



Testimony

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Representatives

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VA HEALTH CARE

Actions Needed to Ensure Medical Facilities' Controlled Substance Programs Meet Requirements

Statement of Randall B. Williamson, Director, Health Care

Accessible Version

Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee:

I am pleased to be here today to discuss our recent report on the controlled substance inspection programs at medical facilities run by the Department of Veterans Affairs (VA).¹ The Veterans Health Administration (VHA), which operates VA's health care system, requires that each of its medical facilities with stocks of controlled substances implement an inspection program to help reduce the risk of employees diverting for their own personal use controlled substances intended for veterans. Diversion of controlled substances such as opioid pain relievