



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Pharmacists' Practices
Delayed Buprenorphine
Refills for Patients with
Opioid Use Disorder at the
New Mexico VA Health Care
System in Albuquerque



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations regarding the policy and practices related to the provision of buprenorphine treatment for patients with opioid use disorder at the New Mexico VA Health Care System in Albuquerque (facility).

Opioid use disorder is recognized as one of the leading preventable causes of [morbidity](#) and premature death in the United States.¹ Buprenorphine is a medication used in the treatment of opioid use disorder. Buprenorphine is an opioid [partial agonist](#) and is utilized to manage the effects of physical dependency on opioids, such as withdrawal symptoms and cravings.

Buprenorphine is strongly recommended as a first-line treatment for patients with opioid use disorder in the VA/Department of Defense Clinical Practice Guideline for the Management of Substance Use Disorders.² Medication assisted treatment with buprenorphine reduces the risks for overdose and mortality in patients with opioid use disorder.³

The OIG received allegations regarding the facility's policy and practices related to provision of buprenorphine treatment for patients with opioid use disorder. The OIG conducted an inspection to evaluate allegations regarding facility pharmacists' mismanagement of buprenorphine early refill orders, Opioid Safety Committee oversight of buprenorphine treatment and risk mitigation strategies, the alignment of facility policies and practices with Veterans Health Administration (VHA) guidance on increasing access to medications for patients with opioid use disorder, and facility leaders' response to a substance use disorder provider's concerns.

During the inspection, the OIG identified a related concern regarding staffing in the facility's outpatient Substance Use Disorder program.

The OIG substantiated that pharmacists declined early refills of buprenorphine despite prescribing providers' documented clinical rationales, which increased patients' risk for adverse clinical outcomes associated with interruption of buprenorphine treatment. The OIG also substantiated that justification for the practice of declining early refills was incorrectly based on a facility policy that was not applicable to the use of buprenorphine for treatment of opioid use

¹ "What is the U.S. Opioid Epidemic?" Department of Health and Human Services, accessed August 4, 2021, <https://www.hhs.gov/opioids/about-the-epidemic/index.html>. "Opioid overdoses accounted for more than 42,000 deaths in 2016," and the US Department of Health and Human Services declared the opioid crisis a public health emergency in 2017. The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

² VA and Department of Defense (DoD), *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders, Version 4.0*, August 2021. VA and DoD, *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders, Version 3.0*, December 2015. The two guidelines contain the same or similar language related to opioid agonist treatment for opioid use disorder.

³ VHA Notice 2020-30, *Buprenorphine Prescribing for Opioid Use Disorder*, September 22, 2020.

disorder. Neither VHA nor the facility's policy on controlled substances prohibited early refills of [Schedule III](#) medications, including buprenorphine.

The OIG determined that facility pharmacists' routine practice was to decline early refills of buprenorphine. Pharmacists' prohibition of early refills was intended to guard against misuse or diversion of opioids. Pharmacists' practices of prohibiting early refills resulted in prescribing providers negotiating with pharmacists or involving Opioid Safety Committee staff for consultation to obtain early refills of buprenorphine or spending extra time altering treatment plans to provide comfort medications for withdrawal symptoms until the next refill date permitted by the pharmacy.

The OIG determined that pharmacy practice made no delineation between prohibition of early refills of partial opioid agonists for opioid use disorder and full opioid agonists for pain, despite the different indications for each medications' use and associated risks. Pharmacy practice of prohibiting early refills of buprenorphine for opioid use disorder, justified under the facility policy that forbids early refills of opioids for pain, was more restrictive than what was allowed by VHA and facility policy guidance applicable to Schedule III controlled substances, and inconsistent with guidelines for evidence-based treatment of opioid use disorder.⁴

The OIG concluded that pharmacists' practices prohibiting early refills interfered with timely access to buprenorphine and could place patients at increased risk for adverse clinical outcomes. None of the patients reviewed by the OIG experienced overdose or death as a result of interrupted buprenorphine treatment. However, one patient experienced withdrawal symptoms with treatment interruption and another patient experienced increased cravings, though neither patient reported relapsing.

During interviews with the OIG, providers and pharmacy staff reported varying understandings of facility policy related to early refills of buprenorphine, and indicated that pharmacy buprenorphine approval practices had changed over time. The OIG determined that VHA and the applicable facility policy, as written, did not prohibit early refills for Schedule III medications such as buprenorphine, thus allowing providers prescriptive authority to approve early refills of buprenorphine when clinically appropriate.⁵ The OIG's inspection findings emphasized the importance that facility pharmacists' practices change to align with the applicable policy.

The OIG did not substantiate that the facility's Opioid Safety Committee Chairperson interfered with prescribing providers' practices regarding buprenorphine orders for patients with opioid use disorder. The OIG determined that the Opioid Safety Committee Chairperson's involvement with buprenorphine treatment was within the scope of an Opioid Safety Committee member's

⁴ Facility Memorandum 115-5, *Opioid Analgesia For Chronic Non-Malignant Pain*, December, 2018. VHA Directive 1108.01(1), *Controlled Substances Management*, May 1, 2019, amended December 2, 2019. Medical Center Policy 119-21, *Controlled Substances for Outpatient Use*, January 28, 2020.

⁵ VHA Directive 1108.01(1). Medical Center Policy 119-21.

responsibility. Opioid Safety Committee members' responsibilities include the deployment of risk mitigation strategies for patients with opioid use disorder.⁶ However, based on information provided during interviews, the OIG found that some prescribing providers were unaware of activities associated with the Opioid Safety Committee's role, leading the providers to view the Opioid Safety Committee's involvement as interference.

The OIG substantiated that the Opioid Safety Committee Pharmacist placed [standing orders](#) for [urine drug screening](#) for buprenorphine patients without coordinating with patients' prescribing providers regarding clinical need for the testing or obtaining informed consent from patients. However, the OIG determined that the Opioid Safety Committee Pharmacist acted within the scope of practice, entered standing orders for urine drug screening as part of the facility's implementation of VHA guidance associated with COVID-19 mitigation strategies, and was not required to obtain a separate consent for urine drug screening.

The OIG did not substantiate that the facility's standard operating procedure (SOP) on buprenorphine treatment for patients with opioid use disorder, enacted in July 2021, was inconsistent with VHA guidance on buprenorphine treatment for patients with opioid use disorder. The OIG was unable to determine whether implementation of the buprenorphine SOP would reduce access to buprenorphine for patients with opioid use disorder, as the SOP was not fully implemented at the time of the OIG's review.

The OIG did not substantiate the allegation that facility practices were inconsistent with VHA guidance on increasing access to buprenorphine for patients with opioid use disorder. The facility Chief of Staff reported that the facility provided buprenorphine treatment for patients with opioid use disorder in the Substance Use Disorder program, pain management clinic, inpatient and residential mental health units, and on a limited basis in some primary care clinics. Facility leaders, in coordination with the Opioid Safety Committee, developed plans for expanding access to buprenorphine in emergency department and primary care settings, consistent with VHA guidance. However, expansion of buprenorphine treatment was limited by availability of [X-waivered providers](#), as well as the need for additional staffing resources to support access for substance use disorder treatment referrals and development of clearly defined processes to ensure continuity of care across treatment settings.

The OIG identified a related concern regarding staffing challenges that affected the Substance Use Disorder program and plans for expanding buprenorphine treatment in other clinical areas. The OIG determined that the facility initiated actions to address the staffing vacancies. The OIG also determined that ongoing review of prescriber staffing levels in accordance with the Substance Use Disorder program's needs and plans for expanding buprenorphine treatment in other clinical areas were warranted.

⁶ Facility Charter 300-42, *Opioid Safety Committee*, September 2020.

The OIG did not substantiate that facility leaders failed to respond to a Substance Use Disorder provider's report of patient safety concerns associated with facility policy and procedures related to buprenorphine for patients with opioid use disorder. The former Chief of Psychiatry reported discussing the issues with the provider, and the Facility Associate Director requested a Veterans Integrated Service Network review of pharmacists' practices related to buprenorphine. However, the OIG noted that actions taken by leaders did not fully address the reported concerns. The OIG found that the facility response did not address the Substance Use Disorder provider's concerns that the pharmacy practice of disallowing early buprenorphine refills did not support evidenced-based practice from a [harm reduction](#) model, interfered with providers' ability to implement individualized patient-centered treatment, and placed patients at increased risk for adverse clinical outcomes.

The OIG made five recommendations to the Facility Director related to aligning facility practices with policy applicable to early refills for buprenorphine; ensuring communication between providers, pharmacists, and patients for early medication refills; clarifying and educating relevant staff on the roles of the Opioid Safety Committee in buprenorphine treatment; revising the facility's buprenorphine SOP; and reviewing Substance Use Disorder provider staffing needs.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the findings and recommendations and provided acceptable action plans (see appendixes A and B). The OIG will follow up on the planned actions until they are completed.



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Abbreviations

CARA	Comprehensive Addiction and Recovery Act
DoD	Department of Defense
EHR	electronic health record
FTE	full-time equivalent
OIG	Office of Inspector General
SOP	standard operating procedure
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations regarding the policy and practices related to the provision of buprenorphine treatment for patients with opioid use disorder at the New Mexico VA Health Care System (facility) in Albuquerque.

Background

The facility, part of Veterans Integrated Service Network (VISN) 22, includes the Raymond G. Murphy VA Medical Center in Albuquerque, New Mexico, and 13 community-based outpatient clinics.⁷ The facility operates 278 hospital beds, including 167 acute hospital beds, 75 residential rehabilitation treatment program beds, and a 36-bed community living center.⁸ From October 1, 2020, through September 30, 2021, the facility served 59,346 patients. The Veterans Health Administration (VHA) classifies the facility as a Level 1b, high complexity facility.⁹

Opioids

Opioids are a class of drugs that includes compounds naturally found in the opium poppy, such as heroin, or synthesized compounds with similar properties, such as morphine, oxycodone, and fentanyl.¹⁰ “Opioids bind to and activate opioid [receptors](#) on cells located in many areas of the brain, spinal cord, and other organs in the body, especially those involved in feelings of pain and pleasure.”¹¹ Opioids are primarily prescribed for the treatment of moderate to severe pain.¹²

In addition to relieving pain, opioids can make a person feel very relaxed or “high.” Opioids can be highly addictive. People who are addicted to opioids and stop using the opioid drugs can

⁷ “VA New Mexico Health Care,” VA, accessed March 28, 2022, <https://www.albuquerque.va.gov/locations/directions.asp>. The facility has one community-based outpatient clinic in Durango, Colorado, and 12 community-based outpatient clinics located in New Mexico: Alamogordo, Artesia, Espanola, Farmington, Gallup, Las Vegas, Northwest Metro-Rio Rancho, Raton, Santa Fe, Silver City, Taos, and Truth or Consequences.

⁸ VHA Handbook 1142.01, *Criteria and Standards for VA Community Living Centers (CLC)*, August 13, 2008. A VA community living center, formerly known as a nursing home care unit, provides a skilled nursing environment for patients needing short and long-stay services.

⁹ VHA Office of Productivity, Efficiency and Staffing. The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, educational and research missions, and complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered the most complex.

¹⁰ “Prescription Opioid DrugFacts,” National Institute on Drug Abuse (NIDA), accessed November 10, 2021, <https://www.drugabuse.gov/publications/drugfacts/prescription-opioids>.

¹¹ The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the “alt” and “left arrow” keys together. “Prescription Opioid DrugFacts,” NIDA website.

¹² “Prescription Opioid DrugFacts,” NIDA website.

experience withdrawal symptoms, including pain, sleep problems, diarrhea, vomiting, cold flashes, uncontrollable movements, and severe cravings. Withdrawal symptoms can be extremely uncomfortable and make it difficult for people to stop using opioids.¹³

Taking too much of an opioid (overdose) can cause [respiratory depression](#) and may lead to death.¹⁴ According to the World Health Organization, more than 70 percent of deaths associated with drug use were related to opioids, and over 30 percent of those deaths were caused by overdose.¹⁵

Opioid Use Disorder

Opioid use disorder is a substance use disorder characterized by continuing substance use despite significant related problems reflected in a pattern of behaviors or symptoms. Symptoms may include impaired control over substance use, social impairments associated with substance use, risky use, and development of pharmacological effects such as tolerance or withdrawal.¹⁶ Opioid use disorder is recognized as one of the leading preventable causes of [morbidity](#) and premature death in the United States.¹⁷

Buprenorphine

Buprenorphine is a medication used in the treatment of opioid use disorder.¹⁸ Buprenorphine is an opioid [partial agonist](#) and is utilized to manage the effects of physical dependency to opioids, such as withdrawal symptoms and cravings.¹⁹ The opioid effects of euphoria and respiratory depression are weaker with buprenorphine than with opioid full [agonists](#).²⁰ Buprenorphine has lower potential for misuse and increases safety in cases of overdose in comparison to opioid full agonists.²¹

¹³ "Prescription Opioid DrugFacts," NIDA website.

¹⁴ "Opioid Overdose," World Health Organization, accessed November 10, 2021, <https://www.who.int/news-room/fact-sheets/detail/opioid-overdose>.

¹⁵ "Opioid Overdose," World Health Organization website.

¹⁶ Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), "Substance Use Disorders," accessed August 4, 2021, <https://doi.org/10.1176/appi.books.9780890425596>.

¹⁷ "What is the U.S. Opioid Epidemic?" Department of Health and Human Services, accessed August 4, 2021, <https://www.hhs.gov/opioids/about-the-epidemic/index.html>. "Opioid overdoses accounted for more than 42,000 deaths in 2016", and the US Department of Health and Human Services declared the opioid crisis a public health emergency in 2017.

¹⁸ "Buprenorphine," Substance Abuse and Mental Health Services Administration (SAMHSA), accessed on August 2, 2021, <https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/buprenorphine>.

¹⁹ "Buprenorphine," SAMHSA website.

²⁰ "Buprenorphine," SAMHSA website.

²¹ "Buprenorphine," SAMHSA website.

Food and Drug Administration-approved opioid use disorder medications include mono-product and combination-product formulations of buprenorphine that also contain naloxone.²² Naloxone is an opioid [antagonist](#), which blocks the effects of other opioids, and is designed to rapidly reverse opioid overdose.²³ The addition of naloxone to buprenorphine in combination-product formulations decreases the likelihood for misuse of the medication.²⁴

Medication-assisted treatment, using either buprenorphine or [methadone](#), is strongly recommended as a first-line treatment for patients with opioid use disorder in the *VA/Department of Defense (DoD) Clinical Practice Guideline for the Management of Substance Use Disorders*.²⁵ Medication-assisted treatment with buprenorphine reduces the risks for overdose and mortality in patients with opioid use disorder.²⁶

VA Opioid Safety Initiative

In 2013, VA developed the Opioid Safety Initiative, a system-wide plan with a multipronged approach to decreasing high risk opioid prescribing practices and mitigating patient safety risks associated with opioid overuse.²⁷ The Opioid Safety Initiative strategies broadly encompass patient and provider education, enhanced pain management approaches, provision of addiction treatment, and implementation of risk mitigation strategies.²⁸ Recommended risk mitigation strategies include performing random [urine drug screening](#), checking [state prescription drug monitoring programs](#), monitoring for overdose potential, providing overdose education, and distributing naloxone rescue medication.²⁹ On July 22, 2016, the [Comprehensive Addiction and Recovery Act](#) (CARA) was signed into law.³⁰ CARA contained a requirement for VA systems to

²² “Buprenorphine,” SAMHSA website. Buprenorphine and naloxone combination products are marketed under brand names, such as Suboxone, and are also available in generic formulations.

²³ “Naloxone,” SAMHSA, accessed August 2, 2021. <https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/naloxone>.

²⁴ “Buprenorphine,” SAMHSA website.

²⁵ VA and DoD, *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders, Version 4.0*, August 2021. VA and DoD, *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders, Version 3.0*, December 2015. The two guidelines contain the same or similar language related to opioid agonist treatment for opioid use disorder. VHA Notice 2020-30, *Buprenorphine Prescribing for Opioid Use Disorder*, September 22, 2020.

²⁶ VHA Notice 2020-30.

²⁷ “Opioid Safety,” VHA Pain Management, accessed November 10, 2021, https://www.va.gov/PAINMANAGEMENT/Opioid_Safety/index.asp. VA Health Services Research & Development, *Improving the Safety of Opioid Treatment*, July 2017, accessed November 10, 2021, https://www.hsrd.research.va.gov/news/feature/opioid_safety.cfm.

²⁸ “Improving the Safety of Opioid Treatment,” VA Health Services Research & Development.

²⁹ VA and DoD, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain, Version 3.0*, February 2017; VHA Directive 1306(1), *Querying State Prescription Drug Monitoring Programs (PDMP)*, October 19, 2016, Amended October 21, 2019.

³⁰ Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695 (2016).

create pain management teams and establish standards for the use of routine and random urine drug screening before and during opioid therapy.³¹

Prior OIG Reports

In a July 2019 report addressing concerns with the facility, the OIG determined that patients had limited access to outpatient mental health care, and patients experienced delays in care. The OIG made 12 recommendations that have been closed.³²

Allegations and Related Concern

Between January 26, 2021, and July 7, 2021, the OIG received multiple allegations regarding the facility's policy and practices related to the provision of buprenorphine treatment for patients with opioid use disorder.

The OIG conducted an inspection to evaluate the following allegations:

- Facility pharmacists declined early refills of buprenorphine despite prescribing providers' documented clinical rationales, which increased risks for adverse clinical outcomes associated with interruption of buprenorphine treatment.
- Justification for the pharmacy practice of declining early refills was incorrectly based on a facility policy that was not applicable to the use of buprenorphine for treatment of opioid use disorder.
- The facility's Opioid Safety Committee Chairperson interfered with prescribing providers' practices regarding buprenorphine orders for patients with opioid use disorders.
- An Opioid Safety Committee pharmacist placed orders for urine drug screening for buprenorphine patients without coordinating with prescribing providers regarding clinical need for the testing or obtaining informed consent from patients.
- The facility's standard operating procedure (SOP) on opioid agonist therapy (buprenorphine) treatment for patients with opioid use disorder (buprenorphine SOP) would reduce access to buprenorphine for patients with opioid use disorders.
- The facility's practices were inconsistent with VHA's guidance on increasing access to buprenorphine for patients with opioid use disorders.
- Facility leaders failed to respond to a Substance Use Disorder provider's report of patient safety concerns associated with facility policy and procedures related to buprenorphine for patients with opioid use disorders.

³¹ Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, §911, 130 Stat. 695 (2016).

³² VA OIG, [Concerns with Access and Delays in Outpatient Mental Health Care at the New Mexico VA Health Care System, Albuquerque, New Mexico](#), Report No. 17-05572-170, July 23, 2019.

During the inspection, the OIG identified a related concern regarding staffing in the facility's outpatient Substance Use Disorder program.

Scope and Methodology

The OIG initiated the inspection on July 29, 2021, and conducted virtual interviews from September 1 through October 7, 2021.

The OIG interviewed the complainant; the VISN 22 [Academic Detailer](#); the facility's Associate Director, Chief of Staff, Opioid Safety Committee Chairperson and Pharmacist; and relevant facility leaders and staff from Behavioral Health, CARA Pain Team, Pharmacy, and Substance Use Disorder program.

The OIG reviewed relevant documents dated October 2019 to September 2021 including the electronic health records (EHRs) of 21 patients who were identified by the complainant or by facility staff members as potentially affected, VHA and facility policies and procedures, applicable federal and state laws and regulations, clinical practice guidelines, administrative reports, committee meeting minutes, and other documents relevant to the report. The OIG also reviewed email communication between pertinent VHA staff members during the time frame of this hotline.

