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# VA HEALTH CARE

Progress Made Towards Improving Opioid Safety, but Further Efforts to Assess Progress and Reduce Risk Are Needed

Accessible Version

# GAO Highlights

Highlights of GAO-18-380, a report to congressional committees

### Why GAO Did This Study

The Comprehensive Addiction and Recovery Act of 2016 and Senate Report 114-57 included provisions for GAO to report on VHA's OSI and the opioid prescribing practices of its health care providers.

This report examines, among other issues, (1) the extent to which VHA has met OSI goals established in 2014 and (2) the extent to which VHA providers adhere to key opioid risk mitigation strategies. To do this work, GAO reviewed data and documents related to OSI efforts and goals and interviewed VHA officials. In addition, GAO reviewed a random, nongeneralizable selection of medical records for 103 veterans who were prescribed opioids at five selected VHA medical facilities from March 2016 through March 2017. GAO selected the facilities to obtain diversity in geography and rates of opioid prescribing. At the selected facilities, GAO reviewed facility data and documents related to opioid safety and interviewed officials.

### What GAO Recommends

GAO is making five recommendations to VHA, including that it document actions and develop measurable outcomes related to its OSI goals, ensure that providers are adhering to opioid risk mitigation strategies, and ensure that all its regional networks have implemented academic detailing programs and that all VHA medical facilities have a designated primary care pain champion, as required. The Department of Veterans Affairs concurred with GAO's recommendations and described steps it will take to implement them.

View GAO-18-380. For more information, contact A. Nicole Clowers at (202) 512-7114 or clowersa@gao.gov.

# VA HEALTH CARE

### Progress Made Towards Improving Opioid Safety, but Further Efforts to Assess Progress and Reduce Risk Are Needed

### What GAO Found

The Veterans Health Administration (VHA) has made progress improving opioid safety through its Opioid Safety Initiative (OSI). Launched in 2013, the OSI aims to help ensure that veterans are prescribed opioids in a safe and effective manner. Since the OSI began, VHA has seen reductions in opioid prescribing rates. For example, from the fourth guarter of fiscal year 2013 to the first guarter of fiscal year 2018, the percentage of patients dispensed an opioid decreased from about 17 percent to about 10 percent, or by about 267,000 veterans. Also, available evidence suggests VHA has accomplished six of nine OSI goals established in 2014; however, it is unclear whether the remaining three goals have been fully met. For example, in the case of OSI goal four (establishing safe and effective regional tapering programs for patients on opioids and benzodiazepines), GAO found that VHA lacked documentation that its regional networks established these programs. VHA also did not establish measures of safety or effectiveness under this goal. These limitations prevent VHA from fully evaluating progress and accurately determining the extent to which its efforts to help ensure safe and effective prescribing of opioids have been successful.

In a review of a nongeneralizable sample of 103 veterans' medical records at five selected VHA medical facilities, GAO found that VHA providers did not always adhere to key opioid risk mitigation strategies, which are required by VHA policy or relevant to OSI goals. For example, among 53 veterans who were prescribed long-term opioid therapy (defined as a 90-day supply in the last 6 months), GAO found that

- 40 veterans did not have their names queried in a state-run prescription drug monitoring program database. The databases are used to identify patients who are receiving multiple prescriptions that may place them at greater risk for misusing opioids or overdosing;
- 21 veterans did not have a urine drug screening within the year prior to having their prescription filled. The screenings are used to determine whether veterans are taking their opioid medications as prescribed; and
- 12 veterans did not provide written informed consent. Informed consent is a formal acknowledgement that the veteran has been educated on the risks and benefits of opioid use prior to initiating long-term opioid therapy.

GAO found several factors that may have contributed to inconsistent adherence to key opioid risk mitigation strategies at the selected VHA facilities. For example, four of the five selected facilities did not have a pain champion (a primary care position required by VHA that can help providers adhere to opioid risk mitigation strategies), and not all facilities had access to academic detailing, a program in which trained clinical pharmacists work one-on-one with providers to better inform them about evidence-based care related to the appropriate treatment of relevant medical conditions. In addition, three of the five facilities did not consistently review veterans' medical records to ensure provider adherence to these strategies. To the extent that these factors affect all VHA facilities, VHA will continue to face challenges ensuring that its providers prescribe opioids in a safe and effective manner.

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### Abbreviations

CARA DOD	Comprehensive Addiction and Recovery Act of 2016 Department of Defense
OSI	Opioid Safety Initiative
OTRR	Opioid Therapy Risk Report
PDMP	prescription drug monitoring program
STORM	Stratification Tool for Opioid Risk Mitigation
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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**Congressional Committees** 

The United States is in the midst of an unprecedented opioid epidemic. According to 2016 data from the Substance and Mental Health Services Administration, nearly 12 million people age 12 or older misused opioids in the previous year. In addition, Centers for Disease Control data show that over 42,000 people died as a result of an opioid overdose in 2016 either from prescription opioids or illicit opioids such as heroin—a fivefold increase since 1999. According to the Department of Veterans Affairs' (VA) Veterans Health Administration (VHA), veterans are twice as likely to die from an accidental overdose when compared to the non-veteran population.

VHA has found that in its primary care settings, more than 50 percent of male veterans report having chronic pain, and the incidence among female veterans may be higher.<sup>1</sup> To help ensure that veterans are prescribed and use opioid pain medications in a safe and effective manner, VHA launched its national Opioid Safety Initiative (OSI) in 2013.<sup>2</sup> In 2014, VHA established a number of goals and requirements under the OSI aimed at improving the safety and care of veterans who are prescribed opioids for pain. In addition, in 2017, VA, along with the Department of Defense (DOD), updated its clinical practice guidelines related to opioid therapy for chronic pain to increase providers' awareness of evidence-based pain management practices.<sup>3</sup>

The Comprehensive Addiction and Recovery Act (CARA) of 2016 requires VA to implement a number of efforts aimed at improving opioid

<sup>1</sup>Veterans Affairs Academic Detailing Service, *Pain Management Opioid Safety VA Education Guide* (Washington, D.C.: 2014).

<sup>2</sup>According to VHA officials, the OSI rolled out nationwide during the 4<sup>th</sup> quarter of fiscal year 2013. Prior to the national roll out, according to officials, an OSI pilot task force was chartered in August 2012 and pilot programs were ongoing at various VHA facilities.

<sup>3</sup>Veterans Health Administration/Department of Defense, The Management of Opioid Therapy for Chronic Pain Working Group, *VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain* (Washington, D.C.: February 2017). Clinical practice guidelines are summaries of potential health care interventions designed to assist providers in their decision-making when creating a plan of care for a patient. Clinical practice guidelines typically describe the level of evidence associated with each intervention and provide recommendations based on that evidence. safety for veterans. CARA also includes a provision for GAO to assess VHA's recent efforts under the OSI as well as the opioid prescribing practices of VHA health care providers.<sup>4</sup> In addition, a Senate Report accompanying H.R. 2029, enacted as the 2016 Consolidated Appropriations Act, included a provision for GAO to review the effectiveness of the OSI and overall opioid prescribing patterns throughout VHA.<sup>5</sup> In this report, we

- describe key efforts VHA has undertaken since 2013 as a part of the OSI;
- examine the extent to which VHA has met its OSI goals established in 2014 and implemented certain provisions of CARA related to monitoring veterans who are prescribed opioids; and
- examine the extent to which VHA providers adhere to selected opioid risk mitigation strategies and clinical practice guideline recommendations related to prescribing opioids.

To describe key efforts VHA has undertaken since 2013 as a part of the OSI, we reviewed VHA documents and interviewed VHA Central Office officials regarding OSI efforts, including VHA efforts to monitor and address opioid prescribing patterns. We also analyzed data VHA collects under the OSI on four metrics related to rates of opioid prescribing and urine drug screening among certain veterans from the fourth guarter of fiscal year 2013 (roughly when the national OSI began at VHA) to the first guarter of fiscal year 2018, the most current guarter of data available at the time of our review. We also analyzed VHA data from its academic detailing programs on the frequency with which program representatives consulted with VHA providers on issues related to opioid safety.<sup>6</sup> We assessed the reliability of the data sources by reviewing relevant documentation, interviewing knowledgeable agency officials, and reviewing the data for missing values and outliers. Through these steps, we determined that the data were sufficiently reliable for the purposes of this reporting objective.

<sup>&</sup>lt;sup>4</sup>Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, § 913, 130 Stat. 695, 762.

<sup>&</sup>lt;sup>5</sup>See Pub. L. No. 114-31,129 Stat. 2242 (2015); S. Rep. 114-57, at 47 (2015).

<sup>&</sup>lt;sup>6</sup>Academic detailing is a program in which trained clinical pharmacists work one-on-one with providers to better inform them about evidence-based care related to the appropriate treatment of relevant medical conditions.

To examine VHA's progress on its 2014 OSI goals, we reviewed VHA documents and data relevant to OSI goals, including VHA opioid safety training data and OSI metric data. We also interviewed VHA Central Office officials, selected Veteran Integrated Service Network (VISN) officials, and VHA medical facility officials from 5 of 170 VHA medical facilities that we selected for our review.<sup>7</sup> We selected the 5 VHA medical facilities based on variation in geography and to reflect the full range of variation in the rate of change over time in the percentage of veterans who have been prescribed an opioid.<sup>8</sup> Our findings from the selected facilities are not generalizable to all VHA medical facilities. We examined VHA's progress on its OSI goals in the context of federal internal control standards for documentation requirements and the establishment and review of performance measures and indicators.<sup>9</sup> We assessed the reliability of the data sources by reviewing relevant documentation, interviewing knowledgeable agency officials, and reviewing the data for missing values and outliers. Through these steps, for the purposes of this reporting objective, we determined that the VISN-level opioid safety training assignment data were not reliable; however, all other data sources we analyzed were sufficiently reliable. To assess whether VHA is meeting certain provisions of CARA related to monitoring veterans who

<sup>9</sup>GAO, Standards for Internal Control in the Federal Government, GAO-14-704G (Washington, D.C.: Sept. 10, 2014) and Standards for Internal Control in the Federal Government, GAO/AIMD-00-21.3.1 (Washington, D.C.: Nov. 1, 1999). Internal control is a process effected by an entity's management, oversight body, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

<sup>&</sup>lt;sup>7</sup>VISNs are regional networks that manage the VHA medical facilities located in their region. In October 2015, VHA began to implement a realignment of its VISN boundaries which will result in the number of its VISNs decreasing from 21 to 18. For the purposes of this report, "VHA medical facilities" refers to medical centers, health care systems, or outpatient centers, including any affiliated community-based clinics.

