



DEPARTMENT OF VETERANS AFFAIRS  
**OFFICE OF INSPECTOR GENERAL**

*Office of Audits and Evaluations*

VETERANS HEALTH ADMINISTRATION

State Prescription Drug  
Monitoring Programs Need  
Increased Use and Oversight

AUDIT

REPORT #18-02830-164

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## Executive Summary

Controlled substances, such as opioids, may improve patient health, function, and quality of life, but can also present serious health risks when clinicians are not aware of all the controlled substances their patients have been prescribed or are using—sometimes misusing.<sup>1</sup> In recent years, veterans have been hit particularly hard by the opioid crisis and are more likely to die from opioid overdoses than civilians. A Centers for Disease Control and Prevention (CDC) evaluation found that most fatal overdoses were associated with patients who received opioids from multiple prescribers or with patients who received high total daily opioid dosages. In addition, the concurrent use of benzodiazepines and opioids puts patients at risk of a fatal overdose.<sup>2</sup>

Prior OIG and Government Accountability Office (GAO) reviews found VA clinicians do not consistently query state prescription drug monitoring program (PDMP) databases and use the information to coordinate and manage patients' care. Because using PDMP databases is essential to VA's ongoing efforts to combat veteran opioid abuse, overmedication, and deaths, the OIG conducted this audit to determine whether VA clinicians effectively used state-operated PDMP database information to manage and coordinate the care of patients prescribed opioids.

VA recognizes the benefit of its clinicians having complete information about their patients' controlled substance prescriptions. It requires VA clinicians to complete a PDMP query when they prescribe patients opioids or other controlled substances if a query has not been completed within the past year. Clinicians who prescribe veterans opioids can query PDMP databases for valuable information about the controlled substances their patients have received outside of VA, including the names and dosages of the controlled substances, dates the controlled substances were dispensed, the names of the prescribing clinicians, and in some cases the active morphine-equivalent daily dose.<sup>3</sup> Clinicians can use this information to reduce the risk of opioid overdose among veterans.

## What the Audit Found

During the 12-month period from April 1, 2017, through March 31, 2018, the audit team estimated that clinicians did not annually check PDMP databases for 567,000 of the 779,000 VA

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<sup>1</sup> A controlled substance is a drug or other substance that is tightly controlled by the government because it may cause addiction.

<sup>2</sup> Deborah Dowell et al., "CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016," *Morbidity and Mortality Weekly Report Recommendations and Reports* 2016; 65 (March 2016): 28-29; Benzodiazepines are a class of drugs that produce central nervous system depression and are most commonly used to treat anxiety and insomnia.

<sup>3</sup> The morphine equivalent daily dose is a calculation of a patient's opioid intake.

patients (73 percent) prescribed opioids.<sup>4</sup> Furthermore, VA clinicians should have considered whether quarterly or more frequent PDMP database queries were needed for 266,000 of the patients, as recommended by the CDC, who were on long-term opioid therapy for chronic pain. The audit team estimated that 107,000 of the 567,000 VA patients prescribed opioids (19 percent) were at risk of care coordination and management problems because VA clinicians did not perform the required queries and were unaware of controlled substance prescriptions the patients obtained from non-VA clinicians and pharmacies.

The audit team applied GAO standards to assess the implementation of the PDMP requirements in Veterans Health Administration (VHA) Directive 1306, *Querying State Prescription Drug Monitoring Programs*. After applying GAO's standards and finding that VHA clinicians did not complete a majority of the required PDMP queries, the OIG concluded that VHA lacked an effective internal control system to monitor and evaluate the performance of PDMP queries as part of the Opioid Safety Initiative.<sup>5</sup>

The internal control weaknesses at facilities lay in communication, training, and local policies that deviated from the national one. VA clinicians did not perform required queries because VHA did not effectively communicate its policy on PDMP queries to staff. While VHA provided national pain management training that mentioned PDMP queries should be conducted, it did not clearly inform its clinicians that VHA policy requires the queries. VHA officials believed the training was comprehensive at the time but acknowledged it needed to be updated to clearly reflect the requirement. Staff at the six reviewed VA medical facilities also were not always aware of local or VA policy requirements on using PDMP databases, due to ineffective communication and training at the medical facilities. Furthermore, some medical facilities established local policies that were less stringent than the national policy, and the responsible Veterans Integrated Service Network (VISN) and medical facility directors did not review the policies to ensure they complied with VHA's PDMP policy.

VHA also did not address significant developments after it issued VHA Directive 1306. VHA did not update the directive to include a discussion of the CDC's recommendation that high-risk patients on long-term opioid therapy for chronic pain receive at least quarterly or more frequent PDMP queries based on their risk factors, even though it was included in a February 2017 update to the *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain* (Clinical Practice Guideline).<sup>6</sup> VHA officials stated they did not update the directive to discuss the

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<sup>4</sup> The audit team excluded patients from the state of Missouri and U.S. territories which did not have operational PDMP databases during the review period and adjusted the population of 825,000 VA patients prescribed opioids to 779,000 patients for its projections.

<sup>5</sup> *The Comprehensive Addiction and Recovery Act of 2016*, Pub. L. No. 114-198, Stat. 696 (2016) required the expansion of the Opioid Safety Initiative to all medical facilities.

<sup>6</sup> The Opioid Therapy for Chronic Pain Work Group, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, May 2017.

Clinical Practice Guideline because the guideline is not a requirement. In addition, VHA did not revise the directive to address the increased patient care coordination risks when VA pharmacies fill controlled substance prescriptions issued by non-VA care clinicians. An official from the Office of Primary Care, the office that developed the directive, explained it was expressly intended for VA prescribers, not dispensers. Therefore, the directive did not address whether VA pharmacists or clinicians are responsible for ensuring patients have required PDMP queries when non-VA prescriptions for controlled substances are filled at VA pharmacies.

Finally, the OIG found inadequate national VHA oversight and monitoring led to insufficient local monitoring and accountability at VA medical facilities. VISNs did not ensure VA medical facility leaders were aware of their clinicians' low PDMP query rates and did not ensure the implementation of local controls and procedures, such as clinical reminders, to improve the completion of PDMP queries. This lack of effective national and local oversight and monitoring occurred because VHA officials did not always consider PDMP queries a high priority as they implemented the Opioid Safety Initiative and focused on the reduction of VHA-issued opioid prescriptions.

## What the OIG Recommended

The OIG made eight recommendations to the under secretary for health:<sup>7</sup>

1. Develop national processes to oversee medical facility compliance with VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*, and coordinate the possible automated information technology solutions and inter-office and -disciplinary communications necessary to improve prescription drug monitoring program monitoring and usage in Veterans Health Administration.
2. Update the Pain Management and Opioid Safety training course to specifically address VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*, query requirements and recommendations.
3. Ensure VA clinicians who prescribe opioids take the Pain Management and Opioid Safety training once, with annual refresher training.
4. Add an addendum to VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*, that references the *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain* and ensure VA clinicians are educated and receive annual training on the Clinical Practice Guideline, including the Centers for Disease Control and

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<sup>7</sup> Recommendations directed to the under secretary for health were submitted to the executive in charge, who has the authority to perform the functions and duties of the under secretary for health. Additionally, the recommendations apply to the individual within VHA who assumes the responsibilities for the executive in charge, whether in an acting or permanent position.

Prevention's recommended frequency for prescription drug monitoring program queries based on the patients' risk factors.

5. Direct Veterans Integrated Service Networks and their VA medical facilities to ensure local policies are consistent with VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*.
6. Develop automated information technology solutions to facilitate clinicians' access to prescription drug monitoring program query information and reinforce the need to complete minimum annual VA-required prescription drug monitoring program queries.
7. Ensure non-VA care clinicians are in good standing and have a current state medical license that requires adherence to their state's prescription drug monitoring program query requirements; adhere to the Veterans Affairs Opioid Safety Initiative Guidelines, including guidelines for prescription drug monitoring program queries; and are monitored to ensure appropriate corrective actions are taken if their prescribing practices are found to be inconsistent with *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.
8. Ensure Veterans Integrated Service Networks implement an effective prescription drug monitoring program oversight process that includes the review of compliance rates with medical facility directors.

## Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with Recommendations 1–5, 7, and 8, and submitted acceptable corrective action plans for all recommendations. The VA Office of Information and Technology, through the executive in charge, concurred with Recommendation 6 and submitted an acceptable corrective action plan. The OIG will monitor implementation of planned actions and will close the recommendations when VA provides sufficient evidence demonstrating progress in addressing the intent of the recommendations and the issues identified.



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## Abbreviations

CDC	Centers for Disease Control and Prevention
DEA	Drug Enforcement Administration
DoD	Department of Defense
DUSHOM	deputy under secretary for health for operations and management
FY	fiscal year
GAO	Government Accountability Office
HCS	health care system
HHS	Department of Health and Human Services
OIG	Office of Inspector General
PDMP	Prescription Drug Monitoring Program
VAMC	Veterans Affairs Medical Center
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network





## Introduction

The OIG conducted this audit to determine whether VA clinicians effectively used state-operated prescription drug monitoring program (PDMP) database information to manage and coordinate the care of patients prescribed opioids in VA, as well as controlled substances in the community. Specifically, this audit evaluated the extent to which

- VA clinicians completed required PDMP queries;
- VA clinicians' lack of awareness of the controlled substances obtained from non-VA clinicians and pharmacies affected risks to their patients' safety, as well as care management and coordination; and
- National and local governance issues affected the rates of PDMP queries.

Although the specific reporting requirements differ by state, pharmacies that dispense controlled substances are generally required to transmit information to PDMPs about the prescriber, the controlled substance dispensed (e.g., dosage, quantity, and date), and the dispensing location. Some PDMPs also calculate the active morphine-equivalent daily dose. Clinicians can then query the PDMP databases to see their patients' complete controlled substance prescription history and use this information to enhance their prescribing decisions, coordinate the patients' care, and educate patients about their medications. VA clinicians' use of state-operated PDMP databases is critical to VA's efforts to combat veteran opioid abuse, overmedication, and deaths.

## VA Opioid Prescriptions and Their Risks

From April 1, 2017, to March 31, 2018, VA pharmacies dispensed about 5.2 million opioid prescriptions to more than 825,000 patients, including high-risk patients who were diagnosed with opioid use disorder. VA defines opioid use disorder as a brain disease that can develop after repeated opioid use, and patients with substance use disorders are more likely to experience greater risks for opioid use disorder and overdose than patients without substance use disorders. Like other chronic diseases (e.g., hypertension or diabetes), opioid use disorder typically requires ongoing management.<sup>8</sup> An April 2011 VA-funded study found veterans were more likely than civilians to die from overdoses.<sup>9</sup> A 2019 study using VHA data found that the overall rate of opioid overdoses among veterans had increased between 2010 and 2016, but that the percentage

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<sup>8</sup> VA Pharmacy Benefits Management Academic Detailing Service, *Opioid Use Disorder: A VA Clinician's Guide to Identification and Management of Opioid Use Disorder* (2016).