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, Pub. L. No. 95-452, 92 Stat. 1101, as amended (codified at 5 U.S.C. App. 3). 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 inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

1. Pharmacists' Mismanagement of Buprenorphine Early Refill Orders

The OIG substantiated that facility pharmacists declined early refills of buprenorphine despite prescribing providers' documented clinical rationales, which increased patients' risk for adverse clinical outcomes associated with interruption of buprenorphine treatment.³³ The OIG also substantiated that justification for the practice of declining early refills was incorrectly based on a facility policy that was not applicable to the use of buprenorphine for treatment of opioid use disorder. Neither VHA nor the facility's policy on controlled substances prohibited early refills of [Schedule III](#) medications, including buprenorphine.³⁴

VHA policy on substance use disorders requires that treatment be provided "consistent with evidence-based treatment guidelines" and references the VA/DoD Clinical Practice Guideline on Management of Substance Use Disorder.³⁵ The VA/DoD Clinical Practice Guideline indicates that opioid agonist treatment for opioid use disorder improves safety, promotes treatment retention and abstinence, and "the benefits [of opioid agonist treatment] strongly outweigh the risks given the risk of fatal outcomes if OUD [opioid use disorder] remains untreated."³⁶

VHA policy on controlled substances allows for refills of Schedule III medications, such as buprenorphine, when authorized by the prescribing provider.³⁷ Specifically, VHA defines that the acceptable process for a patient-initiated request to refill prescriptions for Schedule III controlled substances is for pharmacy staff to inform the patient's healthcare provider that the patient has requested such a refill. The healthcare provider's response may include writing a renewal prescription of the requested medication.³⁸

³³ For the remainder of the report, the term buprenorphine refers to both mono-product and combination-product formulations of the medication.

³⁴ Facility Memorandum 115-5, *Opioid Analgesia For Chronic Non-Malignant Pain*, December, 2018. This policy establishes requirements for opioids for the long-term management of patients with chronic non-malignant pain at the facility and outlines procedures, and responsibilities of patients and providers. The policy states that "NO EARLY REFILLS OR RENEWALS ARE PERMITTED" including opioids that were overtaken, reported misplaced, lost, stolen, damaged, discarded, or for travel reasons."

VHA Directive 1108.01(1), *Controlled Substances Management*, May 1, 2019, amended December 2, 2019.

Medical Center Policy 119-21, *Controlled Substances for Outpatient Use*, January 28, 2020.

³⁵ VHA Handbook 1160.04, *VHA Programs for Veterans with Substance Use Disorders (SUD)*, March 7, 2012.

³⁶ VA and DoD, *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders*, Version 4.0.

³⁷ VHA Directive 1108.01(1).

³⁸ VHA Directive 1108.01(1).

Pharmacy Practices Misaligned with Prescribing Providers' Clinical Practices

During interviews with the OIG, providers indicated that when a patient requests an early refill, they must weigh risks and benefits, and use clinical judgment to determine whether provision of an early refill for buprenorphine is appropriate for a given patient. Buprenorphine reduces or eliminates opioid withdrawal symptoms, blunts the effects of illicit opioids, and decreases opioid cravings. Clinical guidelines state that discontinuing or tapering medication treating opioid use disorder for “nonmedical reasons or because of ongoing substance misuse is generally inappropriate.”³⁹ After withdrawal from buprenorphine, a patient’s risk of opioid overdose and death increases if the patient relapses to opioid use.⁴⁰ Some prescribing providers expressed concerns that the pharmacy practice of prohibiting early refills of buprenorphine could interrupt recommended treatment, placing patients at increased risks for relapse, overdose, and death.

The OIG determined that facility pharmacists’ routine practice was to decline early refills of buprenorphine. Pharmacists’ prohibition of early refills was intended to guard against misuse or diversion of opioids. Pharmacists’ practices of prohibiting early refills resulted in prescribing providers negotiating with pharmacists or involving Opioid Safety Committee staff for consultation to obtain early refills of buprenorphine or spending extra time altering treatment plans to provide comfort medications for withdrawal symptoms until the next refill date permitted by the pharmacy.

During EHR reviews, the OIG found evidence of interruption of buprenorphine treatment for two patients that was inconsistent with prescribing providers’ treatment recommendations. None of the patients reviewed by the OIG experienced overdose or death as a result of interrupted buprenorphine treatment. Patient Case Example 1 illustrates a patient who experienced withdrawal symptoms with treatment interruption, and Patient Case Example 2 illustrates a patient who experienced increased cravings, though neither patient reported relapsing.

Patient Case Example 1

The patient who was in their fifties, was provided ongoing medication management with buprenorphine/naloxone for a substance use disorder.⁴¹ In summer 2020, a pharmacy technician documented a telephoned buprenorphine renewal request by the patient that could not be filled because no refills were available and the most recently dispensed buprenorphine prescription “must last [specified 30 day period].” Two days later, a pharmacist documented a telephone

³⁹ SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, updated 2021.

⁴⁰ VA/DoD *Clinical Practice Guideline for the Management of Substance Use Disorders*, Version 4.0. VA/DoD *Clinical Practice Guideline for the Management of Substance Use Disorders*, Version 3.0.

⁴¹ The OIG uses the singular form of they (their) in this instance for privacy purposes.

request for refill due to a claim the medication was stolen, but noted the date the current supply must last until, as early refills were “not allowed per policy” and special approval, determined on a case-by-case basis, was needed from the pharmacy vault supervisor.⁴² The patient’s psychiatrist responded to the pharmacist’s notation, and documented in the EHR that the patient “is an extremely reliable user of Suboxone and to the best of my knowledge this has not ever happened before. Please inform me of pharmacy’s decision, since withdrawal would put the veteran at very high risk of overdose” and the patient “will need to be treated with detox medication for withdrawal.”⁴³ A subsequent EHR note by the pharmacy vault supervisor indicated “Per VA policy we do not replacer [sic] stolen opioids and suboxone is treated as an Opioid. Patient may need to be provided with other medications for with drawaal [sic] symtoms [sic] till [the patient’s] next due date.”

One week later, the patient had a follow-up psychiatry appointment. The patient’s psychiatrist noted that the patient lost two weeks of medication and pharmacy policy prohibited an early refill of the medication. The psychiatrist documented the patient was provided comfort medications that were reportedly helpful for withdrawal symptoms.

Patient Case Example 2

The patient who was in their sixties, received ongoing medication management with buprenorphine/naloxone for a substance use disorder.⁴⁴ In early 2021, a substance use disorder clinic nurse documented in the patient’s EHR that the patient called and requested information on a buprenorphine/naloxone refill that had not arrived by mail. The patient admitted to not securing the most recent fill of medication and that some medication may have been taken by a friend. The patient reported having only four pills left. The nurse spoke with a pharmacist who documented the patient was not due to start the next buprenorphine/naloxone refill for another nine days, and “Early releases for controlled substances are not allowed per policy. Special approval based on extenuating circumstances must go through inpatient Pharmacy Supervisor.” Later that morning, a different pharmacist documented that the patient called, reported buprenorphine/naloxone

⁴² VHA Directive 1108.01(1), *Controlled Substances Management*, May 1, 2019, amended December 2, 2019. The amended version contains the same or similar language regarding storage requirements for controlled substances. The pharmacy vault supervisor has responsibility for the pharmacy vault where controlled substances are stored.

⁴³ “Buprenorphine,” SAMHSA website. Suboxone is the brand name for one combination product formulation of buprenorphine and naloxone.

⁴⁴ The OIG uses the singular form of they (their) in this instance for privacy purposes.

would run out the next day, and requested an early refill. The pharmacist placed the patient's psychiatrist as a cosigner to this note.

On the following day, the patient's psychiatrist documented a response to the second pharmacist's EHR note in the patient's EHR, that the patient was adherent to the medication since 2007 with no previous history of misuse and "While it is unfortunate that there was a confusion about the medication, this does not justify exposing [the patient] to the extreme risk of opioid use and overdose that would occur in the setting of Suboxone withdrawal." The psychiatrist placed a new order for the medication. Later that day, the pharmacy vault supervisor documented the medication was mailed the previous day, and would be delivered the following day. The pharmacy vault supervisor called and advised the patient not to start the most recent fill until eight days after the reported last dose, and communicated that no extra tablets would be given.

Six days after the medication was delivered, during a substance use disorder clinic appointment, the patient reported taking the buprenorphine/naloxone at a lower dosage than prescribed after being advised by the pharmacy vault supervisor to delay taking the medication until it was officially due. The patient reported significant cravings at the lower dose and believed withdrawal medications would not be helpful but reported feeling in no danger of using street drugs and could "hold out" until able to take full prescribed dose per day.

The OIG determined that pharmacy practice made no delineation between prohibition of early refills of partial opioid agonists for opioid use disorder and full opioid agonists for pain, despite the different indications for each medications' use and associated risks. Pharmacy practice of prohibiting early refills of buprenorphine for opioid use disorder, justified under the facility policy that forbids early refills of opioids for pain, was more restrictive than what was allowed by VHA and facility policy guidance applicable to Schedule III controlled substances and inconsistent with guidelines for evidence-based treatment of opioid use disorder.⁴⁵

The OIG concluded that pharmacists' practices prohibiting early refills interfered with timely access to buprenorphine and could place patients at increased risk for adverse clinical outcomes.

Variances in Practices and Staff Understanding

During interviews with the OIG, providers and pharmacy staff reported varying understandings of facility policy related to early refills of buprenorphine, and indicated that pharmacy buprenorphine approval practices had changed over time. Buprenorphine prescribing providers

⁴⁵ Facility Memorandum 115-5, *Opioid Analgesia For Chronic Non-Malignant Pain*, December, 2018. VHA Directive 1108.01(1), *Controlled Substances Management*, May 1, 2019, amended December 2, 2019. Medical Center Policy 119-21, *Controlled Substances for Outpatient Use*, January 28, 2020.

and staff pharmacists reported that historically pharmacy followed a rule of no early refills for controlled substances in an effort to mitigate risks associated with opioid misuse and included buprenorphine within the practice.⁴⁶ The OIG's review of patient EHRs identified instances as recent as December 2020 when the pharmacy vault supervisor documented that "per VA policy Suboxone [buprenorphine] is treated as an opioid and opioids are not replaced or partialled [*sic*]."

When interviewed by the OIG, the pharmacy vault supervisor reported a "hard stop" continued to apply to opioids, but process changes over the last couple years allowed more flexibility with buprenorphine through a review process for approval.⁴⁷ The vault supervisor reported authorizing and releasing early refills of buprenorphine after the vault supervisor or the Opioid Safety Committee Pharmacist had a discussion with the prescribing provider.

During interviews with the OIG, the Chief of Pharmacy told the OIG that the prescribing provider has the authority to determine whether an early buprenorphine refill should be authorized. Some prescribing providers and staff pharmacists reported that the authorization involved joint decision making with pharmacists or the pharmacy vault supervisor after providers discussed justification for the early refills. Other prescribing providers discussed the need to engage the Opioid Safety Committee in discussions to secure approval, and described that despite documenting clinical rationale, they did not have the authority to make the final decision on an early refill. Patient Case Example 3 illustrates prescribing providers negotiating with pharmacists and involving Opioid Safety Committee staff to obtain early refills of buprenorphine.

Patient Case Example 3

The patient was in their forties with a history of a psychotic disorder and at risk for overdose, received buprenorphine/naloxone for opioid use disorder.⁴⁸ In early 2020, the patient's psychiatrist documented that the patient needed a new buprenorphine/naloxone prescription because the most recent refill was lost two days prior due to an inpatient admission. The Opioid Safety Committee Pharmacist documented the case was discussed with the pharmacy vault supervisor and given the patient's high-risk status, a five-day supply would be dispensed to last until the next appointment. The pharmacy vault supervisor wrote

⁴⁶ Facility Memorandum 115-5, *Opioid Analgesia For Chronic Non-Malignant Pain*, December, 2018. The OIG learned that pharmacists' practice of declining early refills of buprenorphine was incorrectly justified using a facility policy that prohibited early refills of full opioid medications for chronic, non-malignant pain, which was not applicable to buprenorphine, a partial opioid agonist used for treatment of opioid use disorder. Therefore, the pharmacy practice of no early refills should not have been applied to buprenorphine for opioid use disorder.

⁴⁷ For the purposes of this report, staff referred to the prohibition of early refills as a "hard stop."

⁴⁸ The OIG uses the singular form of they (their) in this instance for privacy purposes.

an addendum noting the patient should be advised that more would not be given the next time the medication was lost or stolen.

In late 2020, another psychiatrist documented the patient presented for a walk-in appointment and requested a buprenorphine/naloxone refill due to being about to run out. The psychiatrist noted the patient appeared confused about the currently prescribed dose, and that a higher dose had been prescribed in the past. The psychiatrist further documented the patient was at risk for overdose and that it would be detrimental to the patient's condition and safety to allow the patient to withdraw. The psychiatrist recommended continuation of the higher dose the patient had reported taking until their next visit.

The following day, the pharmacy vault supervisor documented in the EHR order "Per VA policy suboxone is treated as an opioid and opioids are not replaced or partialled [sic] for overuse/taking incorrectly. The patient is due for [the patient's] next refill [date] and cannot have any before then." Subsequent documentation by an Acting Chief of Psychiatry noted that the case was discussed with the pharmacy vault supervisor and the patient was at high risk of relapse on heroin and would get a limited supply of medication. The pharmacy vault supervisor's subsequent note documented allowance of a four-day extra refill and stated that the patient should be advised future extra fills would not be allowed, not to self-adjust medication, and to talk to a provider if the dose was not working.

In summer 2021, the pharmacy vault supervisor documented approving another early refill of buprenorphine/naloxone and stated the provider should notify the patient that this is a one-time early refill. The Opioid Safety Committee Pharmacist responded, documenting "Agreed however given very high risk would not recommend withholding Suboxone in future. Monitor closely as [Substance Use Disorder program] has been doing. Continue short fills as necessary." The patient's psychiatrist also documented an addendum stating, "I concur that the extreme risk picture presented by this veteran and the severity of [the patient's] primary psychotic disorder and complete lack of any psychosocial support including housing mandates that we act for [the patient's] safety with Suboxone whenever needed."

Another prescribing provider reported challenges in coordination with pharmacy and provided an example that occurred in summer 2021, of a pharmacist initially refusing an early buprenorphine partial refill order for a patient who reportedly lost the medication. The provider described, "I advocated vigorously for my patient and I thought it was completely inappropriate that they [pharmacists] would not do that." The OIG reviewed the patient's EHR and found that the provider requested a bridge dose until the ordered refill arrived. The provider advised the

pharmacist that the patient was in early withdrawal. After further discussion during which the provider stressed the need for the medication, the vault pharmacist agreed to release a partial refill. The provider reported that despite the patient being at the provider's office during the discussion with pharmacy, the pharmacist declined to provide buprenorphine for immediate pickup and advised that the medication would have to be mailed to the patient, delaying the patient's access to the medication. According to the provider, the patient suffered no adverse clinical outcome, but the patient was placed at increased risk for withdrawal because of delayed access to buprenorphine caused by the pharmacist.

The OIG determined that VHA and the applicable facility policy, as written, did not prohibit early refills for Schedule III medications such as buprenorphine, thus allowing providers prescriptive authority to approve early refills of buprenorphine when clinically appropriate.⁴⁹ The OIG's inspection findings emphasized the importance that facility pharmacists' practices change to align with the applicable policy.

2. Opioid Safety Committee's Role in Buprenorphine Treatment and Risk Mitigation Strategies

The OIG did not substantiate that the facility's Opioid Safety Committee staff interfered with buprenorphine prescriber's practices or inappropriately ordered urine drug screening for patients with opioid use disorder.

The facility Opioid Safety Committee was established in accordance with CARA.⁵⁰ The Opioid Safety Committee has responsibility for reviewing care for patients with high-risk opioid prescriptions and developing risk mitigation strategies or modifying treatment plans for patients at risk for adverse clinical outcomes related to an opioid prescription or opioid use disorder.⁵¹

Alleged Opioid Safety Committee Interference

The OIG did not substantiate that the facility's Opioid Safety Committee Chairperson interfered with prescribing providers' practices regarding buprenorphine orders for patients with opioid use disorder.

The OIG determined that the Opioid Safety Committee Chairperson's involvement with buprenorphine treatment was within the scope of an Opioid Safety Committee member's responsibility. The Opioid Safety Committee Chairperson told the OIG of having a "liaison role

⁴⁹ VHA Directive 1108.01(1). Medical Center Policy 119-21.

⁵⁰ Facility Charter 300-42, *Opioid Safety Committee*, September 2020. CARA of 2016, Pub. L. 114-198, 130 Stat. 695 (2016). The clinical director for the CARA Pain Team (Opioid Safety Committee Chairperson) was designated as the chairperson of both the Opioid Safety Committee and the Integrated Pain Committee, to which the Opioid Safety Committee reports. Facility Charter 300-45, *Integrated Pain Committee*, September 2020. Both committees have a responsibility to review patients with high-risk opioid prescriptions.

⁵¹ Facility Charter 300-45; Facility Charter 300-42.

and consultative role” with the intent of “making sure patients [with opioid use disorder] are treated appropriately and that risk mitigation strategies are followed.” The Opioid Safety Committee Pharmacist described the Opioid Safety Committee’s role and responsibilities similarly.⁵² However, based on information provided during interviews, the OIG found that some prescribing providers were unaware of activities associated with the Opioid Safety Committee’s role, leading the providers to view the Opioid Safety Committee’s involvement as interference.

During interviews, the OIG learned that some staff pharmacists contacted the Opioid Safety Committee Pharmacist to review buprenorphine orders, including early refills and orders lacking documentation of risk mitigation strategies. In some instances, that consultation resulted in the Opioid Safety Committee Chairperson or Opioid Safety Committee Pharmacist contacting the prescribing provider about an order, rather than pharmacy staff communicating directly with the prescribing provider.

One prescribing provider described being contacted by the Opioid Safety Committee Chairperson about a buprenorphine order for the provider’s patient that was held in the pharmacy due to incomplete information. Based on information received from the involved provider and the Opioid Safety Committee Chairperson, pharmacy staff contacted the Opioid Safety Committee Pharmacist for consultation. The Opioid Safety Committee Pharmacist reviewed the case and discussed the issue with the Opioid Safety Committee Chairperson, who then reached out to the involved provider to discuss the order.

The involved provider expressed confusion regarding the Opioid Safety Committee Chairperson’s intervention and described the interaction as “inappropriate” interference with prescribing practices that fell outside of the Opioid Safety Committee Chairperson’s scope of practice as a non-prescriber. The Opioid Safety Committee Chairperson reported that contacting the involved provider was intended to clarify and resolve concerns about the order, but acknowledged there was miscommunication and a lack of understanding of the Opioid Safety Committee’s intervention. The provider revised and resubmitted the order, which was filled by the pharmacy and released to the patient on the same day.

The OIG determined that provision of clinical consultation falls within the purview of the Opioid Safety Committee; however, consultation regarding approval of a medication order should fall to an Opioid Safety Committee member with the appropriate scope of practice, such as the Opioid Safety Committee Pharmacist.⁵³

⁵² VHA Directive 1108.01(1). The Opioid Safety Committee Pharmacist is a clinical pharmacy specialist whose scope of practice included collaborative medication management with patients’ healthcare teams. VHA policy states that “It is imperative that clinical pharmacists with a scope of practice, as part of collaborative medication management have the ability to perform physical assessment; hold prescriptive authority; order, interpret, and monitor laboratory results; develop patient-centered therapeutic plans; and manage acute and chronic disease states and processes in which medications are the primary treatment.”

⁵³ Facility Charter 300-42.

The OIG concluded that the Opioid Safety Committee Chairperson did not interfere with provider prescribing practices for buprenorphine orders; however, the OIG found that some prescribing providers were unclear of the Opioid Safety Committee Chairperson's and Opioid Safety Committee Pharmacist's role in reviewing buprenorphine treatment and deploying risk mitigation strategies for patients with opioid use disorder.

Alleged Inappropriate Urine Drug Screen Orders

The OIG substantiated that the Opioid Safety Committee Pharmacist placed orders for urine drug screening for buprenorphine patients without coordinating with patients' prescribing providers regarding clinical need for the testing or obtaining informed consent from patients. However, the OIG determined that the Opioid Safety Committee Pharmacist acted within the scope of practice, entered [standing orders](#) for urine drug screening as part of the facility's implementation of VHA guidance associated with COVID-19 mitigation strategies, and was not required to obtain a separate consent for urine drug screening.⁵⁴

Opioid Safety Committee members are responsible for "deploying risk mitigation strategies" such as urine drug screening "or modifying treatment plans" for patients at elevated risk of experiencing an adverse clinical outcome related to an opioid prescription or opioid use disorder diagnosis to "reduce the likelihood of these events and improve patient outcomes."⁵⁵

VHA guidance references postponing routine and "non-urgent" outpatient care as a strategy for reducing risk of COVID-19 transmission.⁵⁶ The VISN 22 Academic Detailer provided guidance to the facility regarding suspension of urine drug screening requirements as a part of COVID-19 mitigation plans.

Patients agree to routine and random urine drug screening, breathalyzer testing, and pill counts as part of their treatment agreement for buprenorphine therapy. Use of standing orders for urine drug screening provided for flexible implementation of the risk mitigation strategy by allowing patients to complete laboratory testing when onsite for other essential medical care. The Opioid Safety Committee Pharmacist reported placing standing orders for urine drug screening during

⁵⁴ VHA Handbook 1108.11(1), *Clinical Pharmacy Services*, July 1, 2015, amended June 29, 2017. World Health Organization, "Naming the Coronavirus Disease (COVID-19) and the Virus that Causes It," accessed November 10, 2021, [https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-\(covid-2019\)-and-the-virus-that-causes-it](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it). COVID-19 (coronavirus disease) is an infectious disease caused by the "severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)." VHA Office of Emergency Management, *COVID-19 Response Plan*, Version 1.6, March 23, 2020. VHA's COVID-19 response plan referenced postponing routine and "non-urgent" outpatient care as a strategy to reduce risk for COVID-19 transmission. VHA Handbook 1004.01(5), *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, amended September 17, 2021. "When the proposed treatment plan involves multiple or recurrent treatments and procedures, it is generally not necessary to repeat the informed consent discussion for each new treatment or procedure, provided that the original consent encompassed the treatments or procedures to be performed."

⁵⁵ Facility Charter 300-42.

⁵⁶ VHA, *COVID-19 Response Plan*.

COVID-19, when reviewing substance use disorder patients if a screening had not been ordered in the previous six months. In describing the process, the Opioid Safety Committee Pharmacist indicated that communication with prescribing providers about this practice prior to entering the standing orders was not formalized.

The OIG concluded that an Opioid Safety Committee Pharmacist placed standing orders for urine drug screening or obtaining informed consent from patients. However, the OIG concluded that the Opioid Safety Committee Pharmacist acted within the scope of practice and entered standing urine drug screening orders as part of the facility's implementation of VHA guidance for COVID-19 mitigation. The OIG concluded that the Opioid Safety Committee members including the Opioid Safety Committee Pharmacist were not required to obtain a consent for urine drug screening separate from patients' consent for buprenorphine treatment.

3. Facility Alignment with VHA Guidance on Increasing Access to Medications for Patients with Opioid Use Disorder

In response to the national opioid epidemic, which is identified as one of the leading preventable causes of premature death, VHA guidance directed facilities to “increase access to and remove barriers to prescribing medications for treatment of opioid use disorder.”⁵⁷

Facility Standard Operating Procedure on Opioid Agonist Therapy for Opioid Use Disorder

The OIG did not substantiate that the facility's buprenorphine SOP, enacted in July 2021, was inconsistent with VHA guidance on buprenorphine treatment for patients with opioid use disorder.⁵⁸ The OIG was unable to determine whether implementation of the buprenorphine SOP would reduce access to buprenorphine for patients with opioid use disorder, as the SOP was not fully implemented at the time of the OIG's review. Prescribing providers working in the outpatient Substance Use Disorder program indicated that implementation of the phased treatment protocol as detailed in the buprenorphine SOP would require increased frequency of visits, and current staffing levels were insufficient to provide more frequent visits.⁵⁹

⁵⁷ VHA Notice 2019-18, *Buprenorphine Prescribing for Opioid Use Disorder*, October 9, 2019; VHA Notice 2020-30, *Buprenorphine Prescribing for Opioid Use Disorder*, September 22, 2020.

⁵⁸ Facility SOP ACS CARA-01, *Opioid Agonist Therapy (Buprenorphine) for Opioid Use Disorder*, July 2021; *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders*, Version 4.0, August 2021; *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders*, Version 3.0, December 2015; VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives, *Buprenorphine/Naloxone and Buprenorphine for Opioid Dependence Criteria for Use for Office-Based Opioid Treatment (OBOT) Settings*, August 2014, updated September 2014.

⁵⁹ Staffing concerns in the outpatient Substance Use Disorder program are discussed later in this section.

The facility developed and implemented the buprenorphine SOP. The buprenorphine SOP was modeled on an SOP from another facility within the VISN. The Opioid Safety Committee Chairperson worked in conjunction with the VISN 22 Academic Detailer to adapt the language of the model SOP for the facility and ensure consistency with New Mexico state law.⁶⁰ The buprenorphine SOP underwent review and approval by leaders through established facility processes prior to implementation. The purpose of the buprenorphine SOP was to establish guidelines for prescribing providers and pharmacists on opioid use disorder management using buprenorphine.⁶¹

The OIG reviewed the buprenorphine SOP in relation to relevant VHA guidance on treatment of substance use disorders, New Mexico state law for Schedule III controlled substances, and clinical practice guidelines from professional subject matter expert sources.⁶² The OIG determined that, overall, the elements outlined in the buprenorphine SOP were consistent with relevant guidance. However, the OIG noted a missed opportunity for improved communication during development and implementation of the buprenorphine SOP.

In interviews with the OIG, Substance Use Disorder prescribing providers reported not having awareness of or providing input regarding the buprenorphine SOP prior to receiving notification of the SOP's publication. After receipt of the published buprenorphine SOP, some providers expressed concerns that the rigidity of the treatment protocol detailed in the SOP could potentially reduce patient access to buprenorphine treatment and limit providers' ability to adapt treatment to the individual circumstances of the patient. For example, the buprenorphine SOP detailed a phased treatment protocol that returned patients to a lower treatment phase in response to treatment non-adherence, requiring increased frequency of visits and dispensing medications

⁶⁰ New Mexico Administrative Code 16.19.20, *Occupational and Professional Licensing Pharmacists, Controlled Substances*, accessed October 20, 2021, <https://www.srca.nm.gov/parts/title16/16.019.0020.html>.

⁶¹ Facility SOP ACS CARA-01.

⁶² Facility SOP ACS CARA-01; VHA Handbook 1160.04; *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders*, Version 4.0. *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders*, Version 3.0; New Mexico Administrative Code 16.19.20; New Mexico Administrative Code 16.10.14, *Occupational and Professional Licensing, Medicine and Surgery Practitioners, Management of Pain and Other Conditions with Controlled Substances*, accessed April 12, 2022, <https://www.srca.nm.gov/parts/title16/16.010.0014.html>; SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, updated 2021; SAMHSA, *Treatment Improvement Protocol 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*, 2004; American Society of Addiction Medicine, "The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," May 27, 2015.

in smaller quantities as a strategy to mitigate risks through increased treatment involvement.⁶³ Providers described concerns that strict application of the measures outlined in the protocol could be too restrictive, burdensome, or “punitive” for patients who struggled with adherence due to co-morbid substance use disorders, mental illness, or unstable personal circumstances. Those providers expressed concerns that more restrictive treatment demands could lead some patients to drop out of treatment or cause interruptions in the patients’ access to buprenorphine that would increase risks for overdose and death associated with opioid use disorder.

While the buprenorphine SOP included a statement acknowledging “rare exceptions” when “it may be clinically indicated to deviate from the Phase Protocol based on a review of the prescribing provider and for the patient’s benefit,” some providers shared perceptions that the SOP, as written, would require strict adherence to the phased treatment protocol and expressed concerns that clinically appropriate deviation from the detailed protocol should not be characterized as “rare.”⁶⁴ A facility service leader summarized that the buprenorphine SOP was seen by some Substance Use Disorder program prescribing providers as an overly prescriptive policy requiring strict compliance rather than as a guideline for practice, which would allow flexibility to support a provider’s prescriptive authority when there was an appropriate clinical rationale or justification for deviating from the protocol.

A facility leader and the Opioid Safety Committee Chairperson reported that the buprenorphine SOP was undergoing revisions to address some of the providers’ identified concerns.

The OIG was unable to determine whether the implementation of the buprenorphine SOP would reduce access to buprenorphine for patients with opioid use disorder, as the SOP was not fully implemented at the time of the OIG’s review. The OIG found that failing to solicit input from facility prescribing providers prior to the buprenorphine SOP implementation was a missed opportunity and that SOP revisions that recognized the providers’ input were planned. The OIG recognized the importance of the buprenorphine SOP providing a framework for evidence-based treatment, while allowing adequate flexibility to implement individual patient-centered care plans and supporting clinical practice from a [harm reduction](#) model. The OIG also recognized the importance of ensuring that related facility practices support provisions within the buprenorphine SOP to allow for individualized patient-centered care.

⁶³ Facility SOP ACS-CARA-01. The SOP outlined a three-phase treatment protocol following buprenorphine induction, with the frequency of visits decreasing and the quantity of prescribed medication increasing as patients progressed to higher phases of treatment. Clinical assessment of non-adherence to the treatment plan would consider the following factors: Positive urine drug screens for clinically contraindicated substances that may pose serious safety concerns (i.e., illicit drugs, alcohol, and/or non-prescribed medications), negative urine drug screens for buprenorphine, running out of buprenorphine early (due to overtaking the medication or the medication being lost or stolen), failing to present to the clinic as requested for medication counts and urine drug screens, evidence of urine drug screen tampering, or exhibiting threatening or violent behavior towards staff.

⁶⁴ Facility SOP ACS CARA-01.

Alignment of Facility Practices with VHA Guidance on Increasing Access to Buprenorphine

The OIG did not substantiate that facility practices were inconsistent with VHA guidance on increasing access to buprenorphine for patients with opioid use disorder.⁶⁵

To increase accessibility of medication for patients with opioid use disorder, VHA guidance directs that qualified [X-waivered providers](#) must be allowed to prescribe buprenorphine in clinical settings outside of Substance Use Disorder programs.⁶⁶

The facility Chief of Staff reported that the facility provided buprenorphine treatment for patients with opioid use disorder in the Substance Use Disorder program, pain management clinic, inpatient and residential mental health units, and on a limited basis in some primary care clinics. While the facility had limited availability of X-waivered providers in the Emergency Department and Behavioral Health Urgent Care Clinic, initiation of buprenorphine treatment in those clinical settings was not supported.

Facility leaders, in coordination with the Opioid Safety Committee, developed plans for expanding access to buprenorphine in emergency department and primary care settings, consistent with VHA guidance. However, expansion of buprenorphine treatment was limited by availability of X-waivered providers, as well as the need for additional staffing resources to support access for substance use disorder treatment referrals and development of clearly defined processes to ensure continuity of care across treatment settings. The Chief of Staff described that the facility's ability to initiate buprenorphine treatment for patients with opioid use disorder presenting to the Emergency Department would require two factors: an X-waivered provider must be available in the Emergency Department to start the treatment; and a follow-up process with sufficient availability of X-waivered providers in other clinical areas is needed to assume management of the patient's ongoing buprenorphine treatment following the patient's initial Emergency Department visit. The Opioid Safety Committee Chairperson reported that the facility was in the process of hiring a psychiatrist with specialty training in addiction, using VA Central Office funding. Once on staff, the addiction psychiatrist would support plans to increase access to buprenorphine through the Emergency Department. Additionally, the VISN 22 Academic Detailer reported supporting facility efforts to expand buprenorphine access via offering individualized education on opioid use disorder treatment across clinical settings and resources for providers on becoming X-waivered practitioners.

The OIG concluded that the facility initiated actions consistent with VHA guidance to increase access to buprenorphine for patients with opioid use disorder, but staffing challenges limited expansion of buprenorphine treatment options.

⁶⁵ VHA Notice 2020-30.

⁶⁶ VHA Notice 2019-18. VHA Notice 2020-30.

Related Concern: Substance Use Disorder Program Staffing Challenges

During interviews with the OIG, service leaders and multiple staff acknowledged staffing challenges affecting the facility's Substance Use Disorder program and plans for expanding buprenorphine treatment in other clinical areas.

The Substance Use Disorder program's approved staffing level included three full-time equivalent (FTE) employee prescribing provider positions that had been filled by a combination of one full-time and one part-time psychiatrist and one full-time and one part-time nurse practitioner, with management of buprenorphine treatment being a primary component of those providers' roles.⁶⁷ A provider retirement in August 2020 reduced the program's prescribing provider staffing to two FTE positions, and the position had not been refilled at the time of the OIG's inspection.⁶⁸ Subsequent staff departures between June and September 2021 resulted in the loss of the remaining three prescribing providers.⁶⁹

Service leaders developed temporary plans for coverage, detailing three X-waivered providers from other clinical areas on a part-time basis to keep the program operational. Coverage by the detailed providers resulted in approximately 1.25 FTE prescribing providers availability for the program. Overlaying the Substance Use Disorder program's staffing shortage, prescribing providers shared concerns that implementation of the phased treatment protocol as detailed in the buprenorphine SOP would require increased frequency of visits, which was not possible with current staffing levels. Additionally, attrition of non-prescriber program staff reduced treatment team resources and reportedly caused a shortage of therapists resulting in suspension of some of the program's therapy services.

During interviews, the OIG learned that, in addition to core Substance Use Disorder program staffing shortages, the program had been without a permanent leader for approximately three years, until August 2021, when a newly created Behavioral Health Service position of Section Chief of Outpatient Specialty Services (section chief) was implemented and assumed supervisory responsibility for the program. The section chief indicated understanding from facility leaders that increasing staffing levels in the Substance Use Disorder program was a high priority. The

⁶⁷ Congressional Research Service, "Federal Workforce Statistics Sources: OPM and OMB," updated June 24, 2021. Full time equivalent (FTE) is a metric that uses to the total number of hours worked, instead of the number of employees, to describe staffing. A full-time employee counts as 1.0 FTE, while a part-time employee counts as a fraction of 1.0 FTE based on the average number of hours worked.

⁶⁸ The facility has been unsuccessful in recruiting a replacement for the vacant position. Recruitment efforts were ongoing.

⁶⁹ A 0.5 FTE Substance Use Disorder prescribing provider retired in June 2021. A second 0.5 FTE Substance Use Disorder prescribing provider retired in July 2021. The final 1.0 FTE Substance Use Disorder prescribing provider was absent on extended leave beginning in September 2021 and reported plans to retire in December 2021 at the conclusion of that extended leave period.

section chief reported that a request for prescribing provider staffing for the program was submitted to the facility's Resource Management Board in September 2021. The staffing request detailed hiring to fill two vacant FTE, while noting that one FTE position was not yet eligible for backfill until the provider, who went on extended leave in September 2021, officially retired in December 2021. In addition to backfilling the vacant positions, the request provided justification for an additional FTE prescribing provider, and also noted that a request for an additional FTE registered nurse position would be submitted separately.

Mental health provider shortages and hiring delays were identified in a prior OIG report as a factor that negatively affected access and contributed to delays in outpatient mental health care at the facility.⁷⁰ Additionally, OIG reports detailing VHA occupational staffing shortages for 2018, 2019, 2020, and 2021 indicated that the facility consistently identified psychiatry as a severe shortage occupation.⁷¹

The Chief of Staff acknowledged challenges for addressing the identified staffing issues, noting the need for staff with appropriate training in substance use disorders, and specifically the difficulty of recruiting physicians with addiction medicine training. The Chief of Staff reported that recruitment and relocation incentives were available to support hiring efforts for positions that were challenging to fill, but also noted a shortage of psychiatrists in the state resulted in competition for available providers. The Chief of Staff indicated corresponding efforts to address staffing needs via other advanced practice providers, including a nurse practitioner and physician assistant with the necessary training in treatment of substance use disorders.

The OIG determined that the facility leaders initiated actions to address the staffing vacancies and that ongoing review of prescriber staffing levels in accordance with the Substance Use Disorder program's needs and plans for expanding buprenorphine treatment in other clinical areas was warranted.

4. Facility Leaders' Response to the Substance Use Disorder Provider's Concerns

The OIG did not substantiate that facility leaders failed to respond to a Substance Use Disorder provider's report of patient safety concerns associated with facility policy and procedures related to buprenorphine for patients with opioid use disorder. However, the OIG acknowledged that

⁷⁰ VA OIG, [Concerns with Access and Delays in Outpatient Mental Health Care at the New Mexico VA Health Care System](#), Report No. 17-05572-170, July 23, 2019.

⁷¹ VA OIG, [OIG Determination of Veterans Health Administration's Occupational Staffing Shortages Fiscal Year 2021](#), Report No. 21-01357-271, September 28, 2021; VA OIG, [OIG Determination of Veterans Health Administration's Occupational Staffing Shortages Fiscal Year 2020](#), Report No. 20-01249-259, September 23, 2020; VA Office of Inspector General, [OIG Determination of Veterans Health Administration's Occupational Staffing Shortages FY 2019](#), Report No. 19-00346-241, September 30, 2019; VA OIG, [OIG Determination of Veterans Health Administration's Occupational Staffing Shortages FY 2018](#), Report No. 18-01693-196, June 14, 2018.

actions taken by leaders did not fully address the provider's reported concerns about pharmacy practices for buprenorphine early refill orders.

According to VHA policy, facility leaders may take actions including management reviews for quality management purposes.⁷²

In response to the Substance Use Disorder provider's reported concerns, the former Chief of Psychiatry reported discussing the issues with the provider, and the Facility Associate Director requested a VISN review of pharmacists' practices related to buprenorphine. Following the Facility Associate Director's request, the VISN 22 Academic Detailer, a doctor of pharmacy, completed a review of pharmacists' practices.⁷³ The OIG found that the VISN's review included recommendations, but did not require the facility to initiate action or respond to the recommendations.

In an interview with the OIG, the former Chief of Psychiatry reported having met with the Substance Use Disorder provider on several occasions. During these meetings, the two discussed the provider's concerns and interactions with pharmacy, as well as pharmacy and provider responsibilities for medication orders. Facility policy requires that prior to verifying a medication order, pharmacists are responsible for reviewing each medication for appropriateness and completeness, and discussing and clarifying concerns, issues, or questions with the prescriber to ensure the safe, appropriate, and legal use of medication.⁷⁴ The former Chief of Psychiatry acknowledged that despite multiple efforts to address the provider's concerns, tensions between the Substance Use Disorder provider and pharmacists remained.

The OIG found that the Facility Associate Director informed the Substance Use Disorder provider of requesting an external pharmacy team review and advised that an SOP was needed at the facility. The facility enacted the buprenorphine SOP in July 2021.⁷⁵ The OIG identified a need to expand communication between prescribing providers, pharmacists, and patients and noted communication should apply to all early controlled substance refills and not be limited to lost medications only.⁷⁶

The OIG found that the facility response did not address the Substance Use Disorder provider's concerns that the pharmacy practice of disallowing buprenorphine early refills did not support evidenced-based practice from a harm reduction model, interfered with a prescribing provider's

⁷² VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

⁷³ Because the VISN considers the review to be a Quality Management activity under VHA Directive 1320, and protected under 38 U.S.C. § 5705, the OIG has not included any substantive reference to the VISN review in this published report.

⁷⁴ Medical Center Policy 119-54, *Outpatient Medication Orders*, November 2020.

⁷⁵ Facility SOP ACS CARA-01.

⁷⁶ Medical Center Policy 119-1, *Notification of Loss of Controlled Substances*, October 2020.

ability to implement individualized patient-centered treatment, and placed patients at increased risk for adverse clinical outcomes.

Conclusion

The OIG substantiated that pharmacists declined early refills of buprenorphine despite prescribing providers' documented clinical rationales, which increased patients' risk for adverse clinical outcomes associated with interruption of buprenorphine treatment. The OIG also substantiated that justification for the practice of declining early refills was incorrectly based on a facility policy that was not applicable to the use of buprenorphine for treatment of opioid use disorder. Neither VHA nor the facility's applicable policy on controlled substances prohibited early refills of Schedule III medications, including buprenorphine.

The OIG determined that facility pharmacists' routine practice was to decline early refills of buprenorphine. Pharmacists' prohibition of early refills was intended to guard against misuse or diversion of opioids. Pharmacists' practices of prohibiting early refills resulted in prescribing providers negotiating with pharmacists or involving Opioid Safety Committee staff for consultation to obtain early refills of buprenorphine or spending extra time altering treatment plans to provide comfort medications for withdrawal symptoms until the next refill date permitted by the pharmacy.

The OIG determined that pharmacy practice made no delineation between prohibition of early refills of partial opioid agonists for opioid use disorder and full opioid agonists for pain, despite the different indications for each medications' use and associated risks. Pharmacy practice of prohibiting early refills of buprenorphine for opioid use disorder, justified under the facility policy that forbids early refills of opioids for pain, was more restrictive than what was allowed by VHA and facility policy guidance applicable to Schedule III controlled substances and inconsistent with guidelines for evidence-based treatment of opioid use disorder.⁷⁷ The OIG concluded that pharmacists' practices prohibiting early refills interfered with timely access to buprenorphine and could place patients at increased risk for adverse clinical outcomes. None of the patients reviewed by the OIG experienced overdose or death as a result of interrupted buprenorphine treatment. However, one patient experienced withdrawal symptoms with treatment interruption and another patient experienced increased cravings, though neither patient reported relapsing.

During interviews with the OIG, providers and pharmacy staff reported varying understandings of facility policy related to early refills of buprenorphine, and indicated that pharmacy buprenorphine approval practices had changed over time. The OIG determined that VHA and the

⁷⁷ Facility Memorandum 115-5, *Opioid Analgesia For Chronic Non-Malignant Pain*, December, 2018. VHA Directive 1108.01(1), *Controlled Substances Management*, May 1, 2019, amended December 2, 2019. Medical Center Policy 119-21, *Controlled Substances for Outpatient Use*, January 28, 2020.

applicable facility policy, as written, did not prohibit early refills for Schedule III medications such as buprenorphine, thus allowing providers prescriptive authority to approve early refills of buprenorphine when clinically appropriate.⁷⁸ The OIG's inspection findings emphasized the importance that facility pharmacists' practices change to align with the applicable policy.

The OIG did not substantiate that the facility's Opioid Safety Committee Chairperson interfered with prescribing providers' practices regarding buprenorphine orders for patients with opioid use disorder. The OIG determined that the Opioid Safety Committee Chairperson's involvement with buprenorphine treatment was within the scope of an Opioid Safety Committee member's responsibilities. Opioid Safety Committee members' responsibilities include the deployment of risk mitigation strategies for patients with opioid use disorder. However, based on information provided during interviews, the OIG found that some prescribing providers were unaware of activities associated with the Opioid Safety Committee's role, leading the providers to view the Opioid Safety Committee's involvement as interference.

The OIG substantiated that an Opioid Safety Committee Pharmacist placed standing orders for urine drug screening for buprenorphine patients, without coordinating with patients' prescribing providers or obtaining informed consent from patients. However, the OIG determined that the Opioid Safety Committee Pharmacist acted within the scope of practice, entered standing orders for urine drug screening as part of the facility's implementation of VHA guidance associated with COVID-19 mitigation strategies, and was not required to obtain a separate consent for urine drug screening.

The OIG did not substantiate that the facility's SOP on buprenorphine treatment for patients with opioid use disorder, enacted in July 2021, was inconsistent with VHA guidance on buprenorphine treatment for patients with opioid use disorder. The OIG was unable to determine whether implementation of the buprenorphine SOP would reduce access to buprenorphine for patients with opioid use disorder, as the SOP was not fully implemented at the time of the OIG's review. Interviews of prescribing providers working in the outpatient Substance Use Disorder program supported that implementation of the phased treatment protocol as detailed in the buprenorphine SOP would require increased frequency of visits, and current staffing levels were insufficient to provide more frequent visits.

The OIG did not substantiate the allegation that facility practices were inconsistent with VHA guidance on increasing access to buprenorphine for patients with opioid use disorder. The facility's Chief of Staff reported that the facility provided buprenorphine treatment for patients with opioid use disorder in the Substance Use Disorder program, pain management clinic, inpatient and residential mental health units, and on a limited basis in some primary care clinics. Facility leaders, in coordination with the Opioid Safety Committee, developed plans for expanding access to buprenorphine in emergency department and primary care settings,

⁷⁸ VHA Directive 1108.01(1). Medical Center Policy 119-21.

consistent with VHA guidance. However, expansion of buprenorphine treatment was limited by availability of X-waivered providers, as well as the need for additional staffing resources to support access for substance use disorder treatment referrals and development of clearly defined processes to ensure continuity of care across treatment settings.

The OIG identified a related concern regarding staffing challenges that affected the Substance Use Disorder program and plans for expanding buprenorphine treatment in other clinical areas. The OIG determined that facility leaders initiated actions to address the staffing vacancies, and that ongoing review of prescriber staffing levels in accordance with the Substance Use Disorder program's needs and plans for expanding buprenorphine treatment in other clinical areas, was warranted.

The OIG did not substantiate that facility leaders failed to respond to a Substance Use Disorder provider's report of patient safety concerns associated with facility policy and procedures related to buprenorphine for patients with opioid use disorder. The former Chief of Psychiatry reported discussing the issues with the provider and the Facility Associate Director requested a VISN review of pharmacists' practices related to buprenorphine. However, the OIG found that actions taken by leaders did not fully address the reported concerns. The OIG further found that the facility response failed to address the Substance Use Disorder provider's concerns that the pharmacy practice of disallowing early buprenorphine refills did not support evidenced-based practice from a harm reduction model, interfered with a provider's ability to implement individualized patient-centered treatment, and placed patients at increased risk for adverse clinical outcomes.

Recommendations 1–5

1. The New Mexico VA Health Care System Director ensures that facility practice is consistent with Veterans Health Administration and facility policy applicable to early refills of buprenorphine for patients receiving opioid agonist therapy for opioid use disorder and is consistent with evidence-based treatment and prescribing providers' clinical rationale, ensures all relevant staff are educated on the policy, and monitors for compliance with policy.
2. The New Mexico VA Health Care System Director ensures communication between provider, pharmacist, and patient for early medication refills and monitors for compliance with Veterans Health Administration policy.
3. The New Mexico VA Health Care System Director clarifies the roles and responsibilities of the Opioid Safety Committee as related to buprenorphine treatment for patients with opioid use disorder, and ensures relevant staff are educated regarding the Opioid Safety Committee's role in buprenorphine treatment.

4. The New Mexico VA Health Care System Director reviews buprenorphine prescribing provider concerns regarding the *Opioid Agonist Therapy (Buprenorphine) for Opioid Use Disorder* standard operating procedure and ensures the planned revision and implementation of the standard operating procedure is consistent with evidence-based treatment and includes language that specifies allowance for clinical judgment and a patient-centered care approach.
5. The New Mexico VA Health Care System Director reviews prescribing provider staffing levels in accordance with the Substance Use Disorder program's needs and facility's plans for expanding buprenorphine treatment in other clinical areas, and develops an action plan to address recommendations, if any, from the staffing level review.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 1, 2022

From: Network Director VA Desert Pacific Healthcare Network (10N22)

Subj: Healthcare Inspection—Pharmacists' Practices Delayed Buprenorphine Refills for Patients with Opioid Use Disorder at the New Mexico VA Health Care System in Albuquerque

To: Director, Office of Healthcare Inspections (54HL09)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. I have reviewed and concur with the response provided by the Medical Center Director of the New Mexico VA Health Care system regarding the OIG's report, Pharmacists' Practices Delayed Buprenorphine Refills for Patients with Opioid Use Disorder at the New Mexico VA Health Care System in Albuquerque. VA remains committed to honoring our Nation's Veterans by delivering safe and exceptional health care.
2. I would like to thank the Office of Inspector General for their thorough review of this case and recommendations on process improvements. VISN 22 appreciates the opportunity to partner with the OIG on our high reliability journey. We remain steadfast in our commitment to zero harm.
3. If you have additional questions or need further information, please contact the VISN 22 Quality Management Officer.

(Original signed by:)

Michael W. Fisher
Network Director
VA Desert Pacific Healthcare Network

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: May 27, 2022

From: Medical Center Director, New Mexico VA Health Care System (501/00)

Subj: Healthcare Inspection—Pharmacists' Practices Delayed Buprenorphine Refills for Patients with Opioid Use Disorder at the New Mexico VA Health Care System in Albuquerque

To: VA Desert Pacific Healthcare Network Director, VISN 22 (10N22)

1. The New Mexico VA Health Care System appreciates the Office of the Inspector General's review of the Pharmacist's practices delayed Buprenorphine refills for patient with Opioid Use Disorder. The New Mexico VA Health Care System has already worked on many of the recommendations based on the understanding of the issues at the time of the site visit.
2. I have reviewed and concur with the findings, recommendations and action plan as submitted. The action plans will be tracked through to completion and sustainment.
3. If you have any questions or require additional information, please contact Chief, Quality and Patient Safety (QPS).