<sup>&</sup>lt;sup>8</sup>Based on the OSI metric represented by the percentage of patients dispensed an opioid, we calculated the change over time from quarter 4, fiscal year 2012 through quarter 1, fiscal year 2017 for all VHA facilities, including the average change over time of all facilities. We selected one facility that exhibited the average change, two facilities above the average change, and two facilities below the average change. All facilities experienced a decrease in this metric over this time period except one, which experienced no change, while one facility in Manila, Philippines experienced an increase. Our selection process resulted in one facility that had among the greatest decreases and one facility that had among the lowest decreases. The VHA medical facilities we included in our review are based in Roseburg, OR (VISN 20); Hampton, VA (VISN 6); Columbus, OH (VISN 10); Tuscaloosa, AL (VISN 7); and Minneapolis, MN (VISN 23).

are prescribed opioids, we interviewed VHA Central Office officials and reviewed documents related to these provisions.<sup>10</sup>

To examine the extent to which VHA providers adhere to selected opioid risk mitigation strategies and clinical practice guideline recommendations related to prescription opioid therapy, we focused on three key VHA opioid risk mitigation strategies and three VA/DOD clinical practice guideline recommendations—all of which, generally speaking, are strong evidence-based strategies for reducing the potential health risks associated with opioid use.<sup>11</sup> The three opioid risk mitigation strategies are the following:

- an annual urine drug screening for patients on long-term opioid therapy (defined by VHA as having had a 90-day supply in the last 6 months; increasing these screenings is an explicit goal of the OSI;
- a VHA-required annual query of a prescription database maintained by a state prescription drug monitoring program when prescribing controlled substances, including opioids, to check for whether patients are receiving multiple prescriptions;<sup>12</sup> and
- obtaining written informed consent from patients on the use of opioids so that they have an informed understanding of the medications' risks and benefits, as required by VHA policy.<sup>13</sup>

<sup>&</sup>lt;sup>10</sup>CARA requires VHA to ensure that the Opioid Therapy Risk Report (OTRR), an opioid safety monitoring tool, has the ability to track whether a provider prescribed opioids to a veteran without first checking the information in the tool and to include in the OTRR information on the most recent time the tool was accessed by a provider. In addition, CARA requires VHA to modify its electronic medical record system to notify providers if a veteran is receiving opioid therapy and has a history of substance use disorder or prior overdose; has a history of opioid abuse; or is at risk of developing an opioid use disorder.

<sup>&</sup>lt;sup>11</sup>VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain. The guideline contains 18 recommendations.

<sup>&</sup>lt;sup>12</sup>Veterans Health Administration, *Querying State Prescription Drug Monitoring Programs*, VHA Directive 1306 (Washington, D.C.: Oct.19, 2016). This requirement is subject to limitations imposed by states on VA's access to state prescription drug monitoring databases.

<sup>&</sup>lt;sup>13</sup>Veterans Health Administration, *Informed Consent for Long-Term Opioid Therapy for Pain*, VHA Directive 1005 (Washington, D.C.: May 6, 2014). This requirement does not apply to patients enrolled in hospice or patients receiving long-term opioids for cancer pain.

The three clinical practice guideline recommendations are the following:

- the use of non-pharmacological treatments (such as cognitive behavioral therapy and yoga) in addition to or in lieu of opioid therapy;
- the prescribing of naloxone to help reverse opioid overdoses; and
- appropriate follow-up visits with a provider after an opioid is prescribed and after an opioid prescription is changed.<sup>14</sup>

To assess adherence to these opioid risk mitigation strategies and guideline recommendations, we reviewed a random, nongeneralizable sample of medical records for 103 veterans who had received long-term opioid therapy between March 1, 2016 and March 31, 2017. The 103 records we reviewed included a minimum of 20 records each from our five selected facilities. The sample of records also included records for 50 veterans at a greater risk of adverse events due to opioid use, including 25 veterans who received benzodiazepines concurrently with an opioid and another 25 veterans who were categorized as "very high" risk in VHA's opioid safety monitoring tool, the Stratification Tool for Opioid Risk Mitigation (STORM), during the summer and fall of 2017 when the medical record review was conducted.<sup>15</sup> As part of our work, we also reviewed relevant documents and interviewed officials from the five selected VHA medical facilities, the VISNs associated with the facilities, and VHA Central Office.

<sup>&</sup>lt;sup>14</sup>Guidance on the appropriate timing of pain management follow-up visits is provided in both the 2017 and 2010 VA/DOD clinical practice guidelines. Under the 2017 recommendation, follow-up pain management visits should be scheduled at least every 1-4 weeks after any change in medication regimen and at least once every 1-3 months for the duration of the therapy. This was a change from the 2010 recommendation, which we used for our analysis. The 2010 recommendation states that follow-up visits should be scheduled at least every 2-4 weeks after any change in medication regimen and at least once every 1-6 months for the duration of the therapy.

<sup>&</sup>lt;sup>15</sup>Benzodiazepines are a type of depressant that, among other things, produces sedation and relieves anxiety (e.g., Valium and Xanax). According to the 2017 VA/DOD clinical practice guideline for chronic pain, there is evidence that using opioids and benzodiazepines concurrently increases the risk of overdose and overdose death and therefore is not recommended. STORM is a clinical tool that provides 1-year and 3-year risk categories (i.e., low, medium, high, and very high) reflecting a patient's risk of an adverse event if opioids are prescribed, based on the veteran's individual medical history and characteristics. The 25 veterans we reviewed had "very high" risk categories for both the 1-year and 3-year estimates. For example, a patient with an 18 percent risk of a suicide- or overdose-related health care event or death in the next year would be categorized as "very high" risk by the tool.

We conducted this performance audit from November 2016 to May 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Background

### OSI goals and related requirements

To help ensure that veterans are prescribed and use opioid pain medications in a safe and effective manner, VHA launched its OSI nationally in 2013. VHA established nine OSI goals in a December 2014 memorandum. For each of the goals, VHA directed its VISNs and their associated VHA medical facilities to take specified actions to meet the goals. (See table 1.)

#### Table 1: Veterans Health Administration (VHA) Opioid Safety Initiative (OSI) goals and required actions, December 2014

OSI goal	VHA-required action
(1) Educate opioid prescribers regarding the effective use of urine drug screening	Veteran Integrated Service Networks (VISN) will establish a network-wide standardized education program by December 31, 2014
(2) Increase the use of urine drug screening	Urine drug screening targets based on previous urine drug screening rates for all VHA facilities by quarter 2, fiscal year 2015
(3) Facilitate the use of prescription drug monitoring program databases containing patient-level information on prescriptions for controlled substances	VISNs must certify by quarter 2, fiscal year 2015 that facilities have an education program that consists of training and/or education materials for providers
(4) Establish safe and effective VISN tapering programs for veterans using opioids and benzodiazepines	VISNs must develop local tapering protocols and plans to resource the implementation of those tapering protocols
(5) Develop tools to identify veterans at a higher risk for adverse events while using opioids	Develop an opioid risk stratification toolkit; opioid safety education guides must be updated annually
(6) Improve prescribing practices around long-acting opioid formulations	VISNs need to develop local tapering protocols and plans to resource the implementation of those tapering protocols
(7) Review treatment plans for veterans on high doses of opioids	VISN certification that patients with greater than a 200 morphine milligram equivalent dose per day have been reviewed by quarter 2, fiscal year 2015
(8) Offer complementary and alternative medicine modalities for chronic pain at all medical facilities	Each facility must provide evidence that at least two evidence-based behavioral/psychological treatments or approved complementary or alternative modalities can be provided by quarter 2, fiscal year 2015 <sup>a</sup>

OSI goal		VHA-required action
(9) Develop new models of mental health and p care collaboration to manage the prescribing o and benzodiazepines in patients with chronic p	of opioids	Identify strong practices that can be operationalized across VHA by quarter 3, fiscal year 2015; a request for proposal to be released to the field to establish model interdisciplinary teams and strategies for management and tapering of medications at three VHA medical facilities
Source: VHA.   GAO-18-380		
the	erapy for p	o VHA, evidence-based behavioral/psychological treatments include cognitive behavioral bain and relaxation practices, and approved complementary and alternative modalities buncture, acupressure, yoga and progressive relaxation.
to st	o follow trategie:	also developed opioid risk mitigation strategies for its providers when prescribing opioid pain medications to veterans. These key s include one whose increased use is an explicit goal for the OSI that are requirements in VHA policy.
1.	Provi been least preso types	al urine drug screening for veterans on long-term opioid therapy. ders should generally ensure that a urine drug screening has conducted for veterans who are on long-term opioid therapy at once in the 365 days prior to initiating or renewing an opioid cription. <sup>16</sup> Urine drug screening allows providers to monitor the of drugs that are in a veteran's system, including controlled and substances. Increasing the use of urine drug screening is OSI two.
2.	are s dispe suspe and in policy presc presc	al prescription drug monitoring program (PDMP) query. PDMPs tate-run electronic databases used to track the prescribing and nsing of prescriptions for controlled substances, identify ected misuse or diversion (i.e., channeling drugs into illegal use), dentify trends in drug utilization. In 2016, VHA began requiring in 7 that providers query state PDMPs at least once annually when tribing opioids to determine whether their patients have received triptions for opioid medications or other controlled substances non-VA providers. <sup>17</sup>
3.	requi	ned consent for long-term opioid therapy. In 2014, VHA began ring in policy that providers educate their patients on the risks ciated with the use of prescription opioids and to obtain veterans'
	VHA defi the last 6	nes long-term opioid therapy as having had a 90-day supply or more of opioids 6 months.

<sup>&</sup>lt;sup>17</sup>Veterans Health Administration, *Querying State Prescription Drug Monitoring Programs*, VHA Directive 1306 (Washington, D.C.: Oct.19, 2016). This requirement is subject to limitations imposed by states, which can impact VHA providers' access to PDMP databases. According to VHA policy, providers should follow state regulations for PDMP queries if these regulations are more stringent than VHA's policy.

formal acknowledgment of these risks in writing prior to initiating long-term opioid therapy.  $^{\ensuremath{^{18}}}$ 

# Clinical Practice Guidelines for the Treatment of Chronic Pain

In 2010, in coordination with DOD, VA developed clinical practice guidelines for its providers to use when prescribing opioids for chronic pain. These guidelines were updated in 2017.<sup>19</sup> While clinical practice guidelines contain evidence-based recommendations, they are not required to be followed in all clinical situations; therefore, variations in practice may occur based on individual patient needs subject to the discretion of the provider.

The 2017 VA/DOD clinical practice guidelines related to opioid therapy for chronic pain generally complement VHA's OSI goals. For example, the guidelines recommend a conservative use of opioids for chronic pain and emphasize strategies to mitigate the risk of using opioids. The evidence-based clinical practice guideline recommendations include the following:

- 1. <u>Use of non-pharmacological treatments.</u> The guidelines advise not initiating opioid therapy for chronic pain. They also recommend alternatives to opioid therapy, such as non-opioid medications and non-pharmacological treatments. Non-pharmacological treatments for chronic pain include, for example, cognitive behavioral therapy and yoga.
- 2. <u>Naloxone prescribing.</u> Naloxone is a highly effective, potentially lifesaving intervention for reversing opioid overdoses, and it can be prescribed to veterans as a preventive measure. Veterans who are prescribed naloxone can use it when experiencing an overdose or a

<sup>&</sup>lt;sup>18</sup>Veterans Health Administration, *Informed Consent for Long-Term Opioid Therapy for Pain*, VHA Directive 1005 (Washington, D.C.: May 6, 2014). This requirement does not apply to patients enrolled in hospice or patients receiving long-term opioids for cancer pain.

<sup>&</sup>lt;sup>19</sup>A Senate report directed VA, in consultation with DOD, to update its clinical practice guideline for chronic pain no later than December 31, 2016. See S. Rep. No. 114-57, at 46 (2015). According to a VHA official, generally speaking, the recommendations contained in the VA/DOD clinical practice guideline for opioid therapy for chronic pain are largely consistent with the Centers for Disease Control's 2016 Guideline for Prescribing Opioids for Chronic Pain. See Centers for Disease Control, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* (Atlanta: March 18, 2016).

family member can administer it on their behalf. According to the clinical practice guidelines, naloxone should be offered as an antidote to all patients at risk for an opioid overdose, including those who are in the process of tapering from opioids.<sup>20</sup> The guidelines describe several significant risk factors which can indicate the prescribing of naloxone, including the duration and dose of opioids, current or history of depression or substance use disorder, and suicidality.

 <u>Appropriate follow-up visits with a provider</u>. According to the guidelines, follow-up pain management visits should be scheduled at least every 1-4 weeks after any change in medication regimen and at least once every 1-3 months for the duration of the therapy to help ensure that the treatment plan is optimized.<sup>21</sup>

# Under Its OSI, VHA Tracks Opioid Prescribing Patterns, Identifies Prescribing Outliers, and Educates Prescribers

VHA officials told us that the main focus of the OSI is changing the prescribing patterns of providers to better align with evidence-based practices. We found that this has been carried out by VHA through three key efforts: tracking opioid prescribing rates and other trends, identifying irregular prescribing patterns, and educating providers on best practices through academic detailing.

*Tracking Opioid Prescribing Patterns.* Under the OSI, VHA uses quarterly data derived from VHA's electronic medical record system to monitor prescription opioid use among veterans, the related prescribing patterns of VHA providers, and the rates of urine drug screening for veterans

<sup>&</sup>lt;sup>20</sup>CARA directs VHA to maximize the availability of naloxone to veterans and to ensure that veterans who are considered at risk for opioid overdose have access to naloxone and training on its proper administration. Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, § 911(e)(1), 130 Stat. 695, 759.

<sup>&</sup>lt;sup>21</sup>This 2017 recommendation represents a change from the 2010 clinical practice guideline, which states that follow-up visits should be scheduled at least every 1-4 weeks after any change in medication regimen and at least once every 1-6 months for the duration of the therapy.

receiving long-term opioid therapy.<sup>22</sup> Specifically, VHA tracks the following four clinical indicators, known as the OSI metrics, for each of its medical facilities:

- 1. the percentage of patients dispensed an opioid,
- 2. the percentage of patients dispensed an opioid and a benzodiazepine,
- the percentage of patients on long-term opioid therapy who received a urine drug screen within the previous year of having their prescription filled, and
- 4. the percentage of patients dispensed greater than or equal to 100 morphine milligram equivalents per day.<sup>23</sup>

Our analysis of quarterly OSI metric data shows that since the beginning of the OSI in the fourth quarter of fiscal year 2013 to the first quarter of fiscal year 2018 (the most recent data available at the time of our review), the percentage of veterans dispensed an opioid has decreased by 7 percentage points, or roughly 267,000 veterans, while the rate of urine drug screening for veterans on long-term opioid therapy increased significantly—by over 47 percentage points. The increase in the percentage of patients receiving a urine drug screening was driven more by a reduction in the total number of patients on long-term opioid therapy (about 197,000 veterans) than an increase in the number of patients receiving the screening (about 27,000 veterans). (See table 2.)

 Table 2: Changes in Veterans Health Administration (VHA) Opioid Safety Initiative (OSI) metrics, Fourth Quarter Fiscal Year

 2014 through First Quarter, Fiscal Year 2018

OSI metric	Fiscal year 2013 (4th quarter)	Fiscal year 2018 (1st quarter)	Percentage point change
Percentage of patients dispensed an opioid <sup>a</sup>	16.7 (665,786 of 3,984,165 patients)	9.7 (398,899 of 4,130,536 patients)	- 7.1 (- 266,887 patients)
Percentage of patients dispensed an opioid and a benzodiazepine <sup>b</sup>	13.2 (116,739 / 885,142)	6.6 (36,938 / 558,199)	- 6.6 (- 79,801)

<sup>22</sup>VHA defines long-term opioid therapy as having had a 90-day supply or more of opioids in the last 6 months. VHA began making the quarterly opioid prescribing data it tracks publicly available in January 2018. See

https://www.data.va.gov/story/department-veterans-affairs-opioid-prescribing-data (last access date: March 14, 2018).

<sup>23</sup>The 2017 VA/DOD clinical practice guideline for chronic pain does not recommend opioid doses of greater than 90 morphine milligram equivalents per day.

OSI metric	Fiscal year 2013 (4th quarter)	Fiscal year 2018 (1st quarter)	Percentage point change
Percentage of patients on long-	42.2	89.2	+ 47.0 <sup>e</sup>
term opioid therapy having received a urine drug screen within the previous year of having their prescription filled <sup>c</sup>	(182,194 / 431,694)	(209,102 / 234,392)	(+ 26,908)
Percentage of patients dispensed greater than or equal to a 100 morphine milligram equivalents per day <sup>d</sup>	6.5 (56,831 / 869,956)	4.4 (23,968 / 543,782)	- 2.1 (- 32,863)

Source: VHA. | GAO-18-380

Notes: 4th quarter, fiscal year 2013=July to September 2013. 1st quarter, fiscal year 2018=October to December 2017.

<sup>a</sup>Denominator=patients who were dispensed at least one outpatient prescription during the reporting timeframe.

<sup>b</sup>Denominator=patients who were dispensed opioids, including tramadol, in the reporting timeframe.

<sup>c</sup>Denominator=patients who were dispensed at least one opioid medication in the reporting timeframe and had a total supply of opioids greater than or equal to 90 days for the selected quarter and the prior quarter. Increasing the use of urine drug screening is an explicit goal of the OSI.

<sup>d</sup>Denominator=patients who were dispensed opioids, including tramadol, in the reporting timeframe. The 2017 VA/DOD clinical practice guideline for chronic pain does not recommend opioid doses of greater than 90 morphine milligram equivalents per day.

<sup>e</sup>The increase in the rate of urine drug screening was driven more by a reduction in the number of veterans on long-term opioid therapy than an increase in the number of veterans receiving screening over time.

*Identifying Irregular Prescribing Patterns.* As part of its monitoring of the OSI metrics, VHA Central Office has periodically identified VHA medical facilities and VHA providers who deviate from average prescribing rates across VHA. For example:

<u>Facilities.</u> In 2014, VHA Central Office identified 39 of 140 medical facilities across 12 VISNs with relatively higher rates of opioid dispensing as outliers based on the OSI metric percentage of veterans dispensed an opioid.<sup>24</sup> VHA Central Office notified the VISNs of these facilities and required each facility to submit a corrective action plan to VHA Central Office outlining the actions they would take to reduce opioid prescribing. Based on our analysis of VHA documents, we found that the identified facilities in the five VISNs

<sup>&</sup>lt;sup>24</sup>Outlier VHA medical facilities were flagged if the facility's rate of decrease in opioid dispensing between fiscal year 2012 to fiscal year 2014 was less than the national rate of decrease, or if opioid dispensing increased during this time period.

selected for our review submitted information in response to VHA Central Office's request.<sup>25</sup>

Providers. In February 2017, VHA Central Office identified 320 outliers out of 8.351 providers at 94 VHA medical facilities based on the relatively high proportion of their patients who were prescribed opioids.<sup>26</sup> VHA Central Office directed the VHA medical facilities associated with these outlier providers to review their prescribing rates in the context of their clinical practice, and to report back with any feedback given or actions taken. According to officials from the five facilities in our review, outlier providers tended to be surgeons. pain management specialists, or physical rehabilitation providers who might be expected to prescribe opioids at a higher-than-average rate due to the nature of their specialty and the types of patients they treat. According to a VHA Central Office progress report, the facilities provided feedback and follow-up actions for 319 out of 320 outlier providers.<sup>27</sup> In May 2017, VHA identified a second round of 303 outliers out of 8,505 providers; 187 of these providers were previously identified as outliers in February 2017.28 According to one VHA Central Office official, as of September 2017, VHA was reviewing these outlier data and will evaluate whether VHA facilities will be asked to conduct further reviews of these prescribers.

*Educating Providers through Academic Detailing.* To help change the prescribing patterns of providers, VHA has also implemented a system-wide academic detailing program to educate providers and improve the delivery of evidence-based health care at facilities. In 2015, VHA required each VISN to establish such a program to improve performance on all

<sup>27</sup>While we discussed these responses with facility officials in our review, we did not verify or evaluate any actions taken in response to outlier prescribers.

<sup>28</sup>Providers were identified as outliers if (1) the provider wrote at least one opioid prescription; (2) prescribed at least one medication of any type to a minimum of 150 veterans from January 2017 through March 2017; and (3) the provider's percentage of opioid prescriptions was greater than two standard deviations from the national mean for the same time period.

<sup>&</sup>lt;sup>25</sup>We did not review the extent to which these VHA medical facilities completed the steps identified in their action plan or the extent to which VISNs or VHA Central Office monitored the completion of the action plans.

<sup>&</sup>lt;sup>26</sup>Providers were identified as outliers if (1) the provider wrote at least one opioid prescription; (2) prescribed at least one medication of any type to a minimum of 150 veterans from October 2016 through December 2016; and (3) the provider's percentage of opioid prescriptions was greater than two standard deviations from the national mean for the same time period.

OSI metrics.<sup>29</sup> According to VHA Central Office officials, academic detailers are responsible for reviewing facility-level data on the prescribing patterns of providers and identifying potential areas of improvement. Detailers can educate providers with higher-than-average prescribing rates—such as those outliers identified in February and May 2017 by VHA Central Office—to help ensure providers are delivering safe and effective care for pain.

According to VHA, as of January 2018, academic detailers have conducted over 20,000 opioid-related visits to VHA providers. According to VHA officials, their data also show that academic detailing results in greater patient safety for veterans taking opioids. For example, compared with those who did not receive academic detailing visits, providers who did receive such visits experienced (1) greater reductions in the proportion of their patients on high-dose opioids, (2) reductions in their patients' average morphine milligram equivalent daily dosage, and (3) increases in their naloxone prescribing rates.<sup>30</sup>

<sup>&</sup>lt;sup>29</sup>VHA Central Office requires a minimum of three full-time equivalent detailers for each VISN.

<sup>&</sup>lt;sup>30</sup>For example, according to VHA, their data show that from October 2013 to September 2016, the proportion of patients on high-dose opioids decreased by 58 percent among providers who had received an academic detailing visit, compared to a 34 percent decrease among providers who did not receive an academic detailing visit. From October 2015 to September 2016, the average morphine milligram equivalent daily dosage decreased 59 percent among providers who met with a detailer, compared to 31 percent for those who did not. Finally, 1 year after visiting with a detailer, the average number of naloxone prescriptions per month was three times greater among providers who received an academic detailing visit compared with those who did not. See M Bounthavong et al. "Trends in naloxone prescriptions prescribed after implementation of a National Academic Detailing Service in the Veterans Health Administration: A preliminary analysis." *Journal of the American Pharmacists Association* (2017) S68-S72.

VHA Has Made Progress on OSI Goals, but Performance Measurement Limitations Exist for Some Goals and Certain CARA Provisions Have Not Been Fully Implemented

VHA Has Made Progress on Many 2014 OSI Goals, but for Some Goals, Performance Measurement Limitations Prevent an Accurate Determination of their Completion

Based on our analysis of VHA information, we found evidence suggesting that the agency has accomplished six of the nine 2014 OSI goals. For example, the agency has seen increases in the use of urine drug screening for veterans on long-term opioid therapy, and it has developed provider tools to identify veterans at a higher risk for adverse events while using opioids. For several goals, although VHA did not implement the actions required in all those instances, the agency provided us with information or data demonstrating that the goals had effectively been met. However, for three OSI goals, it is unclear if the goal has been fully met because VHA lacks documentation showing that it has implemented the required action under the goal or the required action is still in progress. (See table 3.)

Goals	VHA required action(s)	Were these required action(s) completed?	Did VHA provide documentation that other actions met the goal?
(1) Educate opioid prescribers regarding the effective use of urine drug screening	Each VISN must establish a network-wide standardized education program by December 31, 2014	No	Yes
(2) Increase the use of urine drug screening	Urine drug screening targets based on previous urine drug screening rates for all VHA facilities must be reached by quarter 2, fiscal year 2015 (March 31, 2015)	No	Yes

### Table 3: Status of Veterans Health Administration (VHA) 2014 Opioid Safety Initiative (OSI) Goals as of March 2018

Goals	VHA required action(s)	Were these required action(s) completed?	Did VHA provide documentation that other actions met the goal?
(3) Facilitate the use of prescription drug monitoring program (PDMP) databases, which contain patient-level information on prescriptions received for controlled substances	Each VISN must certify by quarter 2, fiscal year 2015 (March 31, 2015), that all facilities have a program consisting of PDMP training and/or education materials for providers	No	Yes
(4) Establish safe and effective Veteran Integrated Service Network (VISN) tapering programs for veterans using opioids and benzodiazepines	VISNs must develop local tapering protocols and plans to resource the implementation of those tapering protocols	No	No. VHA lacks documentation related to the required action and could not provide evidence to indicate the goal was accomplished.
(5) Develop tools to identify veterans at a higher risk for adverse events while using opioids	An opioid risk stratification toolkit must be developed; opioid safety education guides must be updated annually	Yes	Yes
(6) Improve prescribing practices around long-acting opioid formulations	VISNs must develop local tapering protocols and plans to resource the implementation of those tapering protocols	No	Yes
(7) Review treatment plans for veterans on high doses of opioids	Each VISN must certify that the treatment of all patients with greater than a 200 morphine milligram equivalent dose per day has been reviewed by quarter 2, fiscal year 2015 (March 31, 2015)	No	No. VHA lacks documentation related to the required action and could not provide evidence to indicate the goal was accomplished.
(8) Offer complementary and alternative medicine modalities for chronic pain at all medical facilities	Each facility must provide evidence that at least one evidence-based psychosocial service and one approved complementary and integrative service is available by quarter 2, fiscal year 2015 (March 31, 2015)	Yes	Yes
(9) Develop new models of mental health and primary care collaboration to manage the prescribing of opioids and benzodiazepines in patients with chronic pain	Identify strong practices that can be operationalized across VHA by quarter 3, fiscal year 2015 (June 30, 2015); a request for proposal to be released to the field to establish model interdisciplinary teams and strategies for management and tapering of medications at three VHA medical facilities	No	To be determined. VHA reported other actions are underway to address this goal.

Source: GAO analysis of VHA information. | GAO-18-380

(See appendix I for a more detailed description of VHA's known efforts and data related to each goal).

When asked about the lack of documentation for two of its OSI goals (goals four and seven), VHA officials told us that relevant documentation could not be produced. This lack of documentation is inconsistent with federal internal control standards. Specifically, according to federal internal control standards, management should evaluate and document the results of monitoring.<sup>31</sup> By not documenting the actions it is taking under each of its OSI goals, VHA lacks assurance that these actions have been implemented by the VISNs or VHA medical facilities. As a result, VHA does not know whether it has fully met these OSI goals.

Moreover, for the OSI goal related to establishing safe and effective VISN tapering programs for veterans using opioids and benzodiazepines (goal four), VHA officials told us that they addressed this goal by issuing national tapering guidance, including a provider reference guide in 2014, an opioid taper decision tool in 2016, and the VA/DOD clinical practice guidelines in 2017. However, these actions do not appear to be sufficient for meeting the goal as it is currently written, because issuing national guidance alone does not ensure that safe and effective tapering programs are established.<sup>32</sup> Furthermore, VHA did not specify how safety and effectiveness within a tapering program would be measured, nor did the agency specify a deadline for the required action as described in December 2014. According to federal internal control standards relating to the establishment and review of performance measures and indicators, government agencies should use appropriate information to adequately assess performance, including establishing milestones or numerical targets, as appropriate.<sup>33</sup> Without clearly defined and measurable outcomes, VHA cannot fully assess its progress towards meeting this OSI goal.

<sup>33</sup>GAO-14-704G and GAO/AIMD-00-21.3.1.

<sup>&</sup>lt;sup>31</sup>GAO-14-704G and GAO/AIMD-00-21.3.1.

<sup>&</sup>lt;sup>32</sup>VHA officials told us they have not updated the 2014 OSI goals since the December 2014 memo was issued. According to one VHA official, CARA requirements and the issuance of the VA/DOD clinical practice guideline for chronic pain superseded the 2014 OSI goals and made any follow-up of the 2014 OSI goals obsolete. However, VHA did not provide any documentation during our review indicating that VHA Central Office determined that the 2014 OSI goals became obsolete given new priorities or that this determination was communicated to the medical facilities.

### VHA Has Not Implemented Certain CARA Requirements Related to Monitoring Veterans Prescribed Opioids

We also found that VHA has not implemented two CARA requirements intended to improve opioid safety for veterans. First, CARA requires that VHA's Opioid Therapy Risk Report (OTRR) have the ability to determine whether a provider has prescribed opioids to a veteran without checking that veteran's information in the OTRR.<sup>34</sup> Available to providers through VHA's electronic medical record system, OTRR is a clinical tool that provides information on any opioid and concurrent benzodiazepine prescriptions a veteran is receiving, the veteran's current and prior health conditions, recent and upcoming appointments, and whether any opioid risk mitigation strategies have been employed (such as urine drug screening or PDMP guery).<sup>35</sup> However, we found that VHA Central Office cannot track the extent to which VHA providers use OTRR because this tool does not have this tracking capability.<sup>36</sup> VHA officials said that adding tracking capabilities to OTRR is not a high priority for the agency due to limited resources and competing priorities. Instead, according to a draft memorandum. VHA Central Office is planning to address this CARA provision by requiring VHA providers to document the use of OTRR in a standardized way that VHA can monitor. However, as of March 2018, VHA has not established this requirement or outlined the process for monitoring providers' use of OTRR. Without the ability to track the use of OTRR, VHA cannot sufficiently monitor whether providers are using the

<sup>34</sup>CARA requires the Secretary to include in the OTRR tool information on the most recent time the tool was accessed by a provider with respect to each veteran as well as information on the results of the most recent urine drug test for each veteran. See Pub. L. No. 114-198, § 911(f), 130 Stat. 695, 759. CARA also states that the Secretary shall establish guidance that each provider, before initiating opioid therapy to treat a patient as part of the comprehensive assessment conducted by the health care provider, use the OTRR tool (or any subsequent tool). Pub. L. No. 114-198, § 911(a)(2), 130 Stat. 695, 756.

<sup>35</sup>VHA has another tool, STORM, available to providers to help monitor patients prescribed opioids. It provides risk scores based on veterans' individual medical histories and characteristics indicating the risk of an adverse event if opioids are prescribed. To help providers determine the level of risk if an opioid prescription is started, increased, or reduced, hypothetical risk scores are available to providers through STORM. According to VHA officials, the agency plans to meet some CARA requirements with STORM rather than OTRR.

<sup>36</sup>VHA is able to track generally how many times providers have accessed OTRR, but OTRR cannot provide any more specific details, such as which providers accessed the tool and whether they did so prior to initiating opioid therapy for a particular veteran. In the case of STORM, officials said that they can tell whether providers have accessed STORM, but they cannot track which particular veterans were reviewed.

tool to help reduce the likelihood of opioid-related adverse events occurring among veterans receiving care through VHA.

CARA also requires that VHA modify its electronic medical record system so that any provider who accesses the record of a veteran will be notified whether that veteran is receiving opioid therapy and has a history of substance abuse disorder or prior instances of overdose; has a history of opioid abuse; or is at risk of developing an opioid use disorder. However, we found that VHA does not plan to modify its electronic medical record system to implement this capability. When asked about this provision in CARA, VHA officials said that VHA's medical record currently has realtime alerts to inform providers about veterans' existing opioid prescriptions and that any patient exposed to an opioid could be at risk of developing an opioid use disorder. Additionally, they said that an alert regarding current or past history of opioid use disorder could have an unintended consequence of discouraging veterans from reporting their medical history due to the stigma surrounding drug use disorders.

VHA Providers Do Not Always Adhere to Required Opioid Safety Risk Mitigation Strategies and Guideline Recommendations for Prescribing Opioids in a Safe Manner

VHA Providers at Selected Medical Facilities Do Not Consistently Follow Opioid Risk Mitigation Strategies

Our review of selected VHA medical facilities shows that providers do not always follow three key opioid risk mitigation strategies, two of which are required under VHA policy. Specifically, increasing the use of urine drug screening is an explicit goal of the OSI, and providers should generally ensure that an annual urine drug screening has been conducted. VHA policy requires providers to 1) query state PDMPs at least annually when prescribing opioids to determine if the veteran has obtained opioid medications or other controlled substances from a non-VA provider and 2) obtain written informed consent from patients about the risks of initiating long-term opioid therapy. These strategies are intended to help ensure that patients at VHA medical facilities are safely prescribed opioid medications. Overall, based on our review of 103 veterans at five selected facilities, we found that 75 percent of the veterans in our sample had an annual urine screening, 26 percent had their names queried in a PDMP, and 70 percent provided informed consent.<sup>37</sup>

# Provider Adherence to Three Veterans Health Administration (VHA) Opioid Risk Mitigation Strategies at Five Selected Medical Facilities, March 2016 through March 2017

Increasing the use of urine drug screening is an explicit goal of VHA's Opioid Safety Initiative (OSI), and providers should generally ensure that an annual urine drug screening has been conducted. VHA policy requires providers to (1) query state prescription drug monitoring programs (PDMP) at least annually when prescribing opioids to determine if the veteran has obtained opioid medications or other controlled substances from a non-VA provider, and (2) obtain written informed consent from patients about the risks of initiating long-term opioid therapy. However, our review of medical records for a random nongeneralizable selection of 103 veterans subject to these risk mitigation strategies found that

Of the 53 veterans who received long-term opioid therapy:<sup>a</sup>

- 32 veterans received an annual urine drug screening, which allows providers to monitor the types of medications in a veteran's system, including controlled and illicit substances;
- 13 veterans had their names queried annually in a state PDMP to see if they had received prescriptions for controlled substances, including opioids from non-VHA prescribers; and
- 41 veterans had provided informed consent indicating that they had been educated on the risks and benefits of opioid use. Of the 25 veterans prescribed an opioid and benzodiazepine concurrently:
  - 17 veterans received an annual urine drug screening;
  - 8 veterans had an annual PDMP query; and
  - 22 veterans had provided informed consent.

Of the 25 veterans with the highest risk of an adverse event, such as a suicide, overdose, fall, or accident, based on their Stratified Tool for Opioid Risk Mitigation (STORM) risk score.<sup>b</sup>

- 24 veterans received an annual urine drug screening;
- 5 veterans had an annual PDMP query; and
- 11 veterans had provided informed consent.

Source: GAO analysis of veterans' medical records. | GAO-18-380

<sup>a</sup>VHA defines long-term opioid therapy as a 90-day supply of opioid medication prescribed in a 6month period.

<sup>b</sup>The Stratified Tool for Opioid Risk Management (STORM) is designed to help providers estimate veteran risk for an overdose or suicide-related event and provide suggested interventions to mitigate that risk. It provides 1-year and 3-year risk categories (i.e., low, medium, high, and very high) reflecting a patient's risk of an adverse event if opioids are prescribed, based on the veteran's

<sup>37</sup>Our findings related to urine drug screening and informed consent at the five selected VHA medical facilities are consistent with VHA data for all of its medical facilities. For the period April 1, 2017 through June 31, 2017, VHA data show that nationwide about 87 percent of veterans on long-term opioid therapy received an annual urine drug screening. For the period January 1, 2017 through March 31, 2017, about 83 percent of veterans who were prescribed long-acting or chronic short-acting (excluding schedule IV and V) opioids provided informed consent. However, our results are not consistent with nationwide VHA data for the period April 1, 2017 through June 31, 2017 showing that about 63 percent of veterans for whom long-acting or chronic short-acting opioids were prescribed had their names queried in a PDMP. This inconsistency is partly due to the fact that VHA did not require providers to query the PDMP until October 2016, 7 months into our review of patients from March 2016 to March 2017.

individual medical history and characteristics. The 25 veterans we reviewed had "very high" risk categories for both the 1-year and 3-year estimates. For example, a patient with an 18 percent risk of a suicide- or overdose-related health care event or death in the next year would be categorized as "very high" risk by the tool.

We identified a number of factors that may have contributed to the inconsistent adherence to the three key opioid risk mitigation strategies at our selected VHA medical facilities. These factors may impede providers' ability to consistently follow these strategies for all applicable patients at these facilities. To the extent that these factors are present across other facilities, VHA's ability to ensure that all veterans are prescribed opioids in a safe and effective manner may be limited.

PDMP access issues. Officials at four of the five selected medical facilities faced PDMP access issues. Officials at two facilities told us that not all facility staff can access state PDMPs due to state laws and regulations that do not allow access to all types of providers, such as nurses and pharmacists.<sup>38</sup> Officials at one of these selected facilities explained that nurse practitioners in that state cannot access the state's PDMP, so they must rely on other providers to obtain information from the PDMP about their patients. In addition, in some states, only providers licensed in the state may access the state's PDMP. Because providers at VHA facilities may not be licensed in the state where the VHA facility is located but licensed in another state, these providers may be unable to access the state's PDMP. Officials at two selected facilities also described difficulties accessing PDMPs in neighboring states that are part of the catchment area for the facility and where the veteran may reside. The low rates of adherence we identified may also be attributed to the fact that VHA did not require providers to query the PDMP until October 2016, 7 months into our review of patients from March 2016 to March 2017.

CARA directed VA to ensure access by VHA providers to information on controlled substances prescribing through state PDMPs, including by seeking to enter into memoranda of understanding with states to allow shared access of such information between states and the VA. According to VHA officials, VHA Central Office has not taken steps to develop memoranda of understanding with states, nor has it developed any related guidance. Officials said this issue is likely being addressed by individual VISNs and medical facilities. In addition, VHA officials told us

<sup>&</sup>lt;sup>38</sup>The VHA directive requiring that providers query PDMPs notes that the requirement is subject to limitations imposed by states, which can impact VHA providers' access to PDMP databases.

they have communicated with Members of Congress and the National Governors Association to address issues related to VHA provider access to the state PDMPs.<sup>39</sup>

Lack of required staff to support providers. We also found that not all of the selected medical facilities and their respective VISNs had filled required staff positions that can help ensure provider adherence to opioid risk mitigation strategies—specifically, academic detailers and pain champions.