<sup>9</sup> Amy Bohnert et al., "Accidental poisoning mortality among patients in the Department of Veterans Affairs Health System," *Medical Care*, 49, no. 4 (April 2011): 393–96.

of overdose deaths where veterans received VA-prescribed opioids within three months of their death had declined from 54 percent in 2010 to 26 percent in 2016.<sup>10</sup>

The Drug Enforcement Administration (DEA) uses numbered schedules to classify all controlled substances, including prescribed opioids, based on whether they have a currently accepted medical use, their relative abuse potential, and likelihood of causing dependence when abused.<sup>11</sup> The lower the schedule number, the greater the drug’s potential for abuse—Schedule I drugs have the highest potential for abuse and severe psychological or physical dependence, while Schedule V drugs have the lowest potential for abuse.<sup>12</sup> Table 1 shows the number of patients with and without opioid use disorder diagnoses and the number of opioid prescriptions they were issued, broken down by controlled substance schedule.

**Table 1. VA Opioid Prescription Data**

DEA schedules	Number of patients	Number of prescriptions
<b><i>Patients diagnosed with opioid use disorder</i></b>		
Schedule II (High risk)	69,100	442,000
Schedule III and IV (Medium risk)	47,300	280,000
Schedule V (Low risk)	1,200	1,800
<b>Total</b>	<b>118,000</b>	<b>724,000</b>
<b><i>Patients not diagnosed with opioid use disorder</i></b>		
Schedule II (High risk)	681,000	3,000,000
Schedule III and IV (Medium risk)	450,000	1,400,000
Schedule V (Low risk)	34,500	43,600
<b>Total</b>	<b>1,200,000</b>	<b>4,400,000</b>

*Source: OIG analysis of VA Corporate Data Warehouse data on VA opioid prescriptions issued from April 1, 2017, through March 31, 2018.*

*Note: Patients may be prescribed multiple opioids from different DEA schedules. Thus, patients may be counted in more than one category in the table and the sum of the patient totals will be greater than the 825,000 unique patients prescribed opioids in VA during the review period. All the numbers in this table, including the totals, have been rounded. The columns do not sum.*

<sup>10</sup> L. A. Lewei et al., “Changing trends in opioid overdose deaths and prescription opioid receipt among veterans,” *American Journal of Preventive Medicine*, published electronically May 22, 2019, accessed on June 14, 2019, <https://doi.org/10.1016/j.amepre.2019.01.016>.

<sup>11</sup> This report uses the terms “opioids” and “controlled substances” based on the context of the discussion. The audit team used opioid prescriptions issued by VA clinicians to identify its sample universe. However, VHA Directive 1306 applies to all controlled substances prescribed in VA.

<sup>12</sup> The Controlled Substances Act as codified under 21 U.S.C. § 812 defines Schedule I drugs as “drugs with no currently accepted medical use and high potential for abuse.” VA only prescribes Schedule II–V drugs.

## The Benefits of Prescription Drug Monitoring Programs

The federal government supports the use of PDMP databases to combat opioid abuse. The President's fiscal year (FY) 2018 budget request included \$22 million in the budgets of the Departments of Justice and Health and Human Services (HHS), \$12 million and \$10 million respectively, to support the operation of PDMP databases. The CDC has identified benefits when clinicians use PDMP database information to manage and coordinate patients' care, such as changes in clinicians' prescribing behaviors, patients' use of multiple clinicians, and fewer substance abuse treatment admissions.<sup>13</sup> The CDC found most fatal opioid overdoses were associated with patients who received opioids from multiple prescribers or received high total daily opioid dosages, and identified a greater risk of fatal overdoses when patients concurrently used benzodiazepines and opioids.<sup>14</sup> Subsequently, VA has committed to using PDMP database information to improve clinical care, further the national public health benefits offered by PDMPs, and reduce the risk of overdose among veterans who obtain opioid prescriptions from both VA and non-VA clinicians in the same year.

## VA Requirements and Guidelines for Completing PDMP Queries

VA clinicians are required to comply with VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*, and ensure that all patients prescribed more than a five-day supply of controlled substances such as opioids receive a PDMP query at least once a year.<sup>15</sup>

Specifically, VHA requires VA clinicians who prescribe opioids to

- Register for the PDMP in their state of practice, as permitted by state law;
- Query the PDMP before starting therapy with a controlled substance;
- Query the PDMP at least annually, or any time a query is clinically indicated;
- Query the PDMP as permitted by applicable state law and in accordance with the laws of the state in which the clinicians are licensed to practice; and
- Document the results of the PDMP in a progress note in the electronic health record.

In addition to these requirements, VA clinicians should consider guidance outlined in the *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain* (Clinical Practice

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<sup>13</sup> Centers for Disease Control and Prevention, "What States Need to Know about PDMPs," accessed on December 12, 2018, <https://www.cdc.gov/drugoverdose/pdmp/states.html>.

<sup>14</sup> Deborah Dowell et al., "CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016" (March 2016): 28–29.

<sup>15</sup> VA clinicians are not required to complete PDMP queries for hospice patients or when they issue a five-day or smaller supply of opioids under VHA Directive 1306 unless it is required by state law or local policy.

Guideline), which contains specific PDMP query recommendations for VA clinicians who are considering or are using long-term opioid therapy to treat patients for chronic pain.<sup>16</sup> The guideline recommends several strategies to reduce the risk of patients developing opioid use disorder and overdosing, including the use of PDMP queries before and during opioid therapy.

The CDC's recommendation for PDMP database queries at least quarterly is only discussed in the Clinical Practice Guideline and was not referenced in VHA Directive 1306. The directive does state that PDMP queries will help VA clinicians identify patients who receive controlled substances from multiple clinicians. Query information could prevent accidental and intentional misuse or diversion of prescribed medications and support the prevention and early treatment of substance use disorders.<sup>17</sup>

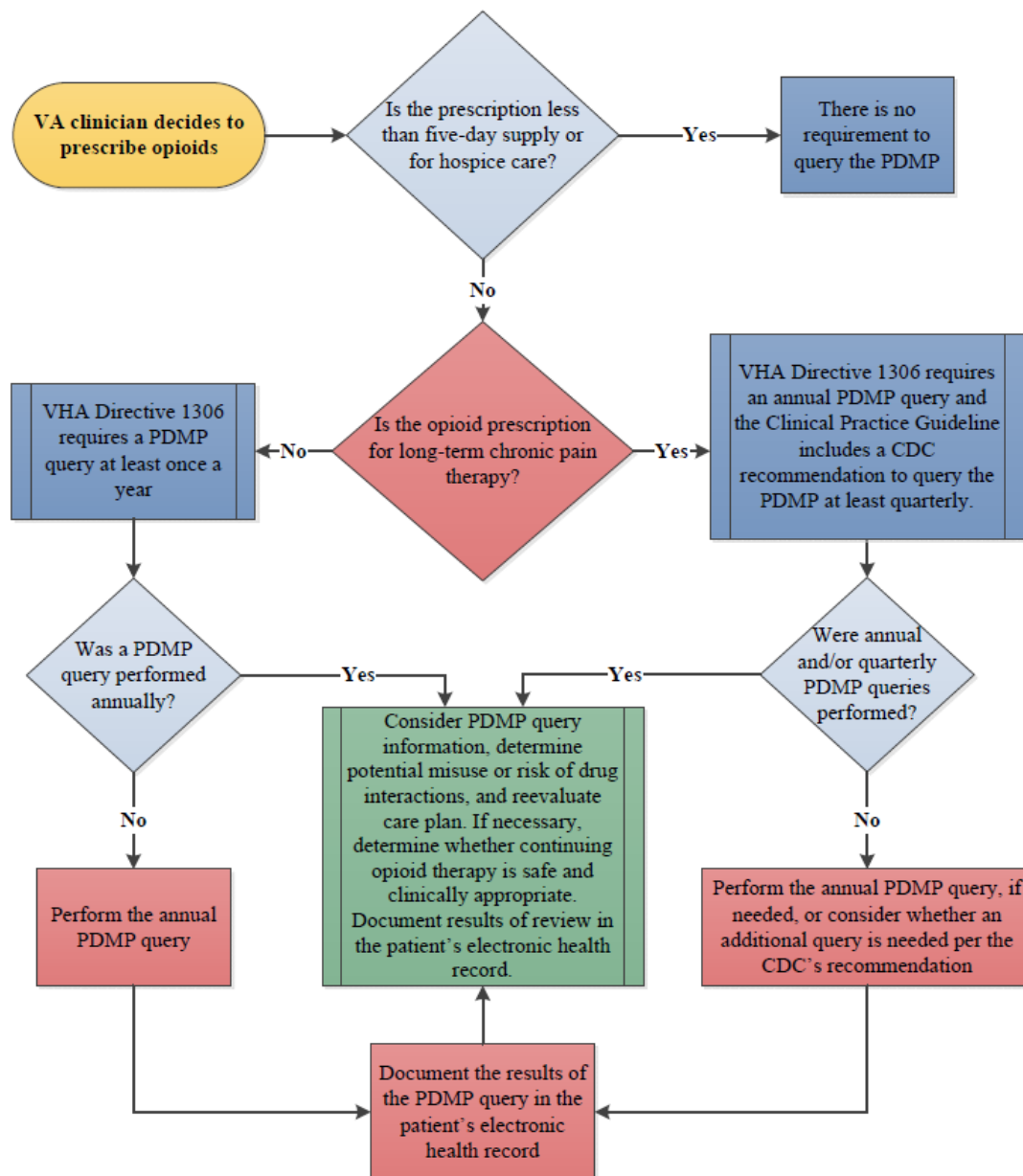
Under the directive, VA clinicians are responsible for reevaluating patient treatment plans if patients receive controlled substances from non-VA clinicians, including whether VA's continued prescription of opioids to patients is safe and clinically appropriate. They should also determine whether patients prefer to receive the controlled substance from their non-VA clinicians, which can include contacting the patients' non-VA clinicians to further coordinate care.<sup>18</sup> Figure 1 demonstrates the general PDMP query and care plan evaluation steps that VA clinicians should follow when they issue or renew VA patients' opioid prescriptions.

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<sup>16</sup> VA/DoD Clinical Practice Guideline, 2017; VHA Directive 1005, *Informed Consent for Long-term Opioid Therapy for Pain*, May 6, 2014, defines long-term opioid therapy as the medically indicated use of opioids on a daily or intermittent basis for 90 or more calendar days to treat non-cancer pain.

<sup>17</sup> Diversion is the intentional transfer of controlled substances from legal sources to the illicit marketplace.

<sup>18</sup> VHA Directive 1605.01, *Privacy and Release of Information*, August 31, 2016, allows VHA to disclose individually-identifiable health information to non-VA health care clinicians without the prior signed, written authorization of the veteran if the information pertains to the treatment of the veteran.



