



Report to the Chairman, Committee on
Veterans' Affairs, House of
Representatives

February 2017

VA HEALTH CARE

Actions Needed to Ensure Medical Facility Controlled Substance Inspection Programs Meet Agency Requirements

GAO Highlights

Highlights of [GAO-17-242](#), a report to the Chairman, Committee on Veterans' Affairs, House of Representatives

Why GAO Did This Study

Diversion of opioid pain relievers and other controlled substances by health care providers has occurred at several VA medical facilities. Such diversions for personal use can pose a threat to patients by depriving them of needed medications. Absent effective practices to mitigate its risk and quickly identify it, diversion can occur undetected. VHA requires each of its facilities to implement a controlled substance inspection program to help reduce the risk of diversion.

GAO was asked to examine VHA's processes to prevent diversion and its oversight of these processes. This report examines VHA's implementation and oversight of controlled substance inspection programs at selected facilities. GAO reviewed VHA policies and interviewed officials from VHA central office and from a nongeneralizable selection of four facilities and the networks that oversee them. Facilities were selected to reflect variation in geography and in the number of opioids dispensed at retail pharmacies in the state in which the facility operates. GAO compared the facilities' implementation and oversight of the programs to VHA's policy requirements and to federal standards for internal control.

What GAO Recommends

GAO is making six recommendations, including that VHA establish procedures to prevent missed inspections, review facilities' inspection procedures, improve coordinator training, and direct facility directors and networks to ensure that facilities correct facility nonadherence to VHA policies. VA concurred with GAO's recommendations.

View [GAO-17-242](#). For more information, contact Randall B. Williamson at (202) 512-7114 or williamsonr@gao.gov.

February 2017

VA HEALTH CARE

Actions Needed to Ensure Medical Facility Controlled Substance Inspection Programs Meet Agency Requirements

What GAO Found

GAO found weaknesses in the way four selected Department of Veterans Affairs (VA) medical facilities were implementing their controlled substance inspection programs. Two of the four did not conduct monthly inspections of controlled substances as required by the Veterans Health Administration (VHA). For example, one facility missed 43 percent of monthly inspections in critical patient care areas and the pharmacy for the period GAO reviewed—January 2015 to February 2016. Further, inspections that three of the four facilities performed did not include or follow three or more of the nine VHA requirements GAO reviewed. At two of the three facilities, for example, inspectors did not properly verify that controlled substances had been transferred from VA pharmacies to patient care areas; nor did inspectors ensure that all controlled substances on hold for destruction were properly documented. The VA Office of the Inspector General identified similar inspection program weaknesses at other VA facilities in 2009 and again in 2014.

GAO found that several factors contributed to nonadherence to VHA policy at selected facilities. First, the two facilities that missed inspections lacked an additional control procedure—such as the use of an alternate controlled substance coordinator—to help prevent missed inspections when inspectors could not conduct them due to professional or other personal responsibilities. Second, while facilities develop their own set of inspection procedures that must follow VHA's policy requirements, three of the four facilities did not ensure their written procedures included the nine VHA program requirements GAO reviewed. Third, VHA relies on coordinators at the facilities to ensure that the inspections are completed appropriately, but GAO found that VHA's training course for the coordinators does not focus on its required inspection procedures. As a result of these weaknesses, VHA cannot ensure that its inspection programs are following all of its requirements.

GAO found inconsistent oversight at the selected facilities of their controlled substance inspection programs by facility directors and the Veterans Integrated Service Networks (network) to which the facilities report. VHA assigns oversight responsibilities to each facility director and network. GAO found that directors at two of the four selected VA medical facilities had not implemented corrective actions to address missed inspections identified in the monthly inspection reports. In addition, two of the four selected networks did not review their facilities' quarterly trend reports, as required by VHA. Such reports identify inspection program trends such as missed inspections and areas for improvement. GAO found that one network that had reviewed the trend reports failed to follow up with a facility to ensure it had submitted missed trend reports. Inconsistent oversight by the directors and networks is contrary to federal internal control standards that state oversight should be ongoing to assess performance and promptly remediate deficiencies in order to achieve objectives, including holding individuals accountable for their responsibilities. Without effective oversight of the inspection programs by directors and networks, VHA lacks reasonable assurance that its programs are being implemented as required to prevent and identify diversion of controlled substances.

Contents

Letter		1
	Background	6
	Selected Facilities Did Not Conduct All Inspections, Follow All Inspection Procedures, or Develop Written Inspection Procedures that Were Fully Consistent with VHA Policy	9
	Oversight of Controlled Substance Inspection Programs by Selected VA Medical Facilities and Their Networks Is Inconsistent	19
	Conclusions	21
	Recommendations for Executive Action	21
	Agency Comments	22
Appendix I	Use of Automated Dispensing Machine Reports to Identify Diversion of Controlled Substances at Selected VA Medical Facilities	26
Appendix II	Comments from the Department of Veterans Affairs	29
Appendix III	GAO Contact and Staff Acknowledgments	34
Table		
	Table 1: Veterans Health Administration's (VHA) Procedures for Monthly Controlled Substance Inspections, as of February 2016	7
Figure		
	Figure 1: Comparison of Written Inspection Procedures at Four VA Medical Facilities with Selected VHA Inspection Requirements, as of February 2016	16

Abbreviations

coordinator	controlled substance coordinator
inspector	controlled substance inspector
memo	memorandum
network	Veterans Integrated Service Network
OIG	Office of the Inspector General
VA	Department of Veterans Affairs
VHA	Veterans Health Administration

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



February 15, 2017

The Honorable David P. Roe
Chairman
Committee on Veterans' Affairs
House of Representatives

Dear Chairman Roe:

The rate of opioid overdose deaths tripled between 2000 and 2014 and the misuse of opioids such as oxycodone was a contributing factor.¹ One way that providers and other health care employees misuse opioids—and other controlled substances that they have ready access to—is by diverting them from patients for their own personal use.² Absent effective practices to mitigate the risk of diversion and quickly identify it after it occurs, providers and others can divert controlled substances over time without anyone knowing. This, in turn, poses a serious threat to patients by depriving them of needed medications. Although data on the frequency of diversion in medical facilities located in the United States—including those run by the Department of Veterans Affairs (VA)—is not available, diversion can occur anywhere in a facility where employees have access to controlled substances. Patient care areas may be more vulnerable to diversion; in these settings, providers can administer and dispose of controlled substances out of the view of others, making diversion by the

¹Centers for Disease Control and Prevention, “Increases in Drug and Opioid Overdose Deaths—United States, 2000-2014,” *Morbidity and Mortality Weekly Report*, vol. 64, no. 50 (2016).

²According to the Controlled Substances Act, as amended, the term “controlled substance” means “a drug or other substance, or immediate precursor, included in [one of five classification schedules].” A controlled substance is placed in a respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence. Examples of controlled substances include pain relievers, such as Percocet or OxyContin, as well as tranquilizers, stimulants, and sedatives available only by prescription. Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242-84 (codified as amended at 21 U.S.C. §§ 801-890, 901-971); 21 C.F.R. Chp. II.

employee easier and detection more difficult, as discussed in the Mayo Clinic Proceedings.³

The Controlled Substances Act and implementing regulations require all medical facilities, including VA facilities, to have effective controls and procedures to adequately safeguard against theft and diversion of controlled substances.⁴ To fulfill this requirement, the Veterans Health Administration (VHA), which operates VA's health care system, required that each of its medical facilities with stocks of controlled substances implement a controlled substance inspection program. VHA requires the programs to conduct monthly inspections following specified procedures outlined in VHA policy in all medical facility areas that are authorized to have controlled substances, such as patient care areas and pharmacies.

In recent years, diversion of controlled substances has occurred at several VA medical facilities. For example, an investigation in 2012 found that a former health care employee at the VA medical facility located in Baltimore, Maryland had been diverting the opioid fentanyl—an anesthetic used for patients undergoing surgical procedures—for his own use. The employee was injecting himself with syringes of fentanyl intended for patients undergoing surgery and then refilling the empty syringes with saline solution. Instead of receiving the prescribed dose of fentanyl with its intended anesthetic effect, patients received saline solution that was tainted with the Hepatitis C virus carried by the employee.⁵ Another investigation in 2012 found that an emergency room nurse at a VA medical facility was injecting herself with syringes of hydromorphone, an opioid pain reliever, intended for patients. After

³K.H. Berge et al., "Diversion of Drugs Within Health Care Facilities, A Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention," *Mayo Clinic Proceedings*, vol. 87, no. 7 (2012).

⁴See 21 U.S.C. § 823; 21 C.F.R. §§ 1301.71-1301.76. The Controlled Substances Act requires persons and entities who manufacture, distribute, or dispense controlled substances or listed chemicals to register with the Drug Enforcement Administration, which by delegation from the U.S. Attorney General is responsible for administering and enforcing the Act and its implementing regulations. Registrants must keep complete and accurate record of inventories of controlled substances and ensure the controlled substances are securely stored and safeguarded. Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242-84 (codified as amended at 21 U.S.C. §§ 801-890, 901-971); 21 C.F.R. Chp. II.

⁵Department of Justice, U.S. Attorney's Office, District of New Hampshire, *Former Employee of Exeter Hospital Pleads Guilty to Charges Related to Multi-State Hepatitis C Outbreak* (New Hampshire: August 2013). This former VA employee also diverted controlled substances while working at medical facilities outside of VA.

identifying discrepancies in the amounts of hydromorphone the nurse documented as having administered to patients, VA officials accused the nurse of diversion. Eventually, the nurse confessed to having diverted hydromorphone for approximately six months.

VHA has faced challenges implementing its controlled substance inspection programs. In 2009 and 2014, the VA Office of the Inspector General (OIG) identified a number of weaknesses in VA medical facilities' implementation of controlled substance inspection programs. For example, the VA OIG found that some VA medical facilities had not conducted the required monthly inspections, and when facilities did conduct the monthly inspections, the inspections were sometimes incomplete because they did not follow all of the required VHA procedures.⁶ The VA OIG recommended that VHA, in conjunction with the Veterans Integrated Service Networks (network) and VA medical facility directors and other leaders, take action to ensure adherence with VHA's requirements.⁷

You requested that we report on VHA's processes to reduce the risk of diversion of controlled substances at its medical facilities and VHA's oversight of these processes. This report examines:

1. the extent to which selected VA medical facilities have implemented controlled substance inspection programs as required by VHA policies, and
2. VHA's oversight of these programs at selected VA medical facilities.

This report also provides information in Appendix I about selected VA medical facilities' use of reports available from facilities' automated dispensing machines—computer-controlled medication storage and

⁶VA Office of the Inspector General, *Healthcare Inspection: Review of Selected Pharmacy Operations in Veterans Health Administration Facilities* (Washington, D.C.: Dec. 3, 2009) and *Combined Assessment Program Summary Report: Evaluation of the Controlled Substances Inspection Program at Veterans Health Administration Facilities* (Washington, D.C.: June 10, 2014).

⁷Networks are responsible for overseeing the day-to-day functions of the VA medical facilities that are within their network.

dispensing cabinets in patient care areas—to help identify diversion of controlled substances.⁸

To examine the implementation of VHA's controlled substance inspection programs at selected facilities, we selected four VA medical facilities to include in our review. We selected the four facilities to achieve variation in geography and in the number of prescriptions for opioid pain relievers dispensed in the states in which the facilities operate.⁹ The four VA medical facilities we selected are located in Washington, D.C.; Milwaukee, Wisconsin; Memphis, Tennessee; and Seattle, Washington. We compared the number of controlled substance inspections that each of the four VA medical facilities reported to us as having been completed from January 2015 through February 2016 to the number of inspections that should have been conducted, based on VHA's policy requirement.¹⁰ We chose this time frame to include an entire year of the most recently completed inspections when we conducted our work. For each of the four selected facilities, we also requested and reviewed a random sample of documents from completed inspections in order to test the reliability of the inspection information provided by the VA medical facilities. To determine the extent to which each VA medical facility's inspection procedures were consistent with certain VHA requirements, we reviewed the inspection procedures in place at each of the four facilities as described in inspection program policies, training manuals, and other guidance documents, and

⁸Automated dispensing machines generate reports that can track medication dispensing activities, such as the number of times providers access controlled substances to administer to patients, and these reports can be used to identify possible cases of diversion.

⁹See Centers for Disease Control and Prevention, *Opioid Painkiller Prescribing: Where You Live Makes a Difference* (Atlanta, GA: July 1, 2014). These prescription data are based on a representative sample of retail, mail service and long-term care pharmacies.

¹⁰We based our review of the implementation of selected facilities' inspection programs on VHA's program requirements included in its 2010 inspection program policy. See Department of Veterans Affairs, Veterans Health Administration Handbook 1108.02, *Inspection of Controlled Substances* (Washington, D.C., Mar. 31, 2010). In late November 2016, VHA issued an update to its inspection program policy. See Department of Veterans Affairs, Veterans Health Administration Directive 1108.02, *Inspection of Controlled Substances* (Washington, D.C., Nov. 28, 2016). We reviewed VHA's 2016 policy updates and found they did not materially affect our findings, as discussed in this report.

compared these procedures to VHA's policy requirements.¹¹ We interviewed relevant officials from the four selected VA facilities—including the controlled substance coordinator (coordinator), controlled substance inspectors (inspector), and pharmacists—to discuss the local operating policies and procedures and how they implemented their procedures. We also analyzed VHA's online training course for coordinators and discussed this course with coordinators in each of the four VA medical facilities as well as other training they had received about VHA's inspection program requirements, including training on the required inspection procedures. We also evaluated facilities' processes for ensuring completion of the inspections, and VHA's coordinator training, against federal standards for internal control related to control activities.¹² Our findings for the four selected VA medical facilities cannot be generalized to other VA medical facilities.

To examine VHA's oversight of selected medical facilities' controlled substance inspection programs, we reviewed VHA and VA medical facility policies and other relevant documents, including a 2014 VHA memorandum (memo), that describe oversight responsibilities.¹³ We compared the oversight responsibilities identified in VHA policies and the 2014 memo to the selected facilities' oversight activities. As part of this comparison, we reviewed documents such as monthly and quarterly inspection reports and interviewed VA medical facility directors and other facility leadership officials, including the chief of staff at the four selected facilities about their oversight activities and any information they review related to the inspection program. We also interviewed officials from VHA's central office, and the four networks associated with each of the four selected VA medical facilities, about their oversight responsibilities and activities related to the controlled substance inspection programs. In

¹¹We included in our review nine selected pharmacy and patient care area requirements related to ordering and receiving, inventory counts, hard-copy prescriptions, and administration of controlled substances. We did not review VHA's requirements for the inspection of research laboratories as it was out of our scope.

¹²GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 10, 2014). GAO, *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.

¹³See VA, VHA Handbook 1108.02, *Inspection of Controlled Substances* (Mar. 31, 2010) and *Memorandum on Controlled Substance Inspection Program Requirement, VA Office of Inspector General-Combined Assessment Program Findings* (Washington, D.C.: July 9, 2014).

addition, we compared the facilities' oversight activities and responsibilities identified in VHA policies and the 2014 VHA memo to federal standards for internal control related to monitoring and oversight.¹⁴

We conducted this performance audit from January 2016 to February 2017 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

According to VHA policy on the inspection of controlled substances, each VA medical facility must establish a controlled substance inspection program, which is to be overseen mainly by the facility's director. VHA's policy stipulates that the VA medical facility director must 1) ensure that the facility's program complies with VHA's requirements, 2) establish local medical facility procedures for the controlled substance inspection program that are consistent with VHA's requirements, and 3) appoint a coordinator, who is responsible for managing the program and the inspectors who conduct the inspections.¹⁵

The coordinator is responsible for ensuring that inspections are conducted unannounced and monthly in each area of the VA medical facility that stores controlled substances. To assist the coordinator, a team of inspectors is to be assigned from various areas of the medical facility to conduct the actual inspections. The coordinator is responsible for ensuring that the inspectors have completed required training and must document annually an assessment of the inspectors' competencies. The coordinator is also responsible for ensuring that the inspections include all of VHA's policy requirements. VHA policy requires the coordinator to develop and submit two reports to the VA medical facility director—a monthly inspection report and a quarterly trend report. According to VHA policy, the monthly inspection report is to summarize the inspection findings. VHA also requires that these reports include information on missed inspections for each month and if missed inspections are identified, the medical facility director is expected to work

¹⁴GAO-14-704G and GAO/AIMD-00-21.3.1.

¹⁵VA, VHA Handbook 1108.02, *Inspection of Controlled Substances* (Mar. 31, 2010).

with the coordinator to develop an action plan to improve performance and continue to monitor for additional missed inspections.¹⁶ The quarterly trend report is to summarize patterns in discrepancies identified through the inspection program—such as discrepancies between the physical count of controlled substances and their recorded inventory by patient care area—problematic trends, and potential areas for improvement in the program.¹⁷ VHA also requires that networks review the quarterly trend reports during an annual quality management visit to the medical facility.¹⁸

VHA’s policy establishes the requirements for the monthly inspection of controlled substances at VA medical facilities and the procedures that inspectors must follow to implement these requirements. There are different procedures for conducting inspections of pharmacies compared to patient care areas such as inpatient units and clinic areas. See table 1.

Table 1: Veterans Health Administration’s (VHA) Procedures for Monthly Controlled Substance Inspections, as of February 2016

Type of requirement	Description of implementing procedure
Pharmacy	
Ensure that all ordered controlled substances have been placed in inventory	Inspectors must verify that <u>all</u> of the controlled substances that the Department of Veterans Affairs (VA) medical facility ordered and received were correctly documented as received into the pharmacy’s inventory. The inspector must obtain all invoices of controlled substances from the office responsible for ordering them since the last controlled substance inspection, and compare each invoice item to the pharmacy’s receipt report.
Perform a physical count of controlled substances in the pharmacy	Inspectors must conduct a complete physical count of <u>all</u> controlled substances in the pharmacy the first month of the quarter. This includes controlled substances that are stored in the pharmacy’s vault and in automated dispensing machines. For subsequent months during the quarter, inspectors must conduct a physical count of ten percent of the controlled substances, based on a random sample. Inspectors must compare the complete and ten percent counts to the pharmacy’s inventory records.
Perform a physical count of the emergency cache	Inspectors must conduct a complete physical count of <u>all</u> controlled substances that VA medical facilities store in case of emergencies such as natural disasters, epidemics and terrorist attacks. These controlled substances are referred to as the emergency cache. Inspectors must conduct this count the first month of the quarter. Facilities may store the emergency cache inside or outside of the pharmacy.

¹⁶VA, *Memorandum on Controlled Substance Inspection Program* (July 9, 2014).

¹⁷VA, VHA Handbook 1108.02, *Inspection of Controlled Substances* (Mar. 31, 2010).

¹⁸This oversight responsibility is included in VHA’s 2014 memo. See VA, *Memorandum on Controlled Substance Inspection Program* (July 9, 2014).

Type of requirement	Description of implementing procedure
Verify the 72-hour inventory counts by pharmacy	Inspectors must verify that pharmacy officials have completed required inventory counts of controlled substances stored in the pharmacy. Pharmacies are required to complete two or three inventory counts weekly, depending on how many days they are open. Inspectors must review pharmacy records to verify that <u>all</u> of these inventory counts of controlled substances were completed since the last controlled substance inspection.
Reconcile one day of pharmacy dispensing	Inspectors must check that the controlled substances that the pharmacy transferred to automated dispensing machines in patient care areas were received. For one day of the pharmacy's dispensing, inspectors validate that the amounts of controlled substances dispensed match the amounts of controlled substances each automated dispensing machine received into inventory.
Verify hard-copy prescriptions	Inspectors must obtain a pharmacy report listing all prescriptions that were not electronically prescribed and signed by a licensed provider since the last controlled substance inspection and, for a sample of these prescriptions, verify that there is a matching hard-copy prescription in the pharmacy. The inspector must verify that the patient and provider names on the report are the same as those on the hard-copy prescription and also verify that the name, strength, and quantity of the prescribed controlled substance on the pharmacy report matches the information on the hard-copy prescription. The inspector must initial each reviewed entry on the pharmacy report and provide the report to the VA medical facility's controlled substance coordinator. Inspectors must review 50 randomly chosen prescriptions or all prescriptions if the report lists less than 50 prescriptions.
Verify documentation of controlled substances on hold for destruction	Inspectors must check that <u>all</u> controlled substances being held in the pharmacy for destruction because they are non-usable (e.g., expired, damaged) are documented on the pharmacy's destruction report.
Patient care areas	
Perform a physical count of controlled substances in patient care areas	Inspectors must conduct a complete physical count the first month of the quarter of <u>all</u> controlled substances in patient care areas, including those stored in automated dispensing machines and locked cabinets. On subsequent months during the quarter, inspectors must conduct a physical count of a minimum of ten controlled substances, based on a random sample of drugs, for example different drugs, strengths or routes of administration such as oral or intravenous. Inspectors must compare the complete and ten percent counts to each area's inventory records.
Validate dispensing of controlled substances	Inspectors are to randomly choose five instances when controlled substances were removed from the automated dispensing machine (or locked cabinets) for each patient care area, or two if there are fewer than five instances when controlled substances were removed. Inspectors must review the veterans' medical records to verify that there is a doctor's order for the controlled substance and documentation that the controlled substance has been administered to the veteran.

Source: VHA. | GAO-17-242

Notes: Our review focused on controlled substance inspection requirements related to ordering and receiving; inventory counts and verification of inventory in the pharmacy and patient care areas; hard-copy prescriptions; and administration of controlled substances. These requirements are included in a VHA Handbook and memorandum. See Department of Veterans Affairs, Veterans Health Administration Handbook 1108.02, *Inspection of Controlled Substances* (Washington, D.C.: Mar. 31, 2010); *Memorandum on Controlled Substance Inspection Program Requirement of Hard Copy Prescriptions with Controlled Substance E-Prescribing Implementation* (Washington, D.C.: July 1, 2013); and *Controlled Substance Inspection Certification Course* (Washington, D.C.: May 4, 2012). In its November 2016 revised policy, VHA eliminated the requirement for inspectors to verify that all controlled substances that were ordered and received were correctly documented as received into the pharmacy's inventory.

Selected Facilities Did Not Conduct All Inspections, Follow All Inspection Procedures, or Develop Written Inspection Procedures that Were Fully Consistent with VHA Policy

Two of Four Selected VA Medical Facilities Did Not Conduct All Required Monthly Inspections

VHA policy requires that facilities inspect multiple patient care areas and pharmacies on a monthly basis. These inspections are intended to help mitigate the risk of drug diversion. We found that from January 2015 through February 2016, one of the four selected facilities we reviewed missed 43 percent of the required monthly inspections, and another facility missed 17 percent of these inspections.¹⁹ The other two VA medical facilities we reviewed fully adhered to VHA's requirement to conduct monthly inspections.

At the VA medical facility that missed 43 percent (131 of 308) of the required monthly inspections, we found that most (about 95 percent) of the facility's missed inspections were for the facility's patient care areas, while the remaining 5 percent of missed inspections at this facility were for the pharmacy. For example, we found that

¹⁹We calculated these percentages by dividing the total number of areas with controlled substances that the VA medical facilities did not inspect by the total number of areas that should have been inspected, from January 2015 through February 2016, according to VHA policy. Over this time period, each applicable area should have been inspected 14 times. The total number of areas that store controlled substances varies by facility. VHA's policy allows on rare occasions that a monthly inspection may be skipped so long as the area skipped is inspected the subsequent month. Further, VHA's 2014 memo contains guidance on the other acceptable reasons for missed inspections, which include unplanned sick leave or other unforeseen circumstances. Because the coordinators at the facilities that missed inspections told us they could not quantify the number of missed inspections that may be due to these acceptable reasons, we did not account for this in our calculations.

-
- inspectors missed monthly inspections in the facility's patient care areas such as the operating room (all 14 inspections missed), bronchoscopy laboratory (all 14 inspections missed), and the intensive care units (7 of 14 inspections were missed). The facility's coordinator told us that the operating room was not inspected at all during our review period because the inspectors assigned to inspect the operating room needed to arrive before or after normal operating room hours to obtain access to the controlled substances and were unable to conduct the inspections due to their conflicting work schedules.²⁰ The bronchoscopy laboratory was not inspected at all during our review period because it was not identified by the coordinator as an area having controlled substances.
 - Inspectors missed inspections in some patient care areas for 2 to 4 consecutive months. These areas included the intensive care units, cardiac catheter laboratory, and interventional radiology.
 - Inspectors also missed inspections of the facility's pharmacy for 3 consecutive months.

At the VA medical facility that missed 17 percent (118 of 702) of the required monthly inspections, we found that most (about 95 percent) of the missed inspections were for the facility's patient care areas, while the remaining 5 percent of missed inspections at this facility were for the pharmacy. For example, we found that

- inspectors missed monthly inspections in patient care areas such as the operating room (5 inspections missed), medical intensive care unit (4 inspections missed), and pain clinic (6 inspections missed).
- Inspectors missed inspections of some patient care areas for 2 or 3 consecutive months. These areas included the operating room, pain clinic and inpatient psychiatry.
- Inspectors also missed inspections of one of the facility's four pharmacies for 2 consecutive months.