- At the time of our review, not all facilities had access to VISN academic detailing services, which, according to VHA, can help ensure that providers follow opioid risk mitigation strategies. While VHA officials said that most VISNs across VHA had implemented an academic detailing program as required by VHA policy, two of the five VISNs for the selected facilities in our review had not.<sup>40</sup> Nationally, as of March 2018, four VISNs had not implemented an academic detailing program. Additionally, 11 facilities across VHA had not received a visit from a detailer.
- At the time of our review, four of five selected facilities did not have a Pain Champion as required by VHA policy beginning in March 2015.<sup>41</sup> Pain champions are generally primary care providers knowledgeable about pain care who can serve as a resource for other primary care providers by promoting safe and effective pain care. According to VHA officials, pain champions play a critical role in opioid safety and can help providers remedy gaps in pain care management for individual patients, such as incomplete opioid risk mitigation strategies.

<sup>&</sup>lt;sup>39</sup>An assessment of legal challenges affecting VHA providers' access to state PDMPs was outside the scope of our review.

<sup>&</sup>lt;sup>40</sup>VHA requires that all VISNs fully implement an academic detailing program by September 30, 2015, defined as having at least three full time equivalent detailers. According to VHA Central Office officials, some VISNs have not met this requirement due to limits on the number of full time equivalent positions at the VISN. See VHA Memorandum, *System-wide Implementation of Academic Detailing and Pain Program Champions* (Washington, D.C.: March 27, 2015).

<sup>&</sup>lt;sup>41</sup>VHA policy requires each medical facility to maintain a 0.25-0.50 full-time equivalent pain champion serving in primary care. See VHA Memorandum, *System-wide Implementation of Academic Detailing and Pain Program Champions* (Washington, D.C.: March 27, 2015).

*Lack of clinical opioid safety alerts.* Another factor that may limit adherence to the opioid risk mitigation strategies is the fact that none of the selected facilities employ electronic reminders to help remind primary care nurses of strategies that have not been completed. Primary care nurses are typically responsible for ensuring adherence to these strategies, and VHA facilities often employ electronic alerts to notify providers when certain tasks need to be completed, such as regular screenings for depression and traumatic brain injury. Although VHA facilities are not required to develop these alerts, according to some primary care nurses we interviewed, it would be helpful to receive a reminder when a veteran is due for a PDMP query, urine drug screening, or has not given long-term opioid use informed consent. According to the nurses, such an alert could be issued through the electronic medical record system.<sup>42</sup>

*Limited facility monitoring.* We found that facilities' monitoring of provider adherence to the opioid risk mitigation strategies was limited across the five selected facilities in our review, which could hinder identification of non-adherence to these strategies. Specifically, while we found that all five medical facilities and VISNs in our review have an active pain management committee, facility officials told us that three of five facility committees do not conduct regular medical record reviews, which VHA encourages under its pain management directive to improve pain management.<sup>43</sup> The directive states that facility pain management committees should monitor the pain management practices at their facility. For example, the pain management committee could monitor providers' care plans for individual veterans, which are to be documented in the veterans' medical records. These types of medical record reviews could help identify providers who are not adhering to VHA's opioid safety requirements.

<sup>&</sup>lt;sup>42</sup>According to facility officials, one facility in our review has alerts to remind prescribers to order a urine drug screening or query the PDMP when ordering an opioid. However, these alerts are not visible to primary care nurses.

<sup>&</sup>lt;sup>43</sup>VHA's Pain Management Directive provides policy and implementation procedures for the improvement of pain management consistent with the VHA National Pain Management Strategy and compliance with generally accepted pain management standards of care. See VHA Directive 2009-053, *Pain Management*, (Washington, D.C.; October 28, 2009).

### Some VHA Providers Do Not Consistently Follow Clinical Practice Guideline Recommendations Related to Opioid Safety

We also found that some VHA providers at selected facilities do not consistently follow selected clinical practice guideline recommendations related to opioid safety. Our findings are based on our review of a random selection of medical records for 103 veterans prescribed opioids between March 2016 and March 2017. These guidelines recommend, for example, that providers consider using non-pharmacological treatments, such as acupuncture and yoga, for chronic pain and prescribe naloxone, a potentially lifesaving drug, as warranted. The guidelines provide evidence-based recommendations designed to assist in provider decision-making; however, they are not VHA requirements and variations in practice will occur based on provider discretion and the needs of individual patients. Overall, we found that, 20 percent of veterans in our sample were prescribed a non-pharmacological therapy, 23 percent of the veterans were prescribed naloxone, 54 percent had appropriate maintenance follow-up visits with a provider while prescribed opioids, and 17 percent had appropriate follow-up visits with a provider after a change in their opioid prescription.

Provider Adherence to Selected Clinical Practice Guideline Recommendations for Management of Opioid Therapy for Chronic Pain at Five Selected Veterans Health Administration (VHA) Medical Facilities, March 2016 through March 2017 Clinical practice guidelines provide evidence-based recommendations designed to assist in provider decision-making; however, they are not VHA requirements and variations in practice will occur based on provider discretion and the needs of individual patients. Our review of medical records for a random, nongeneralizable selection of 103 veterans subject to the recommendations found that Of the 53 veterans who had been prescribed long-term opioids:<sup>a</sup>

• 11 veterans were prescribed a non-pharmacological therapy, such as yoga, or cognitive behavioral therapy;

- 13 veterans were prescribed naloxone, which is a highly effective intervention for reversing an overdose;
- 29 veterans had a maintenance follow-up visit at least once every 30-180 days for the duration of the veteran's opioid therapy; and
- 3 of 21 veterans who had a change in their opioid medication during the time of our review had a follow-up visit between 14 and 28 days following the change.

Of the 25 veterans prescribed a concurrent opioid and benzodiazepine:

- 6 veterans were prescribed a non-pharmacological therapy;
- 4 veterans were prescribed naloxone;
- 11 veterans had a maintenance follow-up visit; and
- 0 of 9 veterans who had a change in their opioid medication during the time of our review had a follow-up visit between 14 and 28 days following the medication change.

Of the 25 veterans with the highest risk of an adverse event, such as a suicide, overdose, fall, or opioid-induced respiratory depression, based on their Stratified Tool for Opioid Risk Mitigation (STORM) risk score:<sup>b</sup>

- 4 veterans were prescribed a non-pharmacological therapy;
- 7 veterans were prescribed naloxone;
- 16 veterans had a maintenance follow-up visit; and
- 5 of 17 veterans who had a change in their opioid medication during the time of our review had a follow-up visit between 14 and 28 days following the medication change.

Source: GAO analysis of veterans' medical records. | GAO-18-380

<sup>a</sup>VHA defines long-term opioid therapy as a 90-day supply of opioid medication prescribed in a 6month period.

<sup>b</sup>The Stratified Tool for Opioid Risk Mitigation (STORM) is designed to help providers estimate veteran risk for an overdose or suicide-related event and provide suggested interventions to mitigate that risk. It provides 1-year and 3-year risk categories (i.e., low, medium, high, and very high) reflecting a patient's risk of an adverse event if opioids are prescribed, based on the veteran's individual medical history and characteristics. The 25 veterans we reviewed had "very high" risk categories for both the 1-year and 3-year estimates. For example, a patient with an 18 percent risk of a suicide- or overdose-related health care event or death in the next year would be categorized as "very high" risk by the tool.

There are a variety of reasons that VHA providers may not always follow clinical practice guideline recommendations. For example, the availability of these non-pharmacological therapies may be limited, according to officials at all five selected VHA medical facilities. Officials at some facilities noted that the availability of these therapies can be particularly challenging for facilities in rural areas.

VHA officials explained that the biggest barrier to providing naloxone is educating providers, so that they consistently consider prescribing naloxone for their patients receiving opioid therapy.<sup>44</sup> According to officials, an education course for providers on naloxone prescribing became available in December 2015, and naloxone education efforts are a key focus of academic detailing programs. According to VHA data, since fiscal year 2014, naloxone distribution has increased. Specifically, as of March 2018, the agency has dispensed almost 142,000 naloxone kits to veterans, an increase of about 58 percent since June 2017.

## Conclusions

VHA is taking important steps under the OSI to help ensure that veterans receive safe care. For example, VHA has begun tracking and publicly reporting data on four key metrics related to opioid prescriptions, and these data show that opioid prescription rates have decreased since 2013. In addition, our review also found that VHA has made progress on most of its 2014 OSI goals. However, for two goals, VHA lacks documentation showing whether VISNs and medical facilities have completed required relevant actions, and in one case, VHA has not specified measurable outcomes, which makes it challenging to determine whether these goals have been accomplished. Without sufficient documentation and measurable outcomes, VHA cannot determine whether these OSI goals to help ensure safe and effective care for veterans prescribed opioids have been fully successful.

Our review also shows that VHA needs to do more to ensure that its providers are following three key opioid risk mitigation strategies when

<sup>&</sup>lt;sup>44</sup>Additionally, primary care nurses at the facilities in our review said they had difficulty finding adequate time and clinic space to provide the necessary education on naloxone to veterans when it was prescribed. They also described technological challenges, such as trying to show veterans education videos with audible sound on computers, and a lack of wireless internet access for the devices used.

prescribing an opioid medication to a veteran: conducting an annual urine drug screening, querying a PDMP, and obtaining written informed consent from the veteran on the benefits and risks of using opioid medications.

VHA has several means at its disposal for improving adherence to these strategies—at a minimum it should ensure that each VISN has a fully staffed academic detailing program and that each facility has a designated primary care pain champion, as VHA policy requires. In addition to enforcing these requirements, VHA should direct its facilities to strengthen monitoring efforts to help ensure providers' adhere to the opioid risk mitigation strategies. These efforts include regular reviews of veterans' medical records and creating electronic alerts reminding providers when these risk mitigation strategies have not been completed. Academic detailers and pain champions would also help educate providers further about evidence-based clinical practice guideline recommendations, such as non-pharmacological alternatives to opioid therapy and prescribing naloxone. Without these efforts to improve adherence to key opioid risk mitigation strategies, VHA's ability to ensure that all veterans are prescribed opioids in a safe and effective manner may be limited.

## **Recommendations for Executive Action**

We are making the following five recommendations to VA:

- The Undersecretary for Health should ensure that Central Office, VISNs, and medical facilities document the actions they take towards achieving OSI goals. (Recommendation 1)
- The Undersecretary for Health should ensure that any OSI goals that have not been met have clearly defined, measurable outcomes, including milestones or numerical targets, as appropriate, and timeframes. (Recommendation 2)
- The Undersecretary for Health should track the use of the OTRR (or any subsequent tool) by providers prior to initiating opioid therapy. (Recommendation 3)
- The Undersecretary for Health should ensure that all VISNs have implemented an academic detailing program that supports all medical facilities in the VISN and that all VHA medical facilities have a designated primary care pain champion as required. (Recommendation 4)

• The Undersecretary for Health should require VHA medical facilities to take steps to ensure provider adherence to opioid risk mitigation strategies, including querying PDMPs, obtaining written informed consent, and conducting urine drug screening. For example, these steps could include creating alerts in the electronic medical record system to remind primary care teams when these actions should be completed or strengthening facility monitoring of providers. (Recommendation 5)

# Agency Comments

We provided a draft of this report to VA for comment. While VA was reviewing a draft of this report, it requested further specificity in recommendation two; as a result, we revised the recommendation to be clearer. In its written comments, which are reproduced in appendix II, VA concurred with our recommendations and provided technical comments, which we have incorporated as appropriate.

In its comments, VA agreed that clarifying ongoing priorities and plans and filling in gaps in implementation will help facilitate progress in its opioid safety efforts. VA stated that it will establish a workgroup to review all OSI goals and ensure that the goals have clearly defined measurable outcomes and timelines, and that documentation requirements are established. VA also informed us that in March 2018 it published a notice requiring VHA clinicians to conduct and document a data-based risk review using one of VHA's clinical decision support tools for opioid management, such as STORM, prior to initiating opioid therapy. VA also stated that it will take actions to ensure that academic detailing programs are fully implemented and primary care pain champions are in place across the system. To improve its clinicians' adherence to opioid risk mitigation strategies, VA stated that it will establish a workgroup to review and develop methods for increasing adherence. VA expects to complete all these actions by April 2019 or earlier.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Veterans Affairs, the Undersecretary for Health, and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or clowersa@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

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A. Nicole Clowers Managing Director, Health Care

Letter

#### List of Committees

The Honorable Johnny Isakson Chairman The Honorable Jon Tester Ranking Member Committee on Veterans' Affairs **United States Senate** The Honorable John Boozman Chairman The Honorable Brian Schatz Ranking Member Subcommittee on Military Construction, Veterans' Affairs, and Related Agencies Committee on Appropriations United States Senate The Honorable Phil Roe Chairman The Honorable Tim Walz Ranking Member Committee on Veterans' Affairs House of Representatives The Honorable John Carter Chairman The Honorable Debbie Wasserman Schultz Ranking Member

Subcommittee on Military Construction, Veterans' Affairs, and Related Agencies

Committee on Appropriations House of Representatives Appendix I: Known Efforts and Data Related to the Veterans Health Administration's (VHA) Opioid Safety Initiative (OSI) 2014 Goals, July 2013-December 2017

Appendix I: Known Efforts and Data Related to the Veterans Health Administration's (VHA) Opioid Safety Initiative (OSI) 2014 Goals, July 2013-December 2017

OSI goals	VHA-required action(s)	Description of known related efforts and data
(1) Educate opioid prescribers regarding the effective use of urine drug screening	Each Veteran Integrated Service Network (VISN) must establish a network-wide standardized education program by December 31, 2014	According to VHA training system data, 13 of 21 VISNs developed at least one education course addressing the use of urine drug screening from January 1, 2015 through April 29, 2017. Ten of the 13 VISNs developed at least one course by the deadline (December 31, 2014) as required. Further, 6 of the 13 VISNs had at least one course with 30 or fewer providers completing it. Because we found the VISN course assignment data unreliable, we could not determine the completion rates for these courses. However, we found that, in response to a 2015 White House memorandum that required all federal employee opioid prescribers to complete training on the appropriate prescribing of opioids (which included discussion of urine drug screening) by April 15, 2017, of 20,231 prescribers who were identified and assigned the course, 19,242 completed it, for a completion rate of about 95 percent, according to VHA data from January 1, 2015 through April 29, 2017.
(2) Increase the use of urine drug screening	Urine drug screening targets based on previous urine drug screening rates for all VHA facilities must be reached by 2nd quarter, fiscal year 2015 (March 31, 2015)	According to VHA data, 151 of 157 facilities met or exceeded their urine drug screening target by the deadline (March 31, 2015) as required. In addition, VHA OSI metric data also show that there has been a 47 percentage point increase nationally in the percentage of patients on long-term opioid therapy who received a urine drug screen from the 4th quarter of fiscal year 2013 to the 1st quarter of fiscal year 2018. The increase in the percentage of patients receiving a urine drug screening was driven more by a reduction in the total number of patients on long-term opioid therapy rather than an increase in the number of patients receiving the screening.

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OSI goals	VHA-required action(s)	Description of known related efforts and data
(3) Facilitate the use of prescription drug monitoring program (PDMP) databases, which contain patient-level information on prescriptions received for controlled	Each VISN must certify by 2nd quarter, fiscal year 2015 (March 31, 2015), that all facilities have a program consisting of PDMP training and/or education materials for providers	VHA Central Office lacks certifications from all VISNs that programs were established. Although officials at the five VISNs in our review told us they had supported training efforts on the use of PDMPs, only one VISN in our review provided documentation that it had established a program by the deadline (March 31, 2015) as required.
substances		However, in October 2016, VHA issued a directive requiring providers to query state PDMPs for patients prescribed opioids and also issued guidance on how PDMPs should be accessed and how these efforts should be documented in VA's electronic health record system. In addition, according to VHA officials, querying the PDMP was added to the 2015 White House-required opioid safety training, as described earlier. According to VHA data, there has been a 22 percent increase in the querying of PDMPs by providers from 4th quarter, fiscal year 2016 to 3rd quarter, fiscal year 2017.
(4) Establish safe and effective VISN tapering programs for veterans using opioids and benzodiazepines	VISNs must develop local tapering protocols and plans to resource the implementation of those tapering protocols	VHA Central Office lacks documentation from all VISNs regarding VISN-specific protocols and implementation plans. Only one of the five VISNs in our review provided documentation regarding a VISN-specific protocol relating to patients on opioids and benzodiazepines, which was developed in 2013. Four of the five VISNs did not provide documentation of a VISN-specific protocol or implementation plans. <sup>a</sup>
		However, VHA officials told us that they addressed this goal by issuing national tapering guidance including a provider reference guide in 2014, an opioid taper decision tool in 2016, and the VA/DOD clinical practice guideline in 2017. VHA officials said that the issuance of this guidance made the VISN-required action irrelevant. In addition, VHA OSI metric data show that there has been a 6.6 percentage point decrease nationally in the percentage of patients dispensed an opioid and benzodiazepine from the fourth quarter of fiscal year 2013 to the first quarter of fiscal year 2018.
(5) Develop tools to identify patients at a higher risk for adverse events while using opioids	An opioid risk stratification toolkit must be developed; opioid safety education guides must be updated annually	In 2016, VHA released its opioid risk stratification toolkit in the form of an opioid safety monitoring tool called the Stratification Tool for Opioid Risk Mitigation. <sup>b</sup> In addition, VHA updated its pain management opioid safety education guide and quick reference guide for providers in July 2017.

OSI goals	VHA-required action(s)	Description of known related efforts and data
(6) Improve prescribing practices around long-acting opioid formulations	VISNs must develop local tapering protocols and plans to resource the implementation of those tapering protocols	VHA Central Office lacks documentation from all VISNs regarding VISN-specific protocols and implementation plans. Only one of the five VISNs in our review provided documentation regarding a VISN-specific protocol relating to patients on opioids and benzodiazepines, which was developed in 2013. Four of the five VISNs did not provide documentation of a VISN-specific protocol or implementation plans. <sup>a</sup>
		As earlier described, VHA officials said that issuance of guidance nationally made the VISN-required action irrelevant. In addition, according to VHA data, the percentage of patients who were prescribed long-acting opioids by providers nationally has decreased by about 1 percentage point from quarter 3, fiscal year 2014 to quarter 3, fiscal year 2017, representing a decrease of about 44,000 patients prescribed long-acting opioids and an accompanying increase of about 223,000 patients who used VHA care in the last four quarters.
(7) Review treatment plans for veterans on high doses of opioids <sup>c</sup>	of greater than 200 morphine milligram equivalents has been reviewed by 2nd quarter, fiscal year 2015 (March 31,	VHA Central Office lacks certifications from all VISNs that reviews were conducted. Although officials at the five VISNs in our review told us they had completed these reviews, only one VISN provided us with documentation to conclude that its facilities completed their review.
2015)		However, VHA OSI metric data show that there has been a 2.1 percentage point decrease nationally in the percentage of patients dispensed greater than or equal to 100 morphine milligram equivalents per day from the fourth quarter of fiscal year 2013 to the first quarter of fiscal year 2018.
(8) Offer complementary and alternative medicine modalities for chronic pain at all medical facilities	Each facility must provide evidence that at least two evidence-based behavioral/psychological treatments or approved complementary or alternative modalities can be provided by 2nd quarter, fiscal year 2015 (March 31, 2015)	According to VHA 2nd quarter, fiscal year 2015 data, all VHA medical facilities located in the United States provided at least one psychosocial service and at least one complementary and integrative health service. <sup>d</sup> However, VHA officials indicated that due to the nature of the data, they cannot verify that all psychosocial services provided at that time were evidence-based and that not all complementary and integrative health services provided had a strong evidence base.
OSI goals	VHA-required action(s)	Description of known related efforts and data
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(9) Develop new models of mental health and primary care collaboration to manage the prescribing of opioids and benzodiazepines in patients with chronic pain	Identification of strong practices that can be operationalized across VHA by 3rd quarter, fiscal year 2015 (June 30, 2015); a request for proposal to be released to the field to establish model interdisciplinary teams and strategies for management and tapering of medications at three VHA medical facilities	In February 2016, VHA began a pilot to implement a model of care known as the Collaborative Chronic Care Model into existing Behavioral Health Interdisciplinary Program teams at nine VHA medical facilities. According to a VHA document, the pilot will provide facilitation support to enhance existing Behavioral Health Interdisciplinary Program teams by incorporating evidence-based Collaborative Care Model elements, which can include a care manager to proactively monitor care and progress as well as other tools intended to improve communication between primary care and specialty care. In fiscal year 2017, efforts were expanded to 30 additional VHA medical facilities. According to one VHA official, the pilot is expected to be completed no earlier than August 2019.