**Figure 1.** VA's PDMP Query and Care Plan Evaluation Process  
 Source: OIG's analysis of VA policies and guidance

## Opioid Safety Initiative

VHA initiated the Opioid Safety Initiative in 2013, after the prescription opioid epidemic required VA to find better ways to help veterans manage pain. The Opioid Safety Initiative is made up of four strategies:

1. Clinician and patient education, through individualized outreach from pharmacists (academic detailing), educational programming, and an informed consent requirement for patients prescribed chronic opioid therapy
2. Pain management improvement, by issuing VA policy on stepped pain management to emphasize the interdisciplinary nature of pain management and expanding access to alternative pain therapies such as acupuncture
3. Risk mitigation strategies, including system-level tracking and monitoring of the percent of veterans dispensed opioids, veterans dispensed opioids and benzodiazepines, veterans dispensed high opioid doses, and veterans on long-term opioid therapy with a completed urine drug screening within the previous year
4. Addiction treatment through inpatient and outpatient care, the colocation of primary and behavioral health care, and other initiatives like expanded outpatient treatment of opioid dependence<sup>19</sup>

On December 10, 2014, the acting deputy under secretary for health for operations and management (DUSHOM) issued a memo updating the Opioid Safety Initiative to facilitate the use of PDMP databases. On July 22, 2016, Congress passed the Comprehensive Addiction and Recovery Act of 2016, which directed the VA Secretary to expand the Opioid Safety Initiative to all medical facilities. Expanding the Opioid Safety Initiative ensured VA clinicians had access to information on controlled substances through the PDMP database of each participating state. The law also directed the Secretary to require all employees who are responsible for prescribing opioids to be educated on safe opioid prescribing practices, including the implementation of and full compliance with the Clinical Practice Guideline.<sup>20</sup> The Office of Primary Care then issued VHA Directive 1306 on October 19, 2016, after other services and specialties concurred with the PDMP query requirements.

The Opioid Safety Initiative contains many components. In addition to PDMP queries, it has the Stratification Tool for Opioid Risk Mitigation, the Opioid Therapy Risk Reduction Tool, and the Overdose Education and Naloxone Distribution Program to help combat opioid abuse among veterans. VHA's Pharmacy Benefits Management Services reported to the audit team that from the fourth quarter of FY 2012 through the fourth quarter of FY 2018, the Opioid Safety Initiative had allowed VHA to

- Reduce the number of veterans dispensed opioids by 52 percent, from about 679,000 veterans to about 327,000;

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<sup>19</sup>Walid Gellad et al., "Addressing the Opioid Epidemic in the United States: Lessons from the Department of Veterans Affairs," *Journal of the American Medical Association* 177, no. 5 (May 2018): 611-12.

<sup>20</sup> Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, Stat. 696 (2016).

- Reduce the number of veterans dispensed opioids and a benzodiazepine by 80 percent, from about 123,000 veterans to just over 24,700;
- Increase the percentage of urine drug screenings completed in the past year for veterans on long-term opioid therapy by 54 percent, from 37 percent to 91 percent;
- Reduce the number of veterans on long term opioid therapy by 58 percent, from about 438,000 to about 186,000; and
- Reduce the number of veterans dispensed high doses of opioids (greater than or equal to a 100 morphine-equivalent daily dose) by 73 percent, from almost 59,500 to about 16,200.

## Results and Recommendations

### **Finding: VA Clinicians Did Not Consistently Use State Prescription Drug Monitoring Information to Manage and Coordinate Patients' Care**

VA clinicians did not consistently query PDMP databases when they prescribed patients opioids. Without consistent queries, clinicians could not use PDMP query information to guide and potentially enhance the patients' care coordination and management or their safety. Based on its review results, the audit team estimated that 567,000 of the 779,000 VA patients prescribed opioids (73 percent) did not receive the minimum annual required PDMP queries.<sup>21</sup> An estimated 266,000 of these patients also did not receive more frequent or quarterly PDMP queries as recommended by the CDC, even though they were on long-term opioid therapy for chronic pain and were at higher risk of opioid use disorder and overdose. Finally, the audit team estimated that about 107,000 of the 567,000 patients had obtained controlled substances from non-VA clinicians and pharmacies, based on the PDMP information for the sampled patients who lacked annual PDMP queries. These patients faced increased risks for care coordination and management problems because their VA clinicians were unaware of controlled substances obtained outside of VA.

The audit team attributed VA clinicians' low query rates and use of PDMP information, and lack of awareness of their responsibility to query PDMPs, to the absence of an adequate internal control system. An adequate control system would monitor and evaluate the performance of PDMP queries at VA medical facilities as part of the Opioid Safety Initiative. It was the DUSHOM's responsibility to implement VHA's PDMP query policy under VHA Directive 1306, but the policy did not include any specific national oversight controls to monitor implementation and ensure accountability for performance. Subsequently, VHA relied on Veterans Integrated Service Networks (VISNs) and medical facilities to implement and monitor compliance with VHA Directive 1306 rather than assigning an office or group.

VHA did not clearly communicate the annual PDMP query requirements to clinicians in its mandatory, one-time Pain Management and Opioid Safety training course, and the OIG found that clinicians were not always aware of national or local PDMP query requirements. VA medical facility leaders established local policies that were not as stringent as the directive, and subsequently did not always accurately communicate the directive's requirements to VA medical facility staff.

Moreover, VA is required under the Comprehensive Addiction and Recovery Act of 2016 to educate and train clinicians on the Clinical Practice Guideline. However, VHA did not update its

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<sup>21</sup> The audit team excluded patients from the state of Missouri and U.S. territories which did not have operational PDMP databases during the review period and adjusted the population of 825,000 VA patients prescribed opioids to 779,000 patients for its projections.



Pain Management and Opioid Safety training or VHA Directive 1306 to reflect the updated February 2017 Clinical Practice Guideline. The Clinical Practice Guideline strongly recommends the use of PDMP queries to mitigate patient risks and includes the CDC recommendation that clinicians perform quarterly or more frequent queries for patients on long-term opioid therapy for chronic pain. The audit team's work also indicated that VHA needs to update its PDMP policy to address increased VA clinical responsibilities as VA pharmacies fill a growing number of non-VA care prescriptions for controlled substances.

In the absence of adequate oversight and monitoring from the DUSHOM's office, VISNs and VA medical facilities did not consistently address low PDMP compliance rates and ensure accountability for improved performance. Many of the VISN directors the audit team interviewed did not consider PDMP query compliance a high priority, which could help explain VHA's low PDMP compliance rates across the nation. Although the VISNs' Pharmacy Benefit Management Academic Detailing Service offices tracked PDMP query compliance rates, VISNs did not always ensure that

- Medical facility policies were consistent with VHA Directive 1306 and the policies were as stringent as the directive required,
- VA medical facility leaders were aware of their facilities' low PDMP compliance rates, or
- Local controls, like clinical reminders, were implemented to improve the completion of PDMP queries.

## **What the OIG Did**

The audit team conducted its audit from March 2018 through May 2019. The audit's scope included approximately 825,000 VA patients, excluding those in hospice care, who had a more than five-day supply of opioids filled at a VA pharmacy between April 1, 2017, and March 31, 2018. The audit team selected a total of 180 patients from a random sample of six VA medical facilities. The team then reviewed one or two VA-issued opioid prescriptions for each of the sampled patients to assess whether VA clinicians ensured the required annual PDMP query was completed. The team determined whether VA clinicians completed quarterly or more frequent PDMP queries for the higher-risk, long-term opioid therapy patients in the sample as recommended by the CDC.

The audit team also obtained and reviewed PDMP query information for the sampled patients who did not receive annual PDMP queries.<sup>22</sup> The team performed clinical assessments of those

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<sup>22</sup> The Bay Pines Health Care System did not provide the audit team with PDMP query information for these patients because it was concerned about state disclosure laws, and the state of Florida objected to the release of the PDMP information to the OIG. The audit team did not pursue this information because it had obtained sufficient information from the other reviewed VA medical facilities to meet the audit's objectives.

cases where the data showed patients had received controlled substances prescribed by a non-VA clinician during the review period. The audit team assessed these cases to determine if the failure to complete the required PDMP query at the correct time affected the management and coordination of the patient's care or safety. The team also interviewed clinicians and officials from each reviewed medical facility and VISN, the Office of Primary Care, the Office of Specialty Care Services, Office of Mental Health and Suicide Prevention, and Pharmacy Benefits Management Services. Appendixes B and C provide additional details on audit team actions.

In this finding, the OIG discusses

- VA clinicians' compliance with VHA's minimum annual PDMP query requirement for all patients, including those on long-term opioid therapy;
- An estimate of the potential number of patients at risk of care coordination and management problems and safety issues when VA clinicians prescribed patients opioids but did not ensure the completion of required PDMP queries; and
- Significant weaknesses in VHA's internal control system for PDMP queries.

## Clinicians Did Not Perform Required PDMP Queries for Most Patients Prescribed Opioids

The audit team found that VA clinicians did not perform required annual PDMP queries for 129 of the 180 reviewed patients prescribed opioids during the 12-month period from April 1, 2017, to March 31, 2018. Table 2 shows the results of the audit team's review by VA medical facility.

**Table 2. Patients Without Annual PDMP Queries by Facility**

VA medical facility	Patients reviewed	Patients without annual PDMP queries	Percentage
Bay Pines Health Care System (HCS)	30	25	83
Beckley VA Medical Center (VAMC)	30	16	53
Boise VAMC	30	20	67
Dayton VAMC	30	13	43
Greater Los Angeles HCS	30	27	90
Texas Valley Coastal Bend HCS	30	28	93
<b>Total</b>	<b>180</b>	<b>129</b>	<b>72</b>

*Source: OIG analysis of veterans' electronic health records*

In all these cases, VA clinicians should have completed a query when they issued the prescriptions but did not. This failure to undertake a query is established in the patients' electronic health records, which did not show any documented PDMP queries in the past year. Using these results, the audit team estimated that 567,000 of the 779,000 patients (73 percent) prescribed opioids by VA clinicians during the review period lacked the minimum annual query.<sup>23</sup> Appendix C provides more information on the audit team's statistical sampling methodology and results. PDMP query information could help VA clinicians prevent accidental or intentional misuse or diversion of prescribed medications by patients and their dependents and promote the early treatment of substance use disorders.

The audit team also noted that many of the sampled patients without annual queries were patients on long-term opioid therapy for chronic pain. These patients face greater health risks when they are prescribed additional controlled substances because they can receive high dosages or dangerous combinations of medications that increase their risk of overdose and opioid use disorder. Congress required VA to educate and train clinicians to ensure full compliance with the Clinical Practice Guideline and address the needs of this higher-risk population.<sup>24</sup> The Clinical Practice Guideline recommends several risk mitigation strategies at the start of long-term opioid therapy, including PDMP queries. In addition, the Clinical Practice Guideline references the CDC's recommendation that higher-risk patients on long-term opioid therapy receive more frequent PDMP queries.

VHA policy does not explicitly define the frequency of PDMP queries for patients on long-term opioid therapy for chronic pain, even though the Clinical Practice Guideline includes the CDC's recommendation for quarterly or more frequent queries for this high-risk population. Because the audit team considered the CDC's recommendation a best practice, it also identified long-term chronic pain patients without annual queries who could have benefited from quarterly or more frequent PDMP monitoring.