(Original signed by:)

Robert McKenrick
Medical Center Director

Facility Director Response

Recommendation 1

The New Mexico VA Health Care System Director ensures that facility practice is consistent with Veterans Health Administration and facility policy applicable to early refills of buprenorphine for patients receiving opioid agonist therapy for opioid use disorder and is consistent with evidence-based treatment and prescribing providers' clinical rationale, ensures all relevant staff are educated on the policy, and monitors for compliance with policy.

Concur.

Target date for completion: February 1, 2023

Director Comments

The New Mexico VA Health Care System Director reviewed facility practice, revised the ACS CARA-01, Opioid Agonist Therapy (Buprenorphine) for Opioid Use Disorder SOP, and educated all relevant staff. A Controlled Substance Early Refill Note has been developed in computerized patient record system (CPRS) and will be implemented that allows providers to provide clinical justification for early fills and allows the Opioid Safety Committee and other relevant parties to review trends in early fills to ensure utilization of risk mitigation strategies for all controlled medications and substances with potential for misuse. This note has been added to the SOP as a means to continue to engage in required risk mitigation strategies and applicable to a harm reduction approach to management of opioid use disorder with partial agonist medication. Compliance will be monitored until there is greater than 90% compliance for 6 months.

Recommendation 2

The New Mexico VA Health Care System Director ensures communication between provider, pharmacist, and patient for early medication refills and monitors for compliance with Veterans Health Administration policy.

Concur.

Target date for completion: December 31, 2022

Director Comments

The New Mexico VA Health Care System Director ensures communication between provider, pharmacist, and patient for early medication refills through the use of the Controlled Substance Early Fill note. The note allows providers to document clinical rationale for early fill approval and allows pharmacy to review prior to dispensing. This note will be used to track and trend data on early fills and prompt review by the Opioid Safety Committee for multiple early fills as a

means to ensure patients are treated in accordance with evidence-based care for medications for opioid use disorder. This note will also allow the provider to document the counseling given to the patient and any change in treatment phase or other risk mitigation strategy employed. Audits for compliance will be monitored until there is greater than 90% compliance for 6 consecutive months.

Recommendation 3

The New Mexico VA Health Care System Director clarifies the roles and responsibilities of the Opioid Safety Committee as related to buprenorphine treatment for patients with opioid use disorder, and ensures relevant staff are educated regarding the Opioid Safety Committee's role in buprenorphine treatment.

Concur.

Target date for completion: June 30, 2022

Director Comments

The Opioid Safety Committee's role as related to buprenorphine treatment for patients with opioid use disorder has been clarified in the revised Standard Operating Procedure, ACS CARA-01, Opioid Agonist Therapy (Buprenorphine) for Opioid Use Disorder. The SOP includes responsibility related to ongoing and periodic (as needed) reviews of early fill data, risk mitigation strategies etc. 100% of all relevant staff have been educated.

Recommendation 4

The New Mexico VA Health Care System Director reviews buprenorphine prescribing provider concerns regarding the *Opioid Agonist Therapy (Buprenorphine) for Opioid Use Disorder* standard operating procedure and ensures the planned revision and implementation of the standard operating procedure is consistent with evidence-based treatment and includes language that specifies allowance for clinical judgment and a patient-centered care approach.

Concur.

Target date for completion: June 30, 2022

Director Comments

The New Mexico VA Health Care System Director reviewed buprenorphine prescribing provider concerns regarding the *Opioid Agonist Therapy (Buprenorphine) for Opioid Use Disorder* standard operating procedure and has made revisions to the ACS CARA-01, Opioid Agonist Therapy (Buprenorphine) for Opioid Use Disorder SOP that are consistent with evidence based-treatment and includes language that specifies allowance for clinical judgment and a patient-centered care approach. The ACS CARA-01, Opioid Agonist Therapy (Buprenorphine) for

Opioid Use Disorder SOP is based on evidence-based treatment protocols outlined by Substance Abuse Mental health Services and in accord with other facilities in VISN 22.

Recommendation 5

The New Mexico VA Health Care System Director reviews prescribing provider staffing levels in accordance with the Substance Use Disorder program's needs and facility's plans for expanding buprenorphine treatment in other clinical areas, and develops an action plan to address recommendations, if any, from the staffing level review.

Concur.

Target date for completion: May 27, 2022, Request Closure

Director Comments

The New Mexico VA Health Care System Director reviewed prescribing provider staffing levels and has approved six additional personnel for the Substance Use Disorder clinic and other areas of Behavioral Health Care Line (BHCL) specifically for addiction and increased the number of x-waivered providers. Emergency Medicine services has one x-waivered provider at present with several others in process. The New Mexico VA Health Care System is also training hospitalist providers to increase inductions for inpatient Veterans.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Glossary

To go back, press "alt" and "left arrow" keys.

academic detailer. A trained clinician who provides education to other clinicians on the use of evidence-based decision making.⁷⁹

agonist. "A drug or other chemical agent that binds to a particular receptor and produces a physiological effect, typically one similar to that of the body's own neurotransmitter at that receptor."⁸⁰

antagonist. "A drug or other chemical agent that inhibits the action of another substance." An antagonist may "reduce the effects of the substance by binding to the same receptor without stimulating it, which decreases the number of available receptors (pharmacological antagonism)" or "may combine with the substance to alter and thus inactivate it (chemical antagonism)."⁸¹

Comprehensive Addiction and Recovery Act. Public Law enacted by 114th Congress which authorizes the Attorney General and Secretary of Health and Human Services to address the prescription opioid abuse and heroin crisis.⁸²

harm reduction. An approach to treatment that seeks to reduce the harmful consequences of substance use disorders, including morbidity and mortality. Harm reduction approaches target reducing risky behaviors and mitigating risks with patients for whom abstinence is not a self-identified goal or is not immediately feasible.⁸³

methadone. A "long-acting full opioid agonist" approved by the Food and Drug Administration for the treatment of opioid use disorder. Methadone is a Schedule II controlled drug.⁸⁴

morbidity. A diseased state or symptoms.⁸⁵

⁷⁹ VA Pharmacy Benefits Management Academic Detailing Service, *VA Academic Detailing Implementation Guide*, December 2016.

⁸⁰ American Psychological Association Dictionary of Psychology, *Agonist*, accessed on November 16, 2021, <https://dictionary.apa.org/agonist>.

⁸¹ American Psychological Association Dictionary of Psychology, *Antagonist*, accessed on November 16, 2021, <https://dictionary.apa.org/antagonist>.

⁸² Comprehensive Addiction and Recovery Act of 2016, Pub. L. 114-198, 130 Stat. 695 (2016).

⁸³ Rural Health Information Hub, *Models to Reduce the Harmful Consequences of Substance Use Disorder*, accessed on November 4, 2021, <https://www.ruralhealthinfo.org/toolkits/substance-abuse/2/harm-reduction>.

⁸⁴ "Methadone," SAMHSA website, accessed on January 20, 2022, <https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/methadone>.

⁸⁵ Merriam-Webster Medical Dictionary, *Morbidity*, accessed on November 16, 2021, <https://www.merriam-webster.com/dictionary/morbidity#medicalDictionary>.

partial agonist. A drug or other chemical agent that binds to a particular receptor and stimulates “only somewhat to produce the same physiological effect as the natural neurotransmitter but to a lesser degree.”⁸⁶

receptor. Part of a cell “that binds molecules of a particular neurotransmitter, hormone, drug, or the like and initiates a particular response within the neuron.”⁸⁷

respiratory depression. Slow, ineffective breathing, resulting in too little oxygen availability and increased concentration of carbon dioxide in the blood.⁸⁸

schedule III. Schedule III drugs are defined as “drugs with a moderate to low potential for physical and psychological dependence” and have less potential for abuse than Schedule I or II drugs.⁸⁹

standing order. A written authorization allowing members of a health care team to complete certain clinical tasks without first obtaining a physician order.⁹⁰

state prescription drug monitoring program. “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.”⁹¹

urine drug screen. Laboratory testing used to “monitor compliance with prescribed therapy and detect the use of nonprescribed and illicit substances.”⁹²

X-waivered provider. A provider who is certified to prescribe buprenorphine. An X-waivered provider has met the qualifications set by the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration and obtained a waiver from the U.S. Drug Enforcement Administration to prescribe buprenorphine.⁹³

⁸⁶ American Psychological Association Dictionary of Psychology, *Agonist*, accessed on November 16, 2021, <https://dictionary.apa.org/partial-agonist>.

⁸⁷ American Psychological Association Dictionary of Psychology, *Neuroreceptor*, accessed on November 23, 2021, <https://dictionary.apa.org/neuroreceptor>.

⁸⁸ Khanna et.al “Respiratory depression in low acuity hospital settings – Seeking answers from the PRODIGY trial,” *Journal of Critical Care* 47 (2018): 80-87.

⁸⁹ United States Drug Enforcement Administration, *Drug Scheduling*, accessed November 3, 2021, <https://www.dea.gov/drug-information/drug-scheduling>.

⁹⁰ Jason Leubner and Susan Wild, “Developing Standing Orders to Health Your Team Work to the Highest Level,” *Family Practice Management* 25, no. 3 (May/June 2018): 13-16.

⁹¹ VHA Directive 1306(1).

⁹² Neelima Kale, “Urine Drug Tests: Ordering and Interpretation,” *American Family Physician* 99, no. 1 (January 1, 2019): 33-39.

⁹³ “Become a Buprenorphine Waivered Practitioner,” SAMHSA website, accessed November 4, 2021, <https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner>.

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