Source: VHA, GAO. | GAO-18-380

Notes: OSI goals and required actions were issued via memorandum by VHA Central Office in December 2014. This table is not intended to be an exhaustive description of all of VHA's efforts related to its OSI goals.

VISNs are regional networks that manage the VHA medical facilities located in their area. In October 2015, VHA began to implement a realignment of its VISN boundaries which resulted in the number of its VISNs decreasing from 21 to 18.

<sup>a</sup>One VISN provided evidence of one VHA medical facility's tapering recommendations for patients on opioids and benzodiazepines.

<sup>b</sup>This tool helps providers identify patients who are at a higher risk of adverse events when using opioids depending on their clinical profile.

<sup>c</sup>Patients on high doses of opioids are at greater risk for adverse events. According to the Centers for Disease Control, providers should avoid or carefully justify opioid prescriptions delivering a daily dose of greater than or equal to 90 morphine milligram equivalents.

<sup>d</sup>Based on information we obtained from VHA relative to this goal, "psychosocial" services refer to "behavioral/psychological" treatments, and "integrated health" is a term that may be used to refer to "complementary and alternative" modalities. According to a VHA official, the VHA facility in Manila, the Philippines did not offer at least one psychosocial service and at least one integrative health service for this time period.

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DEPA	ARTMENT OF VETERANS AFFAIRS Washington DC 20420
	May 14, 2018
Ms. A. Nicole Clowers Managing Director Health Care U.S. Government Accountabilit 441 G Street, NW Washington, DC 20548	ty Office
Dear Ms. Clowers:	
Accountability Office's (GAO) of	erans Affairs (VA) has reviewed the Government draft report, "VA HEALTH CARE: Progress Made Safety but Further Efforts to Assess Progress and GAO-18-380).
	general and technical comments, and sets forth the the GAO draft report recommendations.
VA appreciates the opp	ortunity to comment on your draft report.
	Sincerely, Peter M. O'Rourke Chief of Staff
Enclosure	
5	







Enclosure Department of Veterans Affairs (VA) Comments to Government Accountability Office (GAO) Draft Report "VA HEALTH CARE: Progress Made Towards Improving Opioid Safety but Further Efforts to Assess Progress and Reduce Risk Are Needed" (GAO-18-380) strategies to include educational materials, informed consent, urine drug screenings, decision-making tools, documentation, and the potential utilization of a national clinical reminder. The status is in process with a target completion date of April 2019.

## Appendix III: GAO Contact and Staff Acknowledgments

## **GAO** Contact

Angela N. Clowers, (202) 512-7114 or clowersa@gao.gov

## Staff Acknowledgments

In addition to the contact named above, Marcia A. Mann, Assistant Director; Stella Chiang, Analyst-in-Charge; Emily Binek, Krister Friday, Diona Martyn, and Michael Rose made key contributions to this report. Also contributing were Zhi Boon and Emily Wilson.

## Appendix IV: Accessible Data

## Agency Comment Letter

Text of Appendix II: Comments from the Department of Veterans Affairs

Page 1

May 14, 2018

Ms. A. Nicole Clowers Managing Director Health Care

U.S. Government Accountability Office 441 G Street, NW

Washington, DC 20548

Dear Ms. Clowers:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, "VA HEALTH CARE: Progress Made Towards Improving Opioid Safety but Further Efforts to Assess Progress and Reduce Risk Are Needed" (GAO-18-380).

The enclosure provides general and technical comments, and sets forth the actions to be taken to address the GAO draft report recommendations.

VA appreciates the opportunity to comment on your draft report.

Sincerely,

Peter O'Rourke

Chief of Staff

Enclosure

#### Page 2

#### **General Comments:**

Thank you for the recognition of our innovation and progress. We agree that clarifying ongoing priorities and plans and filling in gaps in implementation will help facilitate progress in our continued Opioid Safety efforts. Our action plan describes how we plan to move forward on the recommendations.

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#### Department of Veterans Affairs (VA) Comments to Government Accountability Office (GAO) Draft Report

"VA HEALTH CARE: Progress Made Towards Improving Opioid Safety but Further Efforts to Assess Progress and Reduce Risk Are Needed" (GAO-18-380)

Recommendation 1: The Undersecretary for Health should direct Central Office, VISNs, and medical facilities to document the actions they take towards achieving OSI goals.

#### VA Comment: Concur.

The Department of Veterans Affairs (VA) agrees that continued actions and follow-up are important for tracking progress towards best clinical practices in opioid prescribing. The Veterans Health Administration (VHA) Office of Specialty Care will collaborate with the Office of Mental Health and Suicide Prevention to establish a workgroup to review all new Opioid Safety Initiative (OSI) goals; establish the expected metrics; timelines; and documentation requirements. The status is in process with a target completion date of April 2019. Recommendation 2: The Undersecretary for Health should ensure that any OSI goals that have not been met or any new OSI goals that are developed in the future have clearly defined, measurable outcomes, including milestones or numerical targets, as appropriate, and timeframes.

#### VA Comment: Concur.

VA agrees that continued actions and follow-up are important for tracking progress towards best clinical practices in opioid prescribing. VHA Office of Specialty Care will collaborate with the Office of Mental Health Suicide Prevention, within the established workgroup, to review and evaluate unmet goals that remain pertinent and will ensure all identified and pertinent unmet OSI goals are clearly defined and include measurable outcomes, milestones/metrics and timelines. The status is in process with a target completion date of April 2019.

# Recommendation 3: The Undersecretary for Health should track the use of the OTRR (or any subsequent tool) by providers prior to initiating opioid therapy.

#### VA Comment: Concur.

On March 8, 2018, VHA published VHA Notice 2018-08, Conduct of Data-Based Case Reviews of Patients with Opioid-Related Risk Factors. This notice requires VA clinicians to conduct and document a data-based risk review using one of VHA's clinical decision support tools for opioid management prior to initiating opioid therapy. The Notice established policy on implementation of OSI case reviews and provides instructions concerning the documentation of OSI case reviews within the medical record for patients with an opioid prescription identified as very high risk. VA's Stratification Tool for Opioid Risk Mitigation (STORM) has been adapted to facilitate this practice. Utilization of the standard progress note title will allow tracking of conduct and documentation of this practice. Pharmacy Benefits Management (PBM) Services, the Office of Specialty Care Services/Pain Management, in collaboration with Program Evaluation and Resource Center within the Office of Mental Health and Suicide Prevention, will host upcoming trainings on the utilization of the STORM tool

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within future months. The status is in process with a target completion date of July 2018.

Recommendation 4: The Undersecretary for Health should ensure that all VISNs have implemented an academic detailing program that supports all medical facilities in the VISN and that all VHA medical facilities have a designated primary care pain champion as required.

#### VA Comment: Concur.

In regard to the implementation of Academic Detailing, the Office of the Assistant Deputy Under Secretary for Health for Clinical Operations (ADUSH C/O), with support from PBM Services, will issue a mandatory response for action via electronic mail, i.e., "!asker", on behalf of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) to noncompliant Veterans Integrated Service Networks (VISN) no later than June 2018. The lasker will require the implementation of Academic Detailing programs as outlined in the March 2015, Office of Interim Under Secretary for Health memorandum. To ensure visibility and clarity, a copy of the March 2015, Memorandum will be sent with the lasker as an attachment. Additionally, the issued lasker will officially rescind any previously granted exemption waivers. Each VISN will be required to provide the Office of the DUSHOM and PBM with an attestation memorandum signed by the VISN Director with: 1) an anticipated implementation timeline; and 2) complete implementation of Academic Detailing within their respective VISN.

In relation to the designation of primary care pain champion, the Office of Specialty Care Services/Pain Management, in collaboration with the Office of Primary Care Operations (OPC), will assess VA medical facilities (VAMC) to ensure each VAMC has a designated primary care pain champion. Each VISN will be required to provide OPC with an attestation memorandum signed by the VISN Director. The status is in process with a target completion date of April 2019.

Recommendation 5: The Undersecretary for Health should require VHA medical facilities to take steps to ensure provider adherence to opioid risk mitigation strategies, including querying PDMPs and obtaining written informed consent (as required under VHA policy) and conducting urine drug screening, the increase of which is an 051 goal. For example, these steps could include creating alerts in

#### the electronic medical record to remind primary care teams when these actions should be completed or strengthening facility monitoring of providers.

#### VA Comment: Concur.

The Offices of Primary Care and Mental Health and Suicide Prevention, in collaboration with the National Center for Ethics in Health Care, will develop a workgroup to review and establish requirements concerning opioid mitigation

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strategies to include educational materials, informed consent, urine drug screenings, decision-making tools, documentation, and the potential utilization of a national clinical reminder. The status is in process with a target completion date of April 2019.

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