The audit team found that 40 of the 129 patients who lacked annual PDMP queries were also on long-term opioid therapy for chronic pain, and that none of these patients received the quarterly or more frequent queries recommended by the CDC. Based on these results, an estimated 266,000 of the 567,000 patients who lacked the VA-required annual query (47 percent) should have also been evaluated to determine if quarterly or more frequent PDMP queries were needed.

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<sup>23</sup> The projected national error rate does not equal the sample error rate because the attributes used to select the sampled facilities and patients, VA medical facilities, and veteran population must be considered relative to the national VHA population and the results from the samples must be adjusted (weighted) accordingly to calculate a national projection.

<sup>24</sup> *Comprehensive Addiction and Recovery Act of 2016*.

Example 1 illustrates the risks to patients when VA clinicians do not perform annual PDMP queries or evaluate the need for quarterly or more frequent PDMP queries for long-term opioid therapy patients.

### **Example 1**

*Greater Los Angeles Health Care System (HCS) mental health clinicians began prescribing a Schedule IV benzodiazepine in 2005 to a patient with a history of suicidal ideation, drug abuse/dependence, anxiety, and depression. The patient received 13 benzodiazepine prescriptions during the audit review period, but the mental health clinicians did not ensure the minimum annual PDMP query was completed. A VA primary care clinician who prescribed the patient a Schedule II opioid for chronic back pain in Fall 2017 also did not perform a PDMP query. If the VA primary care clinician had completed a PDMP query, the clinician would have found the patient filled three Schedule II opioid prescriptions in three successive months in late Spring/early Summer 2017, issued by a non-VA clinician. The VA primary care clinician subsequently renewed this Schedule II opioid prescription three additional times through Fall and Winter 2017 and issued the patient a different Schedule II opioid prescription in early 2018 without completing any PDMP queries. The Clinical Practice Guideline strongly discourages the concurrent use of benzodiazepines and opioids due to the increased risk of overdose and death. However, Greater Los Angeles HCS clinicians issued the patient benzodiazepines and opioids concurrently in Fall 2017. This situation was only addressed after the patient informed a new mental health clinician he saw in late Fall 2017 that he was on long-term opioid therapy for chronic pain. At that time, the mental health clinician began tapering the patient off the benzodiazepine. No PDMP queries were completed for this patient until the audit team requested one as part of this audit in March 2018.*

## **Patients Were Placed at Risk When VA Clinicians Did Not Perform PDMP Queries**

The audit team's review of the available PDMP query information for the 129 sampled patients who did not receive annual queries disclosed that 19 patients had obtained controlled substances

from non-VA clinicians and pharmacies.<sup>25</sup> The audit team found no evidence of patient deaths or hospitalizations related to the lack of PDMP queries in the 19 reviewed cases. However, five patients showed increased risk of adverse outcomes such as drug interactions and overdose, as well as diversion of opioids to nonpatients, due to the lack of PDMP queries and inconsistent electronic health record documentation. The inconsistent documentation also did not demonstrate a collaborative plan of care. Example 2 also shows how VA clinicians' failure to query the PDMP and obtain complete information about a patient's controlled substance prescriptions could affect patient safety. If the VA clinicians had obtained PDMP query information at the time of prescription, they could have discussed current pain treatment, patient safety, and the possible simultaneous use of two controlled substances, or revised their patients' treatment plans based on their clinical judgment.

### Example 2

*In Spring 2017, a VA clinician issued a Schedule II opioid for chronic joint pain to a Texas Valley Coastal Bend HCS patient who was diagnosed with posttraumatic stress disorder; borderline personality disorder; and alcohol, cocaine, and opiate use disorders. The clinician issued this prescription without performing a PDMP query, even though the patient had not received a PDMP query within the past year. The query would have revealed the patient had received a 30-day supply of a Schedule IV opioid four days earlier from a non-VA pharmacy and that the patient had filled two additional non-VA prescriptions for the Schedule IV opioid at non-VA pharmacies in early 2017. The patient's VA primary care clinician later issued the patient additional Schedule II opioid prescriptions in Spring 2017 and early 2018 without completing the required minimum annual PDMP query. A query and review of the patient's PDMP record in Spring 2017 would have shown the patient's three, 30-day, non-VA prescriptions for the Schedule IV opioid from Winter through Spring 2017, and the VA prescription for the Schedule II opioid from Spring 2017. The two VA clinicians missed multiple opportunities to identify the increased risk of overdose by issuing concurrent opioids to a patient diagnosed with multiple types of addiction disorders. In addition, the VA clinicians could have used the PDMP query information to better coordinate and manage the care for this patient,*

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<sup>25</sup> These results and the subsequent estimates do not reflect the review of Florida PDMP query information for 25 Bay Pines HCS patients who did not have PDMP queries. Bay Pines HCS did not provide the OIG team with PDMP data for these patients because it was concerned about state disclosure laws, and the Florida Department of Health indicated that the State of Florida was prohibited from releasing the PDMP query information to the OIG for the purposes of this audit. The OIG team decided not to pursue this information through legal processes because it had obtained sufficient information from the other reviewed VA medical facilities to meet the audit's objectives and support its findings.

*because the results of a PDMP query might have influenced their decisions to prescribe the patient the Schedule II opioid.*

Based on its results that showed 19 of the 129 patients who lacked required PDMP queries (15 percent) had obtained controlled substances from non-VA clinicians, the audit team projected that as many as 107,000 of the 567,000 patients who lacked required annual queries (19 percent) had obtained controlled substances from non-VA clinicians.<sup>26</sup> These patients were at increased risk of care coordination and management problems because VA clinicians did not ensure the required annual PDMP query was performed before they prescribed the patients opioids. Thus, they lacked assurance and possibly awareness that their patients had obtained controlled substance prescriptions from non-VA clinicians within the same 12-month period.

The frequency and related risks of patients receiving controlled substance prescriptions from non-VA clinicians will increase as VA implements the VA MISSION Act of 2018 to expand care in the community for veterans enrolled in the VA healthcare system.<sup>27</sup> At the same time, the MISSION Act provides VA an opportunity to strengthen Opioid Safety Initiative implementation and PDMP query compliance because it requires states to make PDMP databases available to licensed VA health care clinicians and their delegates. The MISSION Act also requires VA to ensure safe opioid prescribing practices among contracted non-VA care clinicians who serve VA patients.

## **VHA Did Not Establish an Effective Internal Control System to Ensure the Completion of PDMP Queries**

The audit team evaluated VHA's oversight of its clinicians' use of PDMP databases by assessing VHA's internal controls. The US Government Accountability Office's (GAO) *Standards for Internal Controls in the Federal Government Agencies* (Green Book) defines an internal control as "a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved." For this audit, internal controls would ensure annual checks of the PDMP database were completed. Based on this audit and the OIG's estimate that PDMP queries were not completed for most patients, the OIG concluded that VHA did not establish an effective internal control system for PDMP queries as part of its Opioid Safety Initiative strategy.

Specifically, the OIG found that VHA did not follow several key internal control principles or design an effective system—one that would have ensured consistent implementation of VHA

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<sup>26</sup> The projected national error rate does not equal the sample error rate because the attributes used to stratify the sampled facilities and patients—VA medical facility, veteran population, and DEA schedules of prescribed opioids—must be considered relative to the VHA national population and the sample results must be adjusted (weighted) accordingly to calculate a national projection.

<sup>27</sup> John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018, Pub. L. No. 115-182, S.2372 (2018).

Directive 1306 as well as the effective completion and monitoring of PDMP queries across VHA. VHA did not always ensure

- Adequate controls were designed to achieve Opioid Safety Initiative and PDMP query objectives,
- Necessary information was conveyed to VA medical facility leaders and staff,
- Adequate local policies and controls were implemented by VISNs and VA medical facilities to improve compliance,
- Policies were updated as significant risks or changes developed, and
- VISN and VA medical facility performance and accountability were evaluated to improve performance.

### **VHA Did Not Establish Effective National Controls to Achieve PDMP Query Objectives That Are Part of the Opioid Safety Initiative**

VHA Directive 1306 assigned the DUSHOM responsibility for implementing the directive requirements. However, the directive made VISN and VA medical facilities responsible for ensuring compliance with PDMP query requirements and the safe prescribing of all controlled substances, including opioids. It did not outline the controls the DUSHOM should use to monitor the national implementation of VHA's PDMP policy.

The chief officer for the Office of Specialty Care Services, who helped develop the policy, stated that oversight responsibility was placed on VISN and medical facility managers because they would be the most familiar with individual state requirements. Yet VHA Directive 1306 did not detail the supporting controls or mechanisms the DUSHOM should use to ensure adequate national monitoring and implementation. In effect, the VISNs and VA medical facilities were expected to implement VHA Directive 1306 and monitor compliance. The DUSHOM therefore did not hold VISNs and VA medical facilities accountable for effectively implementing the policy and completing required PDMP queries. Consequently, VHA's PDMP policy implementation did not adhere to the Green Book because it lacked internal controls to evaluate VISN and VA medical facility performance and promote accountability for improved performance.

### **VHA Did Not Clearly Communicate PDMP Query Requirements and Guidelines to Facility Leaders and Clinicians**

VHA included PDMP training as part of a one-time, mandated training course on opioid monitoring, titled "Pain Management and Opioid Safety." As of December 2016, all VHA clinicians who prescribed controlled substances were required to take this course. The course indicated PDMP queries were a good practice that clinicians "should use regularly," but did not



state that annual PDMP queries were required by VHA Directive 1306. VHA officials believed that the training was comprehensive enough at the time but acknowledged that it could be updated to reflect the annual requirement. Moreover, VHA did not update the course to include guidance from the February 2017 Clinical Practice Guideline, which included PDMP queries as a risk mitigation strategy for patients on long-term opioid therapy for chronic pain and the CDC's recommendation for more frequent PDMP queries based on the patients' risk factors. Adding this Clinical Practice Guideline information to the training could result in more frequent PDMP queries for patients. The OIG made recommendations to address these deficiencies.

According to the Office of Specialty Care Services, VHA held 40 program and national calls with medical facilities to brief and train them on VHA Directive 1306. However, the audit team's interviews with 66 of the 97 VA clinicians (68 percent) who did not complete mandatory PDMP queries for the sampled patients revealed the clinicians were generally unaware of the need to complete the PDMP queries or, if they were aware, they did not view the queries as a high clinical priority. Of the 66 clinicians interviewed who did not conduct queries<sup>28</sup>

- 41 clinicians were unaware of VA requirements to query the PDMP when initiating opioid therapy and annually thereafter;
- 11 clinicians said they would not perform a PDMP query unless they determined a clinical need to do so;
- 39 clinicians said medical facility leaders, such as the director and chief of staff, did not communicate PDMP query requirements;
- 30 clinicians said they did not receive communication from their service chiefs regarding PDMP queries; and
- 17 clinicians recalled receiving training related to PDMPs queries.

Of the 17 clinicians, only 10 indicated they received in-person training. The clinicians' responses reflected the absence of specific education and training on the PDMP query requirement and the general lack of attention given to PDMP queries as part of the Opioid Safety Initiative. When the audit team discussed the gaps in the training with the chief officer of the Office of Specialty Care Services, national program director for pain management, and the director of virtual pain education, they agreed the training needed to be updated.

After the audit team discussed its results with the offices of Specialty Care Services, Pharmacy Benefits Management Services, and Healthcare Transformation, the Office of Specialty Care

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<sup>28</sup> The OIG team attempted to contact all 97 VA clinicians who did not perform PDMP queries for the sampled patients. However, 31 either were no longer employed at VA or did not respond to multiple interview requests.



Services indicated that additional factors lessened VA clinicians' ability to complete PDMP queries:

- Lack of a functioning PDMP databases at the time the policy was implemented
- State restrictions on clinician access to PDMP databases based on the clinician's licensure, the clinician's involvement in delivering the specific patient's care, and the ability to delegate the completion of PDMP queries
- State requirements to obtain the patient's verbal consent for PDMP checks or posting of required signage in waiting rooms to educate patients about PDMP checks
- Cumbersome and burdensome state PDMP database registration and training processes
- Less stringent state PDMP database query regulations compared to VA's annual requirement
- Lack of an automated PDMP query process disrupts clinical workflow and interferes with care delivery in a busy primary care or specialty care services clinic, where time spent on PDMP queries is time taken away from patient encounters and face-to-face interactions

While the OIG acknowledged that many factors could influence VA clinicians' PDMP compliance rates, it still considered the general lack of awareness of VA's annual PDMP query requirement among the 66 interviewed clinicians to be a matter of concern.

### **VISN and VA Medical Facilities Did Not Establish Adequate Local PDMP Policies and Controls**

The audit team found that VISN and medical facility directors did not always ensure the local VA medical facilities' PDMP policies met the requirements outlined in VHA Directive 1306. Under the directive, VISN directors would oversee the VA medical facilities' implementation of VHA's PDMP policy and ensure the VA medical facilities within their VISNs established consistent local policies. However, VISN and medical facility directors did not always verify that local policies were consistent with the directive. Two of the six medical facilities the OIG team reviewed had local policies that were less stringent than the requirements in VHA Directive 1306. At the Bay Pines HCS, the local policy stated PDMP queries were only required for Schedule II–IV drugs, even though VHA Directive 1306 also requires queries for Schedule V drugs. At the Boise VA Medical Center (VAMC), the local policy stated PDMP queries were required for opioid prescriptions of more than seven days, while VHA Directive 1306 requires queries for opioid prescriptions greater than five days.

Although the six reviewed VA medical facilities had local policies implementing VHA Directive 1306, interviews with clinicians disclosed that they were not always aware of their facilities' local policies or the related VHA Directive 1306 requirements. Additional management controls—such as periodic reminders to communicate VHA's PDMP policy and the

importance of completing PDMP queries—may be needed to improve VA clinicians' use of the information systems, even if VISNs and VA medical facilities update and correct their local policies.

Some clinicians who did not complete required PDMP queries suggested that in the future, reminder alerts should appear when queries are due or overdue. Other clinicians thought that the automation of the PDMP query process would provide the best solution. During the audit, the OIG team identified a promising practice in VISN 7 VA Southeast Network, where an automated clinical reminder order check in the electronic health record notified clinicians at the time they prescribed controlled substances whether a PDMP query progress note had been completed within the last 12 months. The use of local automated controls, like the clinical reminder order check, could help VISNs and VA medical facilities communicate and reinforce the need to perform PDMP queries.

### **VHA Did Not Update Its PDMP Query Policy to Account for Updated Guidance for High-Risk Patients and the Growing Numbers of Non-VA Prescriptions**

The Office of Primary Care and the Office of Specialty Care Services that developed VHA Directive 1306 have not updated the directive since it was issued on October 19, 2016. While the directive requires a minimum annual query, it also states that queries can be conducted when clinically indicated. After the directive was issued, the February 2017 Clinical Practice Guideline introduced updated risk mitigation strategies for long-term opioid therapy patients, including the CDC's recommendation to perform quarterly or more frequent queries for these high-risk patients. However, VHA did not incorporate the recommendation in VHA Directive 1306 even though it uses VA/Department of Defense (DoD) evidence-based clinical practice guidelines to reduce variations in clinical practice and systematize best practices. Furthermore, VA is required under the Comprehensive Addiction and Recovery Act of 2016 to educate and train clinicians on the Clinical Practice Guideline. However, the acting national program director for pain management stated that the CDC's recommendation and the Clinical Practice Guideline are not policy and therefore do not belong in the directive.

The program offices also have not updated the directive to address the increasing frequency with which VA pharmacies are expected to fill controlled substance prescriptions written by non-VA care clinicians, and the related risks to patients if PDMP queries have not been performed. VA agreed in principle that non-VA clinicians should submit opioid prescriptions directly to VA pharmacies for dispensing, to ensure the prescriptions are recorded in the patients' electronic

health records.<sup>29</sup> However, VHA Directive 1306 does not address VHA's care management and coordination responsibilities in this situation. The directive is silent regarding expectations or requirements for non-VA clinicians to query PDMPs when they prescribe VA patients controlled substances. Moreover, the directive does not address VA staff care coordination and patient management responsibilities when it is not clear the non-VA care clinician has completed a PDMP query and a query has not been completed within the past year by a VA clinician.

The OIG team identified risks from this gap in the policy when it identified 11 veterans in its sample who had 16 non-VA care opioid prescriptions filled at VA pharmacies, but did not have annual PDMP queries documented in their electronic health records. According to the chief consultant and deputy chief consultant in VHA's Pharmacy Benefits Management Services, pharmacy does not have a role in querying PDMPs because VHA Directive 1306 assigns this responsibility to the prescribing clinicians. Nevertheless, Example 3 demonstrates the risks to patients when VA pharmacists fill non-VA opioid prescriptions and are not required to ensure the required annual query has been completed or assess whether another PDMP query should be completed before the non-VA opioid prescription is filled.

### **Example 3**

*A primary care clinician prescribed a Texas Valley Coastal Bend HCS patient a Schedule III opioid for chronic back pain in Fall 2017. The patient had a history of suicidal ideation, posttraumatic stress disorder, and depression, but the clinician placed the patient on long-term opioid therapy for chronic pain without completing a PDMP query or ensuring the required minimum annual PDMP query had been performed. The patient's PDMP query, obtained by OIG in Summer 2018, indicated that the patient filled eight total opioid prescriptions for Schedule II, III, and IV opioids from two Veterans Choice Program (Choice) clinicians during a 44-day period from Spring through Summer 2017. The expected treatment time for the eight prescriptions was 150 days, but by filling them over a 44-day period the patient exhibited potential opioid abuse and medication diversion behavior (the distribution or sale of the drugs). The Texas Valley Coastal Bend HCS pharmacy filled three of the eight prescriptions. The OIG team concluded that if the HCS pharmacy had completed a PDMP query, the patient's frequent refills of opioid prescriptions may have been detected.<sup>30</sup> The*

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<sup>29</sup> In the report *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*, Report No. 17-01846-316, July 31, 2017, the audit team found patients who were prescribed opioids outside VA were at significant risk when VA and non-VA clinicians did not share opioid prescription information. The VA agreed in principle with the OIG's recommendation to require non-VA clinicians to submit opioid prescriptions directly to a VA pharmacy. However, 14-day urgent prescriptions and opioids provided as part of opioid treatment programs were specific clinical exclusions written into community care contracts to ensure quality of veteran care.

<sup>30</sup> Texas Valley Coastal Bend HCS's local policy allows PDMP queries to be delegated to pharmacists.

*OIG team also determined that not all the medications from these eight prescriptions were listed on the patient's electronic health record's Active Medication Note from Summer 2017. Consequently, VA clinicians were unaware of all the patient's medications, increasing the risk to the patient's safety.*

In FY 2018, 1.7 million VA patients, including 39,300 pain management patients, received non-VA care. According to VHA's Pharmacy Benefits Management Services office, VA initially requested non-VA care clinicians who prescribe patients opioids send opioid prescriptions to VA pharmacies so that VA could leverage its pricing for drugs and automate prescription fulfillment to contain costs, as well as mitigate patient management and care coordination risks. VHA did not, however, update VHA Directive 1306 or provide any supplemental guidance to address non-VA care coordination and patient management responsibilities when VA patients fill non-VA controlled substance prescriptions at VA pharmacies. The primary care official in the office responsible for developing VHA Directive 1306 stated that the directive does not include pharmacy because it was expressly intended to provide prescribers, not dispensers, guidance. Three of the VA medical facilities the OIG team visited—Bay Pines HCS, Beckley VAMC, and Dayton VAMC—recognized the gap in VA's national policy and implemented local policies and procedures for PDMP queries before filling non-VA care, controlled substance prescriptions.

### **VHA Did Not Effectively Remediate Low PDMP Compliance Rates and Ensure Accountability**

VHA established the VISN Academic Detailing Service in March 2015 to provide educational outreach visits to clinicians and improve mental health and pain management therapy across all VA medical facilities. One goal of the Academic Detailing Service was to improve VHA performance on all Opioid Safety Initiative metrics. The Academic Detailing Service uses a dashboard to monitor these metrics and annual PDMP query compliance rates at VISNs and medical facilities. However, the reviewed VISNs did not consider PDMP query compliance rates a high priority and did not ensure their VA medical facilities used the Academic Detailing Service data to improve the completion of PDMP queries. The VISN directors were responsible for overseeing their VA medical facilities' implementation of VHA's PDMP policy under VHA Directive 1306, but the Academic Detailing Services were not assigned specific oversight responsibilities for PDMP query compliance of VA medical facilities.

The Academic Detailing Service offices functioned in an advisory capacity. They provided PDMP query compliance rate data, training, and general guidance to staff at VA medical facilities but did not require the six reviewed VA medical facilities with low compliance rates to provide corrective action plans. The OIG team also found that four of the six Academic Detailing Services did not provide compliance rate information directly to their VA medical facility directors and chiefs of staff of Bay Pines HCS, Texas Valley Coastal Bend HCS, Boise VAMC, and Greater Los Angeles HCS. Thus, key local management officials responsible for the

implementation of VHA Directive 1306 and the safe prescription of controlled substances at some VA medical facilities did not receive PDMP query compliance rate information and were not always aware their clinicians needed to improve their PDMP query compliance and usage rates.

In the case of the Bay Pines HCS, VISN 8 did not inform the leaders that the facility had a 25 percent compliance rate until two weeks prior to the OIG team's site visit, although the Academic Detailing Service office had shared this data previously with the HCS pharmacy managers and staff. After the Bay Pines HCS chief of staff became aware of the low compliance rate, she met with clinicians to discuss the PDMP query requirement and provided them a handout reminding them of their responsibilities when prescribing controlled substances.

The VISN 22 pharmacy executive acknowledged the VISN did not monitor PDMP query compliance rates at medical facilities and that the VISN was focused on decreasing opioid prescription rates. Moreover, the Greater Los Angeles HCS medical facility director stated the medical facility's PDMP query compliance rate was not a priority because the VISN and local medical executive committee had not communicated any concerns about it.

Although there was deficient VISN communication with VA medical facility managers about PDMP query compliance, the OIG team noted that VA medical facilities with higher compliance rates had developed supplemental local policies, controls, or procedures to support the implementation of VHA Directive 1306 or the Opioid Safety Initiative, or to comply with state laws:

- During Beckley VAMC Pain Management Consultative Board meetings, clinicians reviewed PDMP query information for patients when they started opioid therapy, appealed the end of their opioid therapy, or requested increased dosages. Beckley VAMC also developed a local policy that requires VA pharmacists to use clinical judgment to determine if PDMP queries were needed before filling non-VA care controlled substance prescriptions.
- Boise VAMC pharmacists used an internal VISN 20 Opioid Risk Registry to determine when patients needed or were due for PDMP queries, and VA pharmacists performed PDMP queries as needed.
- Dayton VAMC's chief of staff shared quarterly PDMP query compliance data with the facility's Clinical Executive Board and with other clinicians to improve compliance.

Table 3 shows the PDMP query compliance rates reported by the respective VISN Academic Detailing Service offices during the audit's 12-month review period for the six reviewed VA medical facilities.

**Table 3. PDMP Query Compliance Rates for Reviewed Facilities,  
April 2017 through March 2018**

VISN	VA medical facility	April to June 2017	July to September 2017	October to December 2018	January to March 2018
5	Beckley VAMC	48%	61%	80%	78%
8	Bay Pines HCS	16%	24%	31%	34%
10	Dayton VAMC	60%	61%	65%	71%
17	Texas Valley Coastal Bend HCS	17%	20%	20%	22%
20	Boise VAMC	73%	73%	71%	72%
22	Greater Los Angeles HCS	46%	44%	46%	48%

Source: Academic Detailing Service Opioid Safety Initiative customized reports.

Note: The VISN Academic Detailing Service offices only monitor compliance with the annual PDMP requirement in VHA Directive 1306.

VISN directors did not generally hold VA medical facility directors and chiefs of staffs accountable for improving low PDMP query compliance rates and did not require corrective actions plans or follow-up on low compliance rates because they did not consider PDMP queries a high VHA priority. As a result, improvements in VA medical facility PDMP query compliance rates depended on the VA medical facility staff's willingness to work with the VISN Academic Detailing Service offices and to voluntarily implement supplemental local PDMP controls.

## Conclusion

VA clinicians did not consistently query PDMPs when they prescribed patients opioids. The OIG team estimated that clinicians did not check the records of 567,000 of the 779,000 VA patients prescribed opioids, as required under VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*. Also based on the Clinical Practice Guideline, VA clinicians should have, as a best practice, considered more frequent PDMP queries for about 266,000 of the patients who were on long-term opioid therapy for chronic pain, but did not. Furthermore, an estimated 107,000 patients that lacked the minimum required PDMP query had also obtained controlled substances from non-VA clinicians. Not querying PDMP databases put some veterans at greater risk of opioid abuse, adverse drug interactions, and drug diversion. The audit's results show that VHA and management officials at all levels of VHA, from the national program offices down to the VA medical facilities, need to improve oversight and monitoring and establish controls to

ensure VHA clinicians effectively use PDMP query information to successfully implement VA's Opioid Safety Initiative.

## Recommendations 1–8

The OIG recommends the under secretary for health<sup>31</sup>

1. Develop national processes to oversee medical facility compliance with VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*, and coordinate the possible automated information technology solutions and inter-office and -disciplinary communications necessary to improve prescription drug monitoring program monitoring and usage in Veterans Health Administration;
2. Update the Pain Management and Opioid Safety training course to specifically address VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*, query requirements and recommendations;
3. Ensure VA clinicians who prescribe opioids take the Pain Management and Opioid Safety training once, with annual refresher training;
4. Add an addendum to VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*, that references the *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain* and ensure VA clinicians are educated and receive annual training on the Clinical Practice Guideline, to include the Centers for Disease Control and Prevention's recommended frequency for prescription drug monitoring program queries based on the patients' risk factors;
5. Direct Veterans Integrated Service Networks and their VA medical facilities to ensure local policies are consistent with VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*;
6. Develop automated information technology solutions to facilitate clinicians' access to prescription drug monitoring program query information and reinforce the need to complete minimum annual VA-required prescription drug monitoring program queries;
7. Ensure non-VA care clinicians are in good standing and have a current state medical license that requires adherence to their state's prescription drug monitoring program query requirements; adhere to the Veterans Affairs Opioid Safety Initiative Guidelines, including guidelines for prescription drug monitoring program queries; and are monitored to ensure appropriate corrective actions are taken if their prescribing practices are found

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<sup>31</sup> Recommendations directed to the under secretary for health were submitted to the executive in charge, who has the authority to perform the functions and duties of the under secretary for health. Additionally, the recommendations apply to the individual within VHA who assumes the responsibilities for the executive in charge, whether in an acting or permanent position.



to be inconsistent with *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*; and

8. Ensure Veterans Integrated Service Networks implement an effective prescription drug monitoring program oversight process that includes the review of compliance rates with medical facility directors.

## Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with Recommendations 1–5, 7, and 8, and provided corrective action plans. The VA Office of Information and Technology, through the executive in charge, concurred with Recommendation 6 and submitted an acceptable corrective action plan. All provided action plans anticipate implementation by July 2020.

In response to Recommendations 1 and 8, the executive in charge stated the Office of the Assistant Deputy Under Secretary for Health for Clinical Operations and subject matter experts from the Office of Primary Care will collaborate with the VHA Support Service Center to assess the feasibility of revising current reporting mechanisms. In addition, the Office of the Assistant Deputy Under Secretary for Health for Clinical Operations will draft a memo to the VHA National Leadership Council recommending an oversight process for PDMP compliance.

For Recommendations 2–4 pertaining to training, VHA Office of Specialty Care Services, working in conjunction with VHA Employee Education System and with input from subject matter experts in the Office of Primary Care and other necessary offices, will update the existing Pain Management and Opioid Safety training module to include additional information on PDMP requirements from VHA Directive 1306 and CDC’s PDMP recommendations in Clinical Practice Guideline. Furthermore, the Office of Specialty Care Services will issue an annual refresher training. In addition, the Office of Primary Care will develop an addendum to VHA Directive 1306 to reference the CDC’s PDMP recommendations and the Clinical Practice Guideline.

For Recommendation 5, the Office of the Assistant Deputy Under Secretary for Health for Clinical Operations will issue guidance to VISNs and VA medical facilities to ensure local policies are consistent with VHA Directive 1306. No more than 30 days after the guidance is issued, each VISN will be required to submit a memo attesting to compliance with VHA Directive 1306 or an anticipated timeline for completion.

The executive in charge stated the VA Office of Information and Technology will be responsible for addressing Recommendation 6. Specifically, the Office of Information and Technology will develop a short-term solution to automate the PDMP query process, including progress note documentation in the Computerized Patient Record System.



Lastly, in response to Recommendation 7, VHA tracks non-VA clinicians' entries into the network and validates completion of Opioid Safety Initiative Guidelines training. If a non-VA clinician does not complete the Opioid Safety Initiative training, the clinician is deactivated in the Provider Profile Management System and can no longer receive referrals from VHA to provide care. Furthermore, each VISN's Community Care Oversight Council will review monthly non-VA clinician opioid prescribing data within the VISN. The council will review the VHA Opioid Safety Initiative Dashboard to monitor non-VA clinicians' percentage of opioids dispensed and concerns raised from other sources including VAMC managers, veterans, veterans' family members, state agencies, or other clinicians. In the event a non-VA clinician is found to have inappropriate or unsafe prescribing practices, VHA will deactivate the non-VA clinician's Provider Profile Management System profile and alert the local VAMC community care office to complete appropriate care coordination activities.

## **OIG Response**

The executive in charge, Office of the Under Secretary for Health, concurred with Recommendations 1–5, 7, and 8, and submitted acceptable corrective action plans for all recommendations. The VA Office of Information and Technology, through the executive in charge, concurred with Recommendation 6 and submitted an acceptable corrective action plan. The OIG will monitor implementation of planned actions and will close the recommendations when VA provides sufficient evidence demonstrating progress in addressing the intent of the recommendations and the issues identified.

## **Appendix A: Background**

### **VA Governance Structure for PDMP Implementation and Monitoring**

Under VHA Directive 1306, the DUSHOM is responsible for implementing the directive and local VISN and VA medical facility officials are responsible for ensuring compliance with VA PDMP query requirements:

- VISN directors are responsible for ensuring all VA medical facilities in their network implement and comply with VHA Directive 1306 and establish local policies that are consistent with the directive and applicable state laws.
- Medical facility directors are responsible for providing leadership that endorses, supports, and promotes the use of PDMP query results as an essential element of comprehensive, coordinated, patient-centered care.
- Medical facility directors are responsible for ensuring VHA Directive 1306 is implemented and local policies and processes are consistent with the directive and applicable state law.
- Medical facility directors are responsible for ensuring their local policies address
  - Education and training on access and use of PDMP databases;
  - Requirements for clinicians or their designees to query PDMP databases;
  - Guidance on who is expected to query the database;
  - Potential conflicts between VA duties and state law or regulations; and
  - Establishing a local predefined progress note titled “State Prescription Drug Monitoring Program.”
- Medical facility chiefs of staff are required to ensure that
  - Prescribers or responsible team members request and maintain PDMP database access;
  - All VA and contract staff receive training on PDMP query requirements; and
  - Clinicians use the PDMP progress note and interpret PDMP query data to make safe and appropriate care decisions.

### **VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain**

VA and DoD published the first Clinical Practice Guideline on the management of opioid therapy for chronic pain in 2003. The intent of the guidance was to improve pain management,

quality of life, and quality of care for veterans. To accomplish this, the Clinical Practice Guideline focused on providing education and guidance to primary care clinicians, researchers, and other healthcare professionals as they encountered patients with persistent pain and its complications. VA and DoD updated the guidance to include the discussion of chronic pain in cancer patients in May 2010 and revised the guideline again in February 2017 to provide clinicians evidence-based information on the treatment of long-term opioid therapy patients. The February 2017 revision included strategies to mitigate long-term opioid therapy risks and a CDC recommendation that clinicians who prescribe opioids for long-term chronic pain patients perform PDMP queries every three months, or more frequently based on the patients' risk factors. The guideline, which includes the CDC's recommendation endorsing more frequent PDMP queries for chronic pain patients, is not part of VHA policy.

## **Recent Legislation Affecting VA's Implementation of PDMP Queries**

Public Law 115-182, VA MISSION Act of 2018, signed on June 6, 2018, established safeguards to protect veterans who might receive non-VA care and be prescribed opioids by non-VA clinicians. The law requires VA to include the relevant medical history and a list of all medications prescribed by VA in community care authorizations. It also requires non-VA care clinicians to submit medical records of any care or services furnished, including records of any opioid prescriptions, to VA to be integrated into the patients' electronic health records and to monitor the prescriptions as outlined in the Opioid Safety Initiative. Furthermore, to increase access to PDMP databases, the MISSION Act forbids states from preventing licensed healthcare clinicians or delegates from accessing their state's PDMP database.<sup>32</sup> It also requires VA to participate in a national network of PDMP databases.<sup>33</sup>

Public Law 115-271, SUPPORT for Patients and Communities Act, signed on October 24, 2018, directs the Secretary of HHS, through the director of the CDC and in coordination with the heads of other departments and agencies, to support the efficient use of PDMP databases.<sup>34</sup> The law directs the HHS Secretary to help states establish, maintain, and enhance the universal use of PDMP databases among clinicians and their delegates, to the extent that state laws allow. In addition, the law directs the HHS Secretary to help states improve their PDMPs by improving operability of PDMP databases. To improve PDMP database operability, the law requires states

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<sup>32</sup> Low PDMP query use and access restrictions were mentioned in published OIG and GAO reports: *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care*, Report No. 17-01846-316, July 31, 2017; and *VA Health Care: Progress Made Towards Improving Opioid Safety, but Further Efforts to Assess Progress and Reduce Risk Are Needed*, GAO-18-380, May 29, 2018. However, the VA MISSION Act of 2018 should eliminate access barriers due to state law.

<sup>33</sup> PMP InterConnect® was developed by the National Association of Boards of Pharmacy to facilitate the transfer of PDMP database information across state lines. As of March 22, 2018, all but five states were participating in this data-sharing collective.

<sup>34</sup> *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act*, Pub. L. No. 115-271, H.R.6 (2018).

to make PDMPs more integrated with electronic health records and to link PDMP query data to other state data systems.

## **Prior OIG Reports Related to Opioid Prescribing and PDMP Query Use**

In the *Review of Pain Management Services in Veterans Health Administration Facilities* (16-00538-282, September 17, 2018), the OIG conducted a healthcare inspection to assess VHA medical facilities' pain management services. Specifically, the audit team conducted an electronic survey of 141 VHA medical facilities from April 27, 2016, through May 11, 2016, and looked at pain management practices involving prescribing opioids and treating substance abuse. During this inspection, the OIG found that 58 of 141 VA medical facilities (41 percent) reported that out-of-state licensed clinicians had no access to PDMP databases. Of the 58 facilities that employed staff who were unable to access PDMP databases, 41 out of 58 (71 percent) reported having alternative processes allowing a review of PDMP data, such as having a licensed state pharmacist or other appropriate clinician review the PDMP database and document the findings in the electronic health record. For this finding, the OIG recommended VHA ensure its medical facilities have formal processes in place for clinicians to access PDMP databases and reconcile medications dispensed by private and VA clinicians, and that these processes comply with the clinicians' state licensing requirements. The executive in charge's response stated VHA had addressed this recommendation as of October 2016 by issuing VHA Directive 1306 and monitoring PDMP query usage through the Opioid Safety Initiative dashboard and Academic Detailing dashboard. However, the current audit still found low compliance with VHA Directive 1306.

In a prior healthcare inspection report, *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care* (17-01846-316, July 31, 2017), the OIG identified the immediate need for improved care coordination between VA and non-VA healthcare clinicians prescribing opioids to veterans. The inspection reviewed prescribing opioids to high-risk veterans, such as those with chronic pain and mental health illnesses, who were receiving VA-purchased care from Choice and other non-VA community care programs. Although VA healthcare clinicians have the Opioid Safety Initiative as a framework to evaluate, treat, and manage patients with chronic pain on long-term opioid therapy, community clinicians were not obligated to adhere to these guidelines. Moreover, the OIG noted VA clinicians face limitations accessing PDMP databases for patients in neighboring states, or because clinicians were not licensed by the state in which they cared for the patients, and that clinicians would not probably access the PDMP database if they were not prescribing the patient controlled substances. The OIG did not make any recommendations at that time for VHA to increase the use of PDMP databases.

## **Appendix B: Scope and Methodology**

### **Scope**

The OIG team conducted its audit work from March 2018 through May 2019 and performed onsite or virtual site visits at the following locations with operational PDMP databases:

- VA Central Office, Washington, DC
- Bay Pines HCS, Bay Pines, Florida
- Beckley VAMC, Beckley, West Virginia
- Boise VAMC, Boise, Idaho
- Dayton VAMC, Dayton, Ohio
- Greater Los Angeles HCS, Los Angeles, California
- Texas Valley Coastal Bend HCS, Harlingen, Texas

The OIG team reviewed a statistical sample of 180 patients and 299 opioid prescriptions filled at VA pharmacies from April 1, 2017, through March 31, 2018. The population consisted of 825,000 VA patients who received 5.2 million opioid prescriptions.

### **Methodology**

The OIG team identified and reviewed applicable laws, regulations, VA policies, standard operating procedures, and guidelines related to PDMP queries for opioid prescriptions. The team also interviewed VHA, VISN, and VA medical facility staff to understand VA's PDMP policies, internal controls, processes, and the general governance structure used to implement and monitor compliance with VA's PDMP query requirements.

The OIG team reviewed the sample of patients and opioid prescriptions in coordination with OIG statisticians to see if clinicians performed a PDMP query at the time they issued the prescriptions. If the clinicians did not perform PDMP queries at that time, the audit team searched for the progress note titled "State Prescription Drug Monitoring Program" to determine if a PDMP query had been performed within the past year as required by VHA Directive 1306. The OIG team also identified the number of patients who lacked annual PDMP queries and received opioids for 90 days or more to treat chronic pain during the audit review period, to determine how many patients might have benefited from the more frequent PDMP monitoring recommended by the CDC. Appendix C provides more information on the review team's statistical sampling methodology and results.

The OIG team requested VA medical facility staff complete PDMP queries and document the results in VA's progress note template for those patients who did not have required annual

PDMP queries. The OIG team reviewed the patients' PDMP query information to identify any controlled substances prescribed by non-VA care clinicians (Choice or other VA fee care) and filled at non-VA pharmacies. The team assessed this information to identify potential care management or coordination issues, such as drug-seeking behavior and dangerous drug combinations. In addition, the audit team followed up with VA clinicians to discuss specific cases, reasons queries were not performed, and any challenges the clinicians encountered in properly completing PDMP queries.

## **Scope Limitations**

This audit had a scope limitation because the OIG team did not pursue the release of PDMP query data from the state of Florida. The Bay Pines HCS did not provide the OIG team the requested PDMP query information for patients who lacked required or recommended PDMP queries due to concerns over state PDMP disclosure laws. Subsequently, the state of Florida also objected to the release of the PDMP query information for the selected Bay Pines HCS patients when the audit team requested the information directly from the state PDMP database. The OIG team did not pursue the release of the PDMP query information from the state of Florida and accepted this scope limitation after determining the audit had obtained sufficient, appropriate PDMP query information and evidence from the other five reviewed VA medical facilities to meet the objectives of the audit and provide a reasonable basis for the audit's findings and conclusions.

## **Fraud Assessment**

The OIG team assessed the risk that fraud, violations of legal and regulatory requirements, and abuse could occur during this audit. The team exercised due diligence in staying alert to any fraud indicators by checking for the following:

- Prescriptions issued after patient dates of death,
- Patients whose home states were different than the location of facilities from which they received prescriptions, and
- Prescriptions issued before the expiration of prior prescriptions.

The OIG team did not identify any instances of fraud or potential fraud during this audit.

## **Data Reliability**

The OIG team used computer-processed data from VHA's Corporate Data Warehouse. To test for reliability, the team determined whether any data were missing from key fields, included any calculation errors, or were outside the time frame requested, and assessed whether the data contained obvious duplication of records, alphabetic or numeric characters in incorrect fields, or illogical relationships among data elements. Furthermore, the OIG team compared the sampled

patients' names, social security numbers, prescription medication names, and issued prescriptions and release dates with information in the patients' electronic health records.

Testing of the data disclosed that they were sufficiently reliable for the review objectives. Comparison of the data with information contained in the patients' medical health records reviewed did not disclose any problems with data reliability.

## **Government Standards**

The OIG conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that the OIG plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for the findings and conclusions based on audit objectives. The OIG believes the evidence obtained provides a reasonable basis for the findings and conclusions based on the audit objectives.

## **Appendix C: Statistical Sampling Methodology**

The OIG team sampled opioid prescriptions filled at VA pharmacies during the 12-month period ending March 31, 2018, to determine whether VA clinicians effectively used state-operated PDMP database information to manage and coordinate the care of patients prescribed opioids in VA and in the community. The team excluded the state of Missouri and US territories that did not have operational PDMP databases at the time of the audit. The team also evaluated if care was provided in accordance with VHA Directive 1306 and the Clinical Practice Guideline recommendations.

### **Population**

The OIG team selected the population based on the parameters of the audit objective and identified 5.2 million opioid prescriptions dispensed to 825,000 VA patients from VA pharmacies during the 12-month period ending March 31, 2018. The OIG team then excluded patients from the state of Missouri and US territories that did not have operational PDMP databases during the period of its review, thus reducing the population the OIG used for its projections from 825,000 to 779,000 VA patients prescribed opioids.

### **Sampling Design**

The OIG team used a multistage stratified sampling approach. In the first stage, it identified a random sample of six VA medical facilities. In the second stage, it selected a stratified random sample of VA patients who were prescribed opioids based on whether the patient had an opioid use disorder diagnosis and the DEA controlled substance schedule of the prescribed opioid. In the third stage, a sample of one or two opioid prescriptions was selected from each patient using simple random sampling. The sampling design resulted in the review of 299 prescriptions for 180 selected patients (30 per medical facility) and allowed the OIG team to project its findings from the sample to the population. Thus, the OIG team projected the number of patients who did not have required PDMP queries, the number of chronic pain patients without required PDMP queries who might have benefited from more frequent PDMP queries, and the number of patients without required PDMP queries who also obtained controlled substances from non-VA care.

### **Weights**

The OIG calculated all estimates in this report using weighted sample data. Weights indicate how many items each sample unit represents in the population. Each sample unit measures a group of patients with similar characteristics—such as those diagnosed with an opioid use disorder and treated with the same prescribed opioid (DEA-controlled substance). Sampling weights are computed by taking the product of the inverse of the probabilities of selection at each stage of sampling. For example, the OIG calculated error rate estimates by summing the



sampling weights for all sample records that contained the error, then dividing that value by the sum of the weights.

## Projections and Margins of Error

The OIG team used WesVar software to calculate the weighted population estimates and associated sampling errors. WesVar employs replication methodology to calculate margins of error and confidence intervals that correctly account for the complexity of the sample design. The margins of error and confidence intervals are indicators of the precision of the estimates. If the OIG team repeated this audit with multiple samples, the confidence intervals would differ for each sample but would include the true population value 90 percent of the time. Using the sample results, the OIG team estimated 567,000 patients (73 percent) lacked the minimum annual PDMP query.

