director
VA Heartland Network VISN 15

VISN Director Response

Recommendation 9

The VA Heartland Network Director ensures the Veterans Integrated Service Network Community Care Oversight Council conducts oversight of community care network providers' opioid prescribing practices and reports results through the Opioid Prescribing Community Providers' SharePoint site.

Concur.

Target date for completion: January 1, 2024

Director Comments

The reasons for noncompliance were considered when developing the action plan. Effective September 1, 2022, Veterans Integrated Service Network (VISN) 15 implemented the VISN Community Care Opioid Safety Initiative Audit Standard Operating Procedure (SOP). This procedure outlines mandatory procedures and processes in compliance with the VHA Memo dated April 21, 2020, VA MISSION Act of 2018 and VHA Patient Safety Events in Community Care; Reporting, Investigation, and Improvement Guidebook. The VISN SOP was communicated to VISN 15 facility leadership on September 15, 2022. Education was provided to facility identified Points of Contact (POC) on October 6 and 7, 2022. Opioid reviews were reported to the VISN 15 Community Care Oversight meetings beginning in Fiscal Year (FY) 23 Q1 for 5 out of 7 sites and uploaded to the Opioid Prescribing Community Provider SharePoint.

The VISN 15 Community Care Manager and VISN 15 Pain Management, Opioid Safety and Prescription Drug Monitoring Program (PMOP) Coordinator provided education on the SOP to facility POCs and Community Care leadership in July 2023. Such education is tracked through an attendance spreadsheet. Facility opioid reviews will be monitored utilizing summary sheets submitted to the VISN 15 Community Care Oversight Committee until a benchmark of 90% is met for two consecutive quarters.

Recommendation 10

The VA Heartland Network Director confirms that the VA Eastern Kansas Health Care System has a local process outlining expectations, roles, and responsibilities for completing reviews of community care network provider's opioid prescribing practices and that the process is shared with system staff, initiated, and monitored.

Concur.

Target date for completion: January 1, 2024

Director Comments

The reasons for noncompliance were considered when developing the action plan. The VISN 15 Community Care Manager and VISN 15 PMOP Coordinator provided VISN 15 Community Care Opioid Safety Initiative Audit SOP education to staff identified to conduct reviews by the VA Eastern Kansas Health Care System Director in July 2023 and tracked attendance using a spreadsheet. This SOP outlines mandatory procedures and processes including expectations, roles, and responsibilities for completing the reviews of community care network provider opioid prescribing practices. The VISN 15 Community Care Manager and VISN 15 PMOP Coordinator will track reviews through the VISN 15 Community Care Oversight meetings using summary sheets submitted by the facility Community Care Oversight Committee until a benchmark of 90% is met for two consecutive quarters.

Appendix G: System Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 13, 2023

From: Director, VA Eastern Kansas Health Care System – Colmery-O'Neil VA Medical Center and Dwight D. Eisenhower VA Medical Center (589A5/00)

Subj: Healthcare Inspection—Review of VHA's Oversight of Community Care Providers' Opioid Prescribing at the VA Eastern Kansas Health Care System in Topeka and Leavenworth

To: Director, VA Heartland Network (10N15)

1. VA Eastern Kansas HCS appreciates the OIG's comprehensive report and efforts to ensure high quality of care to our Veterans. With the action plans and notes provided, Eastern Kansas is in concurrence with the report.

(*Original signed by*:)

Kimberly R. Booker, MHA, BSN, CLSSBB, VA-CM
Acting Medical Center Director
VA Eastern Kansas Health Care System

System Director Response

Recommendation 2

The VA Eastern Kansas Health Care System Director ensures system providers document evidence of Opioid Safety Initiative risk mitigation strategies for patients who are on long-term opioids, as required by Veterans Health Administration policy.

Concur.

Target date for completion: June 30, 2024

Director Comments

The reasons for noncompliance were considered when developing the action plan. The Office of the Chief of Staff (COS) is developing staff education to reinforce use of the EK-OPIATE RISK assessment template to document risk mitigation strategies for patients who are on long-term opioids. Once completed, the COS will designate someone to randomly audit charts monthly to assess appropriate documentation of risk mitigation strategies until a benchmark of 90% is met for two consecutive quarters. The results of the audits will be presented in Medical Executive Board (MEB) quarterly.

Recommendation 8

The VA Eastern Kansas Health Care System Director ensures that medications known to system staff are entered into the patient's medication profile in the electronic health record.

Concur.

Target date for completion: June 30, 2024

Director Comments

The reasons for noncompliance were considered when developing the action plan. The COS is developing education for all staff who perform medication reconciliation to enter any medication that a Veteran is obtaining outside of the VA into the non-VA medication section of the Computerized Patient Record System. Once completed, the COS will designate someone to randomly audit charts monthly to assess compliance with inputting non-VA medications into the patient's medication profile in the electronic health record until a benchmark of 90% is met for two consecutive quarters. The results of the audits will be presented in MEB quarterly.

Recommendation 11

The VA Eastern Kansas Health Care System Director continues efforts to recruit and hire staff to fill vacant pain management positions.

Concur.

Target date for completion: September 30, 2023

Director Comments

The reasons for noncompliance were considered when developing the action plan. The COS has recruited and hired a pain pharmacist and a pain Advanced Practice Registered Nurse to fill vacant pain management positions. Supporting documents will be provided to validate. Monitoring of these corrective actions will be reported to the MEB quarterly.

Recommendation 13

The VA Eastern Kansas Health Care System Director ensures system staff and leaders are educated on the processes to report patient safety concerns involving community care network providers.

Concur.

Target date for completion: June 30, 2024

Director Comments

The reasons for noncompliance were considered when developing the action plan. The Associate Chief Nurse of the Office of Community Care (OCC) is developing education specific to the process of how to report patient safety concerns involving community care network providers. A Talent Management System module is being created outlining the process for staff to report community care provider concerns, the process the complaint follows for completion, and examples of types of concerns to report. Compliance with completing this education will be monitored until a benchmark of 90% is met for two consecutive quarters. Results will be monitored by the OCC committee quarterly.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Inspection Team	Susan Tostenrude, MS, Director Katherine Bostick, LCSW, MPH Sandra Dickinson, MSW, LCSW Vanessa Masullo, MD Aja Parchman, MHA, RN Andrew Waghorn, JD
Other Contributors	Shelby Assad, LCSW Sherry Becker, MSN, RN-BC Rachelle Biddles, PhD Elizabeth Bullock Limin 'Lin' Clegg, PhD Charlie Cruz Reynelda Garoutte, MHA, BSN Mahshid Lee, LCSW Meggan MacFarlane, LCSW Barbara Mallory-Sampat, JD, MSN, RN Erin Mangano, LCSW Dyanne Griffith, JD Ryan McGovern, MS Sheena Mesa, MSN Ed-RN Daphney Morris, MSN, RN Marie E. Parry Rebecca Smith, MSW, LCSW Zaire Smith, LCSW Erica Taylor, MSW, LICSW Ann Ver Linden, MBA, RN

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, VA Heartland Network (10N15)
Director, VA Eastern Kansas Health Care System – Colmery-O'Neil VA Medical Center and Dwight D. Eisenhower VA Medical Center (589A5/00)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Accountability
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate
Kansas: Roger Marshall, Jerry Moran
Missouri: Josh Hawley, Eric Schmitt
U.S. House of Representatives
Kansas: Sharice Davids, Ron Estes, Jake LaTurner, Tracey Mann
Missouri: Mark Alford, Emanuel Cleaver, Sam Graves