We found one factor that contributed to the missed inspections at the two selected VA medical facilities was the lack of an additional control procedure to help prevent the medical facility from missing inspections, such as designating an alternate coordinator or appointing additional inspectors to fill in for the assigned inspector when needed. The

²⁰The coordinators and inspectors at VA medical facilities that adhered to VHA's requirement to conduct monthly inspections did not report difficulties completing the inspections of controlled substances stored in the operating room.

coordinator and inspector roles are usually collateral duties. The coordinators and inspectors at the four VA facilities we selected told us that in addition to their inspection program duties, they had substantive full-time responsibilities and scheduled their inspection work around their facility jobs.²¹ Both of the VA medical facilities that conducted all of the required monthly inspections had an alternate coordinator to assist the coordinator in managing the inspection program, including scheduling the inspections and following up with inspectors to ensure inspections are completed.²² At one of these facilities the alternate coordinator also conducted inspections when inspectors had unforeseen circumstances that prevented them from completing the assigned inspections.

In contrast, the two medical facilities that missed inspections during our review did not have an additional control procedure, such as the use of an alternate coordinator. The coordinators at these two medical facilities told us that managing the inspection program was challenging given their other full-time duties, which included supervising the VA medical facility's patient food service and conducting quality improvement activities. One of the coordinators told us that she had not been informed of the time commitment related to the coordinator position prior to being appointed. According to these two coordinators, it is a challenge to re-assign the inspections when the assigned inspectors cannot conduct the scheduled inspections due to unforeseen circumstances. For example, the coordinators at these two facilities explained that some inspectors waited until the end of the month to conduct their assigned monthly inspections, and because of competing priorities or unexpected health or personal issues, the inspections were sometimes not completed. In these cases, the coordinators told us inspectors may not notify the coordinator in time to find another inspector to complete the monthly inspections, and the coordinators may not have time to complete the inspections themselves. One of the coordinators at these facilities told us that she had requested an alternate coordinator be appointed to help ensure adherence to the

²¹In terms of supervisory accountability, inspectors report directly to their supervisors in the areas where they have full-time facility jobs rather than to the coordinator, according to VHA Central Office and local officials with whom we spoke.

²²One of the two VA medical facilities that conducted all of the required inspections had an alternate coordinator for the entire period we reviewed. The other VA medical facility that conducted all of the required inspections had an inspector who was learning the coordinator role by training with the current coordinator for six months during the period of our review. This inspector performed the role of an alternate coordinator during this time, and is currently the coordinator at this VA medical facility.

monthly inspection requirement and that the request was approved for an alternate coordinator to begin in January 2017.

In VHA's November 28, 2016 update to its inspection policy, VHA added a responsibility related to the monthly inspection requirement and made recommendations regarding the appointment of more than one coordinator for certain purposes and regarding the coordinator's time commitment. First, the update assigns the facility chief of pharmacy responsibility for ensuring that the coordinator has an accurate listing of all automated dispensing machines and controlled substance storage areas. If properly implemented, this update may help ensure that all areas requiring monthly inspections are identified. Second, the update recommends that facility directors (a) appoint more than one coordinator (e.g., an alternate) for the purpose of coverage, program continuity, and succession planning and (b) discuss the time commitment with the coordinator and the coordinator's current supervisor and adjust other duties as necessary to provide adequate time for the coordinator to perform the inspection program duties. The update is likely an improvement as it raises awareness around the time commitment of the coordinator role and it also might address the identified risks of missing inspections by recommending the appointment of more than one coordinator if needed for coverage of program responsibilities. However, because the update does not make the appointment of an alternate coordinator mandatory or require another control activity to address its risk, VHA still might lack reasonable assurance that inspections occur when the primary inspector is unable to fulfill that responsibility.

Federal internal control standards state that to achieve an entity's objective, management should define responsibilities and assign them to key roles throughout the entity. Further, management should design control procedures to help fulfill the defined responsibilities and address any identified risk in not achieving the entity's objective. If management learns that the existing control procedures are not operating as designed, management should review them and analyze and respond to any associated risks of not meeting the defined objective.²³ The two facilities that did not adhere to VHA's requirement to conduct monthly inspections did not have an additional control procedure in place, such as an alternate coordinator, to respond to the risk of missed monthly inspections, which is inconsistent with these internal control standards.

²³[GAO-14-704G](#) and [GAO/AIMD-00-21.3.1](#).

Missed inspections increase the likelihood that VHA may not meet the objective of the program—to reduce the risk of diversion of controlled substances. In 2009 and 2014, the VA OIG also found that VA medical facilities did not always conduct required monthly inspections.²⁴ For example, in 2014 the VA OIG reported that of the 58 VA medical facilities it reviewed, the facilities missed required monthly inspections in 20 percent of patient care areas with controlled substances.

Controlled Substance Inspections Conducted at Three of Four Selected Medical Facilities Did Not Follow Certain VHA Policy Requirements

We found that three of the four selected VA medical facilities, when conducting inspections, did not include, or correctly follow, three or more of the nine VHA requirements we reviewed. The fourth VA medical facility we reviewed had implemented inspection procedures that followed these requirements. The following are examples of inspections not following VHA requirements at these three selected facilities.

- *At three of the selected VA medical facilities, inspectors did not perform physical counts of pharmacy emergency caches of controlled substances as required.* Inspectors at one selected facility did not perform the count at all and at a second facility, inspectors told us that they counted some, but not all, of the cache, as required.²⁵ Inspectors at the third facility only counted the cardboard shipping boxes in which the controlled substances were shipped and did not count the contents, according to the coordinator at the facility. However, without opening these shipping boxes to verify that they actually contained the controlled substances and counting them, inspectors would not know if any controlled substances had been removed from the boxes.
- *At two of the selected VA medical facilities, inspectors did not verify that controlled substances had been properly transferred from VA pharmacies to automated dispensing machines in patient care areas.* At one facility, inspectors verified only a sample of controlled substances dispensed by the pharmacy on a selected day to confirm that the controlled substances were actually transferred to patient care areas. According to VHA's inspection program policy, inspectors are required to verify that all controlled substances transferred by a pharmacy on a selected day were

²⁴VA, Office of the Inspector General, *Review of Selected Pharmacy Operations* (Dec. 3, 2009) and *Evaluation of the Controlled Substances Inspection Program* (June 10, 2014).

²⁵For the emergency cache that the inspectors did count, they told us they compared the amount of inventory to what a facility official had written as the inventory, rather than the actual inventory in the pharmacy's inventory reports.

received in these areas. At a second facility, inspectors told us that they did not conduct this required procedure in one of the facility's two pharmacies. Without checking that all controlled substances were properly transferred from the pharmacy, inspectors may not identify controlled substances that are dispensed by the pharmacy and subsequently diverted rather than stocked in the automated dispensing machines located in patient care areas.

- *At two selected VA medical facilities, inspectors did not verify that all of the controlled substances slated for destruction had been documented.* According to VHA's inspection program policy, facilities' pharmacies are to maintain a list of controlled substances that are scheduled to be destroyed because, for example, the medication is past its expiration date or has been crushed or damaged in some way. According to VHA's inspection program policy, inspectors are required to verify that all relevant medications are included in this list; however, inspectors at two of the selected facilities told us they only verified that a sample of the controlled substances being held for destruction was documented. Because the inspectors reviewed only a sample of these controlled substances, the facility lacks assurance that all controlled substances intended for destruction have been logged into the pharmacy's computer system, thereby increasing the risk that controlled substances could be diverted.
- *At one selected VA medical facility, inspectors did not count all of the controlled substances stored in the patient care areas.* At this facility, inspectors did not count the controlled substances stored in all the automated dispensing machines in the facility's cardiac catheter laboratory, interventional radiology area, and gastrointestinal endoscopy area, according to a facility official. Although each of these areas had two machines that dispensed controlled substances, inspectors only counted the inventory in one of the two machines in each area. In addition, inspectors did not count any inventory of controlled substances stored in this facility's bronchoscopy laboratory. Because the inspectors did not count controlled substances in these areas, the facility lacks assurance that the physical inventory matches the recorded inventory.

Similar to our findings, the VA OIG found in 2009—and again in 2014—that VA medical facilities did not always follow VHA's required procedures in conducting monthly inspections. For example, in 2014 the VA OIG reported that in 24 percent of the facilities' inspections, inspectors did not verify controlled substances had been properly transferred from the facilities' pharmacies to the automated dispensing machines in patient care areas. Furthermore, the VA OIG reported that in 17 percent of the inspections, inspectors did not perform physical counts of the emergency

caches. As a result, inspections in these facilities may not have identified controlled substances that were diverted from their emergency cache or while in transfer from the pharmacy to patient care areas.

In its 2016 inspection policy update, VHA modified its requirement for inspectors to verify that controlled substances are properly transferred from pharmacies to automated dispensing machines. The policy states that in cases where there was no dispensing of controlled substances to a specific automated dispensing machine on the day the inspector selected to review, the inspector should select another day to examine that machine.

Three VA Medical Facilities Did Not Develop Written Controlled Substance Inspection Procedures That Were Fully Consistent with VHA Policy

In comparing the written procedures at the four VA medical facilities we reviewed with selected VHA requirements, we found that three facilities did not have written inspection procedures that were fully consistent with VHA's policy requirements. (See figure 1.) This likely contributed to inspections not following certain VHA policy requirements at the three selected VA medical facilities, as previously discussed. The VA medical facility directors are responsible for establishing local written medical facility policies on the inspection of controlled substances and ensuring that their inspection programs adhere to VHA's policy requirements, according to VHA's inspection program policy. To respond to this requirement, facilities are to develop inspection program procedures and guidance documents describing the procedures for inspectors.

Figure 1: Comparison of Written Inspection Procedures at Four VA Medical Facilities with Selected VHA Inspection Requirements, as of February 2016

Controlled substance inspection procedure required by VHA	VA medical facility A	VA medical facility B	VA medical facility C ^a	VA medical facility D
Required pharmacy inspection procedures				
1. Ensure that all ordered controlled substances have been placed in inventory.	●	●	○	○
2. Perform a physical count of controlled substances in the pharmacy.	●	○	○	●
3. Perform a physical count of the emergency cache.	●	○	○	●
4. Verify the 72-hour inventory counts by pharmacy.	●	●	○	○
5. Reconcile one day of pharmacy dispensing.	●	●	○	●
6. Verify hard-copy prescriptions.	●	○	○	○
7. Verify documentation of controlled substances on hold for destruction.	●	●	○	○
Required patient care area inspection procedures				
8. Perform a physical count of controlled substances in patient care areas.	●	●	○	●
9. Validate dispensing of controlled substances.	●	●	●	●

- Written procedure is consistent with VHA requirement
- Written procedure is absent or inconsistent with VHA requirement

Source: GAO. | GAO-17-242

Note: At the four selected Department of Veterans Affairs (VA) medical facilities, we reviewed written inspection procedures that were included in the local inspection program policies, training manuals and other guidance documents and compared them to Veterans Health Administration's (VHA) inspection program requirements included in VHA's 2010 policy. See Department of Veterans Affairs, Veterans Health Administration Handbook 1108.02, *Inspection of Controlled Substances* (Washington, D.C.: Mar. 31, 2010).

^aVA medical facility C had no written procedures for its pharmacy inspections. Although this VA medical facility's inspection program policy stated that inspections must follow the required procedures included in VHA's Handbook 1108.02, this handbook was not included in the guidance that inspectors told us they used in performing and implementing the inspection procedures.

The one VA medical facility that had implemented all of the selected VHA-required inspection procedures has an ongoing process to specifically conduct comprehensive reviews of the facility's inspection procedures to ensure they are consistent with VHA's requirements. At this facility, the current and prior coordinators had each conducted separate reviews of the facility's procedures in coordination with two pharmacy managers, according to a facility official. Further, the coordinator and two pharmacy managers at this facility review the procedures anytime there is an update to VHA's requirements to ensure that their medical facility is adherent, according to a facility official. For example, the facility conducted a review in 2013 when VHA updated its pharmacy inspection requirements for the review of hard copy prescriptions. As a result of this review, the facility updated its local inspection program policy, the written procedures, and

other guidance documents that the inspectors use to conduct the monthly pharmacy inspections. Moreover, a facility official told us that the coordinator informs the VA medical facility director of the inspection program changes so that the facility director is aware of the new requirements. In contrast, at the other three selected VA medical facilities, the coordinators' reviews of the facilities' inspection procedures were not as comprehensive. At two of these facilities, the coordinators told us that they had compared some, but not all, of their facility's inspection procedures to VHA's requirements. At another facility, the coordinator told us he had compared all of the facility's procedures to the VHA requirements, but he did not involve other facility officials, such as pharmacy managers, to verify the accuracy of his review.

Furthermore, VHA requires that the coordinators have a complete understanding of VHA's inspection procedures and ensure that the inspectors have completed inspections using the required procedures. However, we found in our analysis of the contents of VHA's online coordinator training course that it lacks substantive information about VHA's required inspection procedures. VHA officials told us the coordinator training course is designed to focus on the management aspects of carrying out the coordinator role (e.g., recruiting inspectors, scheduling inspections, and generating required reports) as opposed to VHA's inspection procedures. VHA's online course for inspectors, in comparison, includes substantive information about the required inspection procedures.²⁶ VHA recommends but does not require that the coordinators take the online training course for inspectors. While two of the four coordinators we interviewed told us they were provided helpful on-the-job training at their medical facilities, which included shadowing the prior coordinator, three of them told us that additional coordinator training was needed. In addition to online and on-the-job training, coordinators have opportunities to discuss various aspects of their VA medical facilities' inspection programs on an ongoing basis, for example, by participating in the voluntary bi-monthly meetings that VHA officials facilitate for coordinators. Although VHA officials told us that these bi-monthly meetings often focus on VHA's required inspection procedures,

²⁶VHA requires that inspectors take the inspector online course and have refresher training on an annual basis.

two of the four coordinators told us that they did not regularly participate in these meetings.²⁷

In its 2016 inspection policy update, VHA eliminated one of the requirements that we reviewed—verifying that ordered controlled substances are placed in inventory—and added a requirement that coordinators must take the coordinator online training course within 30 days of their appointment. The update also addresses certain other inspection procedures we reviewed such as verifying the transfer of controlled substances.²⁸ However, these changes do not address the lack of a comprehensive review of medical facilities' inspection procedures or the lack of substantive information about VHA's required inspection procedures in VHA's online training course for coordinators. The lack of a comprehensive review of the medical facilities' inspection procedures and the inadequate coordinator training are inconsistent with federal internal control standards. These standards state that management should periodically review policies and procedures for continued relevance and effectiveness in achieving the entity's objectives or addressing related risks.²⁹ Without a process in place to review medical facilities' local inspection procedures and modify inspection procedures as appropriate, VHA cannot ensure that VA medical facilities' procedures adhere to VHA's policy requirements. Federal internal control standards also state that effective management is essential to achieving results and operational success depends on personnel being properly trained. Training is aimed at developing employee knowledge and skills to achieve organizational goals. While the updated November 2016 policy mandates coordinators' training, VHA's existing training for coordinators does not focus on VHA's required inspection procedures. As a result,

²⁷VHA officials told us they have provided training to coordinators upon request. In September 2016, VHA officials provided in-person training to 26 new coordinators who volunteered to participate. This training included information about VHA's required inspection procedures. VHA officials also make information about the inspection procedures available to coordinators on an internal VA website.

²⁸As another example, VHA added a requirement to its procedure for validating the dispensing of controlled substances. Inspectors are now required to verify the documentation of two signatures for any wasting of partial doses.

²⁹[GAO-14-704G](#) and [GAO/AIMD-00-21.3.1](#).

VHA cannot ensure that all coordinators have adequate information to determine if the inspections have been completed as required.³⁰

Oversight of Controlled Substance Inspection Programs by Selected VA Medical Facilities and Their Networks Is Inconsistent

Facility directors are responsible for reviewing monthly inspection reports that the coordinators at the facilities submit, and these reports must provide information on missed inspections and reasons for missed inspections. They are also responsible for working with coordinators to develop and implement corrective action plans if missed inspections are identified. Medical facility directors are also required to review quarterly trend reports submitted by facility coordinators, which summarize information from the controlled substance inspections and may provide information on problems with the inspection programs and needed improvements.³¹

We found that medical facility directors did not consistently perform these duties at two of the four selected VA medical facilities. At the two VA medical facilities that missed monthly inspections, facility directors did not implement corrective actions to prevent future missed inspections. These facility directors told us they reviewed the monthly inspection reports, and some of these reports that we reviewed showed that inspections were in fact missed. As discussed earlier, one of the facilities missed 43 percent of the required inspections, while the other facility missed 17 percent of the inspections. In addition, one of four medical facility directors did not receive quarterly trend reports during our review period and did not implement a corrective action to ensure that he receives future quarterly trend reports. VHA's 2016 inspection policy update added the requirement that corrective actions to prevent missed inspections are to be documented in the monthly inspection reports that the coordinators submit to the directors. However, the update does not require corrective action plans to be documented for other types of inspection program nonadherence—for example, if an inspection was conducted but did not include all of the required procedures.

³⁰In addition to our findings in this report, in prior work we have identified gaps in training for VHA staff in other VHA programs. As a result of inadequate training, among other problems, we placed VA health care on our High Risk List in 2015. See GAO, *High-Risk Series: An Update*, [GAO-15-290](#) (Washington, D.C.: Feb. 11, 2015).

³¹The oversight responsibilities for VA medical facility directors that we reviewed are included in VHA's 2010 inspection program policy and its 2014 memo. See VA, VHA Handbook 1108.02, *Inspection of Controlled Substances* (Mar. 31, 2010) and *Memorandum on Controlled Substance Inspection Program* (July 9, 2014).

We also found that oversight provided by the four networks to which the four selected VA medical facilities in our review report was inconsistent. The networks are responsible for reviewing their facilities' quarterly trend reports; VHA included this requirement in the 2014 memo it issued in response to the VA OIG findings on implementation problems with the inspection programs.³² Officials from two of the four networks we interviewed told us they did not review the quarterly trend reports. Officials in one of these two networks told us they were unaware of the requirement. An official in the other network told us the network did not review their facilities' quarterly trend reports due to a lack of communication within the network about the requirement. In addition, we found that one of two networks that had reviewed the quarterly trend reports did not take action to ensure that one of the facilities in our review had completed quarterly trend reports. For example, this network found during its site-visit review of this facility that the coordinator had not completed and submitted the quarterly trend reports to the medical facility director, as required. We also found that this coordinator had not completed other quarterly trend reports during our 14-month review period, and the facility's director did not develop a corrective action plan to ensure the completion of these reports in the future.

The inconsistent oversight provided by facility directors and networks of VA's controlled substance inspection programs is contrary to federal internal control standards. These standards state that management should document internal control issues, determine appropriate corrective actions for deficiencies on a timely basis, and complete and document these actions. The standards also state that management should establish and operate monitoring activities to monitor the internal control system and appropriately remediate identified deficiencies on a timely basis. Further, the standards state that an oversight body should also monitor the status of remediation efforts to ensure they are completed on a timely basis. Management, with oversight from the oversight body, should take corrective action as necessary to enforce accountability of individuals performing their internal control responsibilities.³³ Without a process to ensure consistent monitoring by facility directors and networks that includes correcting missed inspections and other nonadherence and

³²See VA, *Memorandum on Controlled Substance Inspection Program* (July 9, 2014).

³³[GAO-14-704G](#) and [GAO/AIMD-00-21.3.1](#).

holding individuals accountable, VHA lacks reasonable assurance that the facilities are meeting the objective of the inspection program.³⁴

Conclusions

VHA's controlled substance inspection programs are one of the primary means VHA uses to reduce the risk of the diversion of controlled substances at its VA medical facilities. However, we found weaknesses in the implementation of these programs. In particular, because of gaps in facilities' local inspection procedures and coordinator training, VHA cannot ensure its controlled substance inspection programs are being correctly implemented. As a result, VHA's ability to detect diversion and protect its veterans from harm that can result from diversion—such as depriving them of needed pain medications—is limited. Further, without ongoing program monitoring by the facility directors and networks, including holding VA medical facilities accountable for identifying and correcting nonadherence to program requirements, VHA lacks reasonable assurance that implementation problems will be corrected on a timely basis.

Although our review focused on four selected facilities, the problems we identified in implementing and overseeing the inspection programs are consistent with the problems identified by the VA OIG in its reviews of controlled substance inspection programs at other VA medical facilities in 2009 and again in 2014. These longstanding program implementation issues and weaknesses in oversight are cause for concern, and VHA has a responsibility to ensure that all of its controlled substance inspection programs are being implemented as it intends.

Recommendations for Executive Action

To help VHA achieve its objective of reducing the risk of diversion through effective implementation and oversight of the controlled substance inspection program, the Secretary of Veterans Affairs should direct the Under Secretary for Health to take the following six actions:

- ensure that VA medical facilities have established an additional control procedure, such as an alternate controlled substance coordinator or

³⁴In addition to our findings in this report, in prior work we have also found inadequate oversight and accountability in other VHA programs, including an insufficient focus on medical facilities' adherence to program requirements. As a result of these problems, among others, we placed VA health care on our High Risk List in 2015. See [GAO-15-290](#).

additional inspectors, to help coordinators meet their responsibilities and prevent missed inspections;

- ensure that VA medical facilities have established a process where coordinators, in conjunction with appropriate stakeholders (e.g., pharmacy officials), periodically compare facility inspection procedures to VHA's policy requirements and modify facility inspection procedures as appropriate;
- improve the training of VA medical facility controlled substance coordinators by ensuring the training includes the inspection procedures that VHA requires;
- ensure that medical facility directors have designed and implemented a process to address nonadherence with program requirements, including documenting the nonadherence and the corrective actions taken to remediate nonadherence or the actions that demonstrate why no remediation is necessary;
- ensure that networks review their facilities' quarterly trend reports and ensure facilities take corrective actions when nonadherence is identified; and
- ensure that networks monitor their medical facilities' efforts to establish and implement a review process to periodically compare facility inspection procedures to VHA's policy requirements.

Agency Comments

We provided a draft of this report to VA for review and comment. In its written comments, reproduced in appendix II, VA concurred with our six recommendations and described plans to implement them by October 2017. The department also provided technical comments, which we incorporated as appropriate.

In its comments, VA stated that to address our first recommendation, VHA will require the medical facility directors to appoint an alternate coordinator for their controlled substance inspection programs—to provide back-up support to the coordinator—and add inspectors to ensure that the monthly inspections are not missed. VA noted that it will communicate these requirements to the facility directors in a memo that VHA Central Office will develop. VA also stated that the facilities' quality managers will report to the networks on whether the facilities have appointed alternate coordinators and added inspectors. Facilities that have not met these requirements will develop action plans for doing so. The networks, in turn, will monitor the facilities' implementation of the requirements and will provide to VHA Central Office any facility action

plans. VA also noted in its comments that officials within VHA Central Office will meet to decide if additional actions are needed to ensure that the medical facilities have alternate coordinators and additional inspectors. To ensure that the actions that VHA identified for medical facilities and networks to conduct on a recurring basis are taken, we encourage VHA to include them in its inspection program policy.

To address our second recommendation, VA stated that VHA will require the medical facility directors to compare their current inspection program policies and procedures with VHA's inspection program policy using a self-assessment guide that VHA developed. VA added that a multidisciplinary group of medical facility staff—including the coordinator and chief of pharmacy—will be responsible for conducting the comparison, while each facility's quality management committee will review the results. If discrepancies between a facility's procedures and VHA's program requirements are identified, the facility must develop an action plan for addressing the issue, and the quality management committees will track the facilities' progress in correcting discrepancies. The networks, in turn, will monitor that the facilities have completed the assessment and corrected any identified discrepancies and will provide VHA Central Office with any action plans. Furthermore, officials within VHA Central Office will meet to decide if additional actions are needed to ensure that the facilities have completed the comparison and corrected any identified discrepancies. To ensure that all of the actions that VHA identified for medical facilities and networks to conduct on a recurring basis are taken, we encourage VHA to include them in its inspection program policy.

To address our third recommendation, VA stated that VHA will require the coordinators to complete its online controlled substance training course for inspectors—which includes detailed information about VHA's inspection procedures. VA noted that it will include this requirement in the memo VHA plans to send to the medical facility directors to address our first recommendation, as described above. In addition, VA stated that VHA will update its inspection program policy to include this new training requirement for coordinators. VA added that the networks will monitor facilities' adherence to the training requirement and will provide action plans to VHA Central Office for facilities whose coordinators have not completed the training course. According to VA, officials within VHA Central Office will also meet to decide if further actions are needed to ensure that the coordinators have taken the online training course for inspectors. In addition to including the new training requirement in its inspection program policy, we encourage VHA to include in policy the

networks' responsibilities for monitoring facilities' adherence to the training requirement.

To address our fourth recommendation, VA stated that VHA Central Office will develop guidance directing the medical facility directors to assess adherence with VHA's inspection program requirements at least quarterly. Further, the facilities' quality management committees will review the monthly and quarterly inspection reports for adherence with VHA's inspection program requirements and will ensure—when nonadherence is identified—that the facilities have established, documented, and completed necessary corrective actions. According to VA, the committees will also report progress on correcting identified nonadherence to the facility directors. In addition, the networks will monitor facilities' progress in correcting nonadherence and will provide to VHA Central Office any action plans for nonadherent facilities. VA stated that officials within VHA Central Office will meet to determine if further actions are needed to ensure that nonadherence is corrected. To ensure that the actions that VHA identified for medical facilities and networks to conduct on a recurring basis are taken, we encourage VHA to include them in its inspection program policy.

To address our fifth and sixth recommendations, VA stated that VHA Central Office will develop a memo outlining the requirements for networks to review their facilities' quarterly inspection reports, ensure facilities take corrective actions when nonadherence is identified, and monitor facilities' efforts to periodically compare their inspection procedures with VHA's inspection policy requirements. VA noted that VHA Central Office will provide this memo to the network directors who, in turn, will disseminate the memo to the medical facility directors. VA stated that the facility quality managers will report to the networks on whether the facilities have taken corrective actions when nonadherence is identified in the quarterly reports as well as compared their inspection procedures with VHA's policy requirements. VA further stated that the networks will provide VHA Central Office with action plans for any facilities with identified nonadherence, while officials within VHA Central Office will meet and decide if further actions are needed to ensure adherence. To ensure that the actions that VHA identified for medical facilities and networks to conduct on a recurring basis are taken, we encourage VHA to include them in its inspection program policy.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees and the Secretary of Veterans Affairs. In addition, the report will be 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 williamsonr@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs are on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.

Sincerely yours,

A handwritten signature in black ink that reads "Randall B. Williamson". The signature is written in a cursive style with a large initial "R".

Randall B. Williamson
Director, Health Care

Appendix I: Use of Automated Dispensing Machine Reports to Identify Diversion of Controlled Substances at Selected VA Medical Facilities

This appendix describes information about the four selected Department of Veterans Affairs (VA) medical facilities' use of information available from their automated dispensing machines that store controlled substances in patient care areas.¹ Specifically, we present information about the extent to which facilities we selected used information available from these machines, the type of information reviewed, and how facilities used the information to help identify potential diversion.²

Veteran Health Administration (VHA) policy states that VA medical facility staff may use information from electronic reports that facility automated dispensing machines generate to help identify potential drug diversion.³ Automated dispensing machines are computerized drug storage and dispensing medication cabinets located in medical facility patient care areas, including surgical and emergency care areas. These machines track information on medication dispensing activities that can be used to identify potential diversion, such as the number of times each nurse removes a controlled substance to administer to a patient, the type and amount of drug dispensed, and the patients to whom the drug was

¹The information in this appendix is based on our review of VHA inspection policies and interviews with VA medical facility officials and documents they provided. Specifically, we interviewed relevant officials from the four selected VA medical facilities, including pharmacy staff and coordinators, to discuss the types of reports they generate and how they use the information in these reports to help identify diversion of controlled substances. We reviewed documents they provided, including examples of monthly reports showing the amount and types of controlled substances that nurses and anesthesia clinicians removed from their inventory to administer to patients.

²Regularly reviewing controlled substance activity reports generated from automated dispensing machines to identify potential outliers—and then further investigating these cases—is considered a leading practice to identify diversion by several organizations. For example, see Minnesota Hospital Association, *Road Map to Controlled Substance Diversion Prevention 2.0*, accessed November 7, 2016, <http://www.mnhospitals.org/Portals/0/Documents/ptsafety/diversion/Road%20Map%20to%20Controlled%20Substance%20Diversion%20Prevention%202.0.pdf>, and K.H. Berge et al., "Diversion of Drugs Within Health Care Facilities, A Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention," *Mayo Clinic Proceedings*, vol. 87, no. 7 (2012).

³See Department of Veterans Affairs, Veterans Health Administration Handbook 1108.02, *Inspection of Controlled Substances* (Washington, D.C.: Mar. 31, 2010) and Veterans Health Administration Directive 1108.02, *Inspection of Controlled Substances* (Nov. 28, 2016).

**Appendix I: Use of Automated Dispensing
Machine Reports to Identify Diversion of
Controlled Substances at Selected VA Medical
Facilities**

administered.⁴ Among the types of reports that can be generated from these machines are the dispensing practices report, which can provide information about potential drug diversion by identifying the average number of drug doses dispensed per month by users of the machines in a given medical facility area, and the transaction report, which provides details of dispensing activity by date, nurse accessing the medicine, and patient.

Below are examples of the information from automated dispensing machines that the four selected VA medical facilities used to help identify diversion.

- In VA medical facility A, a pharmacist reviews dispensing practices reports monthly and sends them to the nurse managers and head of anesthesiology for their review, pointing out certain outliers that the reports automatically flag.⁵ A facility official told us that the facility began reviewing the dispensing practices reports regularly in 2013 after a pharmacist used a report to investigate a discrepancy in which a physician's order for hydromorphone that an emergency room nurse had dispensed could not be verified.⁶ The report showed that the nurse removed a significantly higher quantity of hydromorphone compared to his co-workers during a 12-month period. A pharmacist further reviewed the medical records of 10 patients the nurse treated and found he had dispensed hydromorphone without a physician's order for 6 of the patients. In a state court system the nurse later pled guilty to diverting hydromorphone.
- In VA medical facility B, a pharmacist reviews dispensing practices reports monthly for the most frequently dispensed controlled substances to identify potential outliers. The pharmacist explained that the facility does not use specific criteria to define potential outliers and that the last

⁴These automated dispensing machines generally require user identifier and passwords and have data processing technology and software that can be used to generate different types of reports to monitor controlled substance activities by clinician, patient, and drug type. Several manufacturers produce machines with various software capabilities. The reports' names and content vary depending on the manufacturer.

⁵Because the dispensing practices reports do not account for certain factors that may affect controlled substance activity (e.g., whether nurses are full or part-time), nurse managers and the head of anesthesia are better qualified to interpret activity given their knowledge of the staff and patients in their areas, according to a pharmacy official.

⁶This discrepancy was identified through the controlled substance inspection program.

time the facility identified a potential outlier was in 2012.⁷ In this case the pharmacist contacted the nurse's manager, who explained that the nurse had provided a disproportionate share of the care to patients in that area, which accounted for the nurse's higher-than-expected dispensing of controlled substances.

- VA medical facility C does not regularly review dispensing practices reports to help identify diversion. A pharmacy official from this facility told us he reviews discrepancy reports and may review controlled substance dispensing on occasion, for example, to help resolve a discrepancy with an automated dispensing machine, but that reviewing such data on a regular basis would be very time consuming.⁸
- In VA medical facility D, the inspection program coordinator has identified four nurse outliers as potential diverters since 2015 by analyzing dispensing practices reports, and the coordinator told us that she has provided the results of her analysis to other facility officials for further investigation. The coordinator focuses her reviews on oxycodone and fentanyl because they are highly addictive and are most likely to be diverted, according to the coordinator. The coordinator reviews the total amount of these drugs that each nurse has removed from the automated dispensing machines compared to other nurses in the same patient care areas. After identifying a potential outlier, to determine if the nurse continues to be an outlier the coordinator reviews additional information. For example, the coordinator would review the nurse's dispensing activity over a different time period as well as the types of patients the nurse has treated, since some patients (e.g., those with cancer) have higher than average use of controlled substances.⁹

⁷According to the pharmacist, potential outliers depend on the patient care area as well as the difference in the amounts of controlled substance a nurse dispensed compared to the nurse's peers in the area. To illustrate, she explained that nurses should generally dispense the same amounts of controlled substances in the intensive care unit and if one nurse had removed a significantly higher amount in a month compared to another nurse in that unit, the nurse would be considered an outlier. In comparison, large differences may be reasonable in other units with patients more likely to use different amounts of controlled substances, according to this pharmacist.

⁸The discrepancy is recorded when an automated dispensing machine's electronic controlled substance inventory count differs from the actual count.

⁹The coordinator told us that if a nurse's dispensing activity is two standard deviations or higher than the average amount dispensed the coordinator considers the nurse a potential outlier. According to the coordinator, this review process can take about 3 to 5 months.

Appendix II: Comments from the Department of Veterans Affairs



DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

January 17, 2017

Mr. Randall Williamson
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Williamson:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, "**VA HEALTH CARE: Actions Needed to Ensure Medical Facility Controlled Substance Inspection Programs Meet Agency Requirements**" (GAO-17-242).

The enclosure provides our 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,

A handwritten signature in black ink, appearing to read "Gina S. Farrissee".

Gina S. Farrissee
Deputy Chief of Staff

Enclosure

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***“VA HEALTH CARE: Actions Needed to Ensure Medical Facility Controlled
Substance Inspection Programs Meet Agency Requirements”***
(GAO-17-242)

Recommendation 1: To help VHA achieve its objective of reducing the risk of diversion through effective implementation and oversight of the controlled substance inspection program, the Secretary of Veterans Affairs should direct the Under Secretary for Health to ensure that VA medical facilities have established an additional control procedure, such as an alternate controlled substance coordinator or a pool of extra inspectors, to help coordinators meet their responsibilities and prevent missed inspections.

VA Comment: Concur. This recommendation is related to High Risk Area 1 (Ambiguous policies and inconsistent processes).

The Veterans Health Administration’s (VHA) Directive 1108.02, *Inspection of Controlled Substances*, provides guidance to Facility Directors for ensuring the Controlled Substances Programs develop and remain compliant with the requirements (www.va.gov/vhapublications/ViewPublication.asp?pub_ID=4301). The Office of Pharmacy Benefits Management (PBM) will develop a memorandum that outlines the expectations of Directive 1108.02 and specifically the requirements to:

1. Have mandatory training,
2. Appoint an alternate Controlled Substance Coordinator; and if one is not already appointed, to provide back-up support, and
3. Add inspectors to the program to ensure inspections are not missed.

The Office for the Deputy Under Secretary for Health for Operations and Management (DUSHOM), will provide this memorandum to each facility Director to ensure appropriate actions have been taken to ensure the actions listed in the memorandum are completed. The Facility Quality Managers (QM) will report compliance to the Veterans Integrated Services Network (VISN) QM Officer and for any facility that is non-compliant, an action plan will be developed.

At completion of this action, VHA will do the following: The VISN QM Officer will monitor compliance and provide an action plan for any non-compliant facilities within that VISN to the PBM and the DUSHOM. The two offices will meet and decide whether any further actions are needed. The status is in process, and the target completion date is October 2017.

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***“VA HEALTH CARE: Actions Needed to Ensure Medical Facility Controlled
Substance Inspection Programs Meet Agency Requirements”***
(GAO-17-242)

Recommendation 2: To help VHA achieve its objective of reducing the risk of diversion through effective implementation and oversight of the controlled substance inspection program, the Secretary of Veterans Affairs should direct the Under Secretary for Health to ensure that VA medical facilities have established a process where coordinators, in conjunction with appropriate stakeholders (e.g. pharmacy officials), periodically compare facility inspection procedures to VHA’s policy requirements and modify facility inspection procedures as appropriate.

VA Comment: Concur. This recommendation is related to High Risk Area 1 (Ambiguous policies and inconsistent processes).

Each medical facility director will be required to compare the current inspection program policy and procedures with VHA Directive 1108.02, *Inspection of Controlled Substances*, using the Self-Assessment guide for VHA Directive 1108.02 Inspection of Controlled Substances (see Attachment 1).

The self-assessment will be completed by a multidisciplinary group including the Controlled Substance Coordinator, Chief of Pharmacy or designee, Nurse Executive or designee and QM or designee. The results of the self-assessment will be reviewed by the facility QM Committee. An action plan must be developed for identified deficiencies and progress tracked until completion through the QM committee.

At completion of this action, VHA will do the following: VISN QM Officer will monitor compliance and provide an action plan for any non-compliant facilities within that VISN to PBM and the DUSHOM. The two offices will meet and decide whether any further actions are needed. The status is in process, and the target completion date is October 2017.

Recommendation 3: To help VHA achieve its objective of reducing the risk of diversion through effective implementation and oversight of the controlled substance inspection program, the Secretary of Veterans Affairs should direct the Under Secretary for Health to improve the training of VA medical facility controlled substance coordinators by ensuring the training includes the inspection procedures that VHA requires.

VA Comment: Concur. This recommendation is related to High Risk Area 4 (Inadequate training for VA staff).

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
**“VA HEALTH CARE: Actions Needed to Ensure Medical Facility Controlled
Substance Inspection Programs Meet Agency Requirements”**
(GAO-17-242)

The DUSHOM will provide the memorandum developed in response to Recommendation 1 that outlines the requirements that all current and future Controlled Substance Coordinators complete the Talent Management System web-based Controlled Substance Inspector Certification training program in addition to the Controlled Substance Coordinator Orientation Training Course. The certification course contains detailed information on conducting inspections. VHA Directive 1108.02, *Inspection of Controlled Substances*, will be updated with this requirement.

At completion of this action, VHA will do the following: VISN QM Officer will monitor compliance and provide an action plan for any non-compliant facilities within that VISN to PBM and the DUSHOM. The two offices will meet and decide whether any further actions are needed. The status is in process and the target completion date is October 2017.

Recommendation 4: To help VHA achieve its objective of reducing the risk of diversion through effective implementation and oversight of the controlled substance inspection program, the Secretary of Veterans Affairs should direct the Under Secretary for Health to ensure that medical facility directors have designed and implemented a process to address nonadherence with program requirements, including documenting the nonadherence and the corrective actions taken to remediate nonadherence or the actions that demonstrate why no remediation is necessary.

VA Comment: Concur. This recommendation is related to High Risk Area 1 (Ambiguous policies and inconsistent processes).

PBM will develop guidance to be distributed by the DUSHOM directing medical facility directors to assess adherence with program requirements at least quarterly. The facility QM Committee will review and evaluate monthly and quarterly reports for adherence with requirements and corrective actions taken or required to ensure compliance with program requirements in VHA Directive 1108.02. All corrective actions will be documented and followed through to completion by the QM Committee and reported to the medical facility director.

At completion of this action, VHA will do the following: VISN QM Officer will monitor compliance and provide an action plan for any non-compliant facilities within that VISN to PBM and the DUSHOM. The two offices will meet and decide whether any further actions are needed. The status is in process, and the target completion date is October 2017.

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***“VA HEALTH CARE: Actions Needed to Ensure Medical Facility Controlled
Substance Inspection Programs Meet Agency Requirements”***
(GAO-17-242)

Recommendation 5: To help VHA achieve its objective of reducing the risk of diversion through effective implementation and oversight of the controlled substance inspection program, the Secretary of Veterans Affairs should direct the Under Secretary for Health to ensure that networks (1) review their facilities' quarterly trend reports and assure facilities take corrective actions when nonadherence is identified and (2) monitor their medical facilities' efforts to establish and implement a review process to periodically compare facility inspection procedures to VHA's policy requirements.

VA Comment: Concur. This recommendation is related to High Risk Area 2 (Inadequate oversight and accountability).

VHA's Directive 1108.02, *Inspection of Controlled Substances*, provides guidance to Facility Directors for ensuring the Controlled Substances Programs develop and remain compliant with the requirements. PBM will develop a memorandum that outlines the expectations of Directive 1108.02 and specifically the requirements that Networks will: (1) review their facilities' quarterly trend reports and assure facilities take corrective actions when nonadherence is identified and (2) monitor their medical facilities' efforts to establish and implement a review process to periodically compare facility inspection procedures to VHA's policy requirements.

The DUSHOM will provide this memorandum to each Network Director who will disseminate to the Facility Directors, thereby ensuring appropriate actions have been taken to ensure the actions listed in the memorandum are completed. The Facility QM's will report compliance to the VISN QM Officer and for any facility that is non-compliant; an action plan will be developed.

At completion of this action, VHA will do the following: The VISN QM Officer will monitor compliance and provide an action plan for any non-compliant facilities within that VISN to PBM and the DUSHOM. The two offices will meet and decide whether any further actions are needed. The status is in process, and the target completion date is October 2017.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Randall B. Williamson, (202) 512-7114 or williamsonr@gao.gov

Staff Acknowledgments

In addition to the contact named above, Marcia A. Mann, Assistant Director; Pamela Dooley, Analyst-in-Charge; Mary Ann Curran-Dozier; and Carmen Rivera-Lowitt made key contributions to this report. Also contributing were Muriel Brown, Krister Friday, and Jacquelyn Hamilton.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (<http://www.gao.gov>). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to <http://www.gao.gov> and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <http://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

Connect with GAO

Connect with GAO on [Facebook](#), [Flickr](#), [LinkedIn](#), [Twitter](#), and [YouTube](#). Subscribe to our [RSS Feeds](#) or [E-mail Updates](#). Listen to our [Podcasts](#). Visit GAO on the web at www.gao.gov and read [The Watchblog](#).

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Website: <http://www.gao.gov/fraudnet/fraudnet.htm>

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Katherine Siggerud, Managing Director, siggerudk@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800, U.S. Government Accountability Office, 441 G Street NW, Room 7149, Washington, DC 20548

Strategic Planning and External Liaison

James-Christian Blockwood, Managing Director, spel@gao.gov, (202) 512-4707, U.S. Government Accountability Office, 441 G Street NW, Room 7814, Washington, DC 20548



Please Print on Recycled Paper.