**Table C.1. Statistical Projections Summary**

Category	Projection	Margin of error*	Lower limit*	Upper limit*	Total sample size	Lacked PDMP query in sample
All patients	567,000	58,500	508,500	625,600	180	129
All patients error rate	73%	8%	65%	81%	180	129
Long-term opioid therapy patients with no annual and quarterly query	266,000	63,400	202,600	329,400	129	40
Long-term opioid therapy patients with no annual and quarterly query error rate	47%	10%	37%	57%	129	40
Patients with non-VA controlled substance prescriptions	107,000	45,700	61,200	152,700	129	19
Patients with non-VA controlled substance prescriptions error rate	19%	8%	11%	27%	129	19

Source: VA OIG statistical analysis performed in consultation with the Office of Audits and Evaluations statistician

\* Based on 90 percent confidence interval.

## Appendix D: Management Comments

### Department of Veterans Affairs Memorandum

Date: August 6, 2019

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, VETERANS HEALTH ADMINISTRATION: System Prescription Drug Monitoring Program Need Increased Use and Oversight. Project Number 2018-02830-R7-009 (VIEWS 01242030)

To: Assistant Inspector General for Audits and Evaluations (52)

1. Thank you for the opportunity to review the OIG draft report, VETERANS HEALTH ADMINISTRATION: State Prescription Drug Monitoring Programs Need Increased Use and Oversight. I have reviewed the draft report and provide the attached action plan to address recommendations 1-5, 7, and 8. The Department of Veterans Affairs Office of Information and Technology is responsible for recommendation 6.
2. Thank you for the opportunity to review the draft report. If you have any questions, please email Karen Rasmussen, M.D., Director, GAO OIG Accountability Liaison (GOAL) Office at [VHA10EGGOALAction@va.gov](mailto:VHA10EGGOALAction@va.gov).

(Original signed by)

Richard A. Stone, M.D.

Attachment

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)  
Action Plan

**OIG Draft Report: Veterans Health Administration: State Prescription Drug Monitoring Programs Need Increased Use and Oversight**

**Date of Draft Report: June 11, 2019**

Recommendations/ Actions	Status	Completion Date
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Recommendation 1: Develop national processes to oversee medical facility compliance with VHA Directive 1306 and coordinate the possible automated information technology solutions and inter-office and -disciplinary communications necessary to improve PDMP monitoring and usage in VHA.

VHA Comments: Concur. A small workgroup was convened to examine possible technological solutions to address the monitoring of State Prescription Drug Monitoring Programs (PDMP) throughout the Department of Veterans Affairs (VA) medical facilities. Specifically, the Office of the Assistant Deputy Under Secretary for Health for Clinical Operations (ADUSH C/O), in conjunction with subject matter experts from the VHA Office of Primary Care will collaborate with the VHA Support Service Center to assess the feasibility of revising features of current reporting mechanisms. Furthermore, the Office of the ADUSH C/O will draft an Executive Decision Memorandum addressed to the VHA National Leadership Council recommending an oversight process of the PDMP.

Status: Target Completion Date:

In process July 2020

Recommendation 2: Update the Pain Management and Opioid Safety training course to specifically address Directive 1306 PDMP requirements and recommendations.

VHA Comments: Concur. VHA's Office of Specialty Care Services and Office of Primary Care concur with this recommendation. Working in conjunction with the VHA Employee Education System and with input from subject matter experts in the Office of Primary Care and other necessary offices, VHA's Office of Specialty Care Services will update the existing Talent Management System (TMS) module (31108) to include additional information regarding PDMP requirements and VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*.

Status: Target Completion Date:

In process July 2020

Recommendation 3: Ensure VA clinicians who prescribe opioids take the Pain Management and Opioid Safety training once, with annual refresher training.

VHA Comments: Concur. VHA's Office of Specialty Care Services and Office of Primary Care concur with this recommendation. Working in conjunction with the VHA Employee Education System and with input from subject matter experts in VHA's Office of Primary Care and other necessary offices, VHA's Office of

Specialty Care Services will develop a refresher training to complement the existing required training and updated to include additional information regarding PDMP requirements and VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*.

Status: Target Completion Date:

In process July 2020

Recommendation 4: Add an addendum to Directive 1306 that references the VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain and ensure VA clinicians are educated and receive annual training on the clinical practice guideline, to include the Centers for Disease Control and Prevention's recommended frequency for PDMP queries based on the patients' risk factors.

VHA Comments: Concur. VHA's Office of Primary Care will develop an addendum to VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*. The newly developed addendum will reference and clarify the frequency in which State PDMPs are to be monitored based on a Veteran's risk profile as outlined in the Centers for Disease Control (CDC) and VA/Department of Defense Clinical Practice Guidelines.

VHA's Office of Specialty Care Services, working in conjunction with VHA Employee Education System and with input from subject matter experts from the Office of Primary Care and other applicable program offices, will update the existing TMS Module #31108, *Pain Management and Opioid Safety*, to include additional information regarding PDMP requirements and VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*. The updated module will include the recommendations of the CDC Clinical Practice Guidelines, including the specific recommendation for PDMP queries.

VHA's Office of Specialty Care Services will issue an annual refresher Opioid Safety Training for providers who have completed the more comprehensive TMS #31108.

Status: Target Completion Date:

In process July 2020

Recommendation 5: Direct Veterans Integrated Service Networks and their VA medical facilities to ensure local policies are consistent with VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*.

VHA Comments: Concur. The Office of the ADUSH C/O will issue guidance to Veterans Integrated Service Networks (VISN) and VA medical facilities to ensure local policies are consistent with VHA Directive 1306, *Querying State Prescription Drug Monitoring Programs*. No later than 30 days from dissemination, each VISN is to submit a memorandum attesting compliance with the existing VHA Directive 1306 or an anticipated timeline outlining completion.

Status: Target Completion Date:

In process July 2020

VAOIT is responsible for this recommendation.

Recommendation 6: Develop automated information technology solutions to facilitate providers' access to PDMP information and reinforce the need to complete minimum annual VA-required PDMP queries.

VA OI&T Comments: Concur.

VA's Office of Information and Technology (OIT) will develop a short-term solution which automates the current process of obtaining state prescription drug monitoring program (PDMP) database information. At

present, the Clinician must manually log into the state PDMP, identify the Veteran to be queried, and review the resulting content. The Clinician completes a Progress Note in the Computerized Patient Record System (CPRS) to document compliance with the requirement to review.

The short-term solution will automate the lookup process. The CPRS user will select a patient and then select the tool to retrieve PDMP information. An automated process then queries all PDMP entities available to the Clinician. PDMP information is returned and placed automatically in a Progress Note in CPRS for the Clinician to review.

Status: Target Completion Date:

In process July 2020

Recommendation 7: Ensure Non-VA care providers are in good standing and have a current state medical license that requires adherence to their state's PDMP review requirements; adhere to the Veterans Affairs Opioid Safety Initiative Guidelines, including guidelines for PDMP reviews; and are monitored to ensure appropriate corrective actions are taken if their prescribing practices are found to be inconsistent with VA-DOD Clinical Practice Guidelines for Opioid Therapy for Chronic Pain.

VHA Comments: Concur. VHA Office of Community Care (OCC) agrees that monitoring non-VA providers medical license, Opioid Safety Initiative (OSI) Guidelines training, and opioid prescribing practices are paramount to Veteran safety and high-quality care.

VHA has implemented processes to ensure non-VA providers under the Community Care Network (CCN) contracts, Patient Centered Care Contract (PC3), and Veteran Care Agreements (VCA) have, and maintain, a medical license in good standing.

CCN and PC3 contractors are required to maintain documentation of all accreditation, certification, credentialing, privileging, and licensing for network providers performing services under each contract. The contractor must sign an attestation upon the notice to proceed and annually thereafter, certifying that all accreditation, certification, credentialing, privileging/competency measures and licensing requirements are met for network providers performing services under the contract. VHA reserves the right to perform random inspections of the accreditation, certification, credentialing, privileging/competency measures, and licensing files for any provider within the contractor's network.

VA medical center (VAMC) community care staff are required to ensure VCA providers' medical licenses are in good standing prior to entering into agreements. Documentation for each VCA is maintained for monitoring and historical tracking.

All non-VA providers are required to self-report changes in their status to the relevant CCN or PC3 contractor or the VAMC community care office within 15 days of a change.

VHA acts when a provider's license is revoked, expires, or is under investigation. When warranted, the OCC will deactivate the non-VA providers profile in the Provider Profile Management System (PPMS) and alert the local VAMC community care office to complete appropriate care coordination activities. PPMS is the authoritative OCC database for all non-VA providers.

To ensure all CCN, PC3 and VCA non-VA providers adhere to VA OSI Guidelines, VHA requires providers to complete mandatory OSI Guidelines training within 180 calendar days following entry into a contract or agreement. VHA tracks non-VA providers entry into the network and validates OSI Guidelines training completion. If a non-VA provider does not complete the OSI training, the provider is deactivated in the PPMS and can no longer receive referrals from VHA to provide care.

VHA is developing a monthly non-VA provider opioid prescribing data review process within each VISN. This review will be managed by each VISN's Community Care Oversight Council. The council will review the VHA OSI Dashboard to monitor non-VA providers percentage of opioids dispensed. The council will also review concerns raised from other sources including, VAMC managers, Veterans, Veterans' family members, State agencies, or other providers.

If the council identifies a non-VA provider with a concerning prescribing trend, an in-depth review based on the OSI Guidelines will be completed. If the in-depth review validates a concern, the council will report the findings to the existing VISN and VAMC Patient Safety Manager and notify the contractor's quality management office. For non-VA provider's delivering care through a VCA or local contract, the council will coordinate the review through the local VAMC.

In the event a non-VA provider is found to have inappropriate or unsafe prescribing practices, VHA will deactivate the non-VA providers PPMS profile and alert the local VAMC community care office to complete appropriate care coordination activities.

To demonstrate completion of this recommendation, OCC will provide the following documentation:

- CCN contract credentialing language and annual attestation
- PC3 credentialing language and annual attestation
- VCA Standard Operating Procedure (SOP)
- OSI Guidelines training monthly completion report
- OCC Oversight Council SOP
- Deputy Under Secretary for Health for Operations and Management Memo for opioid prescribing data review

Status: Target Completion Date:

In process November 2019

Recommendation 8: Ensure VISNs implement an effective PDMP oversight process that includes the review of PDMP compliance rates with medical facility directors.

VHA Comments: Concur. The Office of ADUSH C/O convened a small workgroup to examine possible technological solutions to address the monitoring of State PDMPs throughout VA medical facilities. Specifically, the Office of the ADUSH C/O, in conjunction with subject matter experts from VHA's Office of Primary Care, will collaborate with VHA Support Service Center to assess the feasibility of revising features of current reporting mechanisms. Furthermore, the Office of the ADUSH C/O will draft an Executive Decision Memorandum addressed to the VHA National Leadership Council recommending an oversight process of the PDMP.

Status: Target Completion Date:

In process July 2020

<p><i>For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.</i></p>
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## OIG Contact and Staff Acknowledgments

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<b>Contact</b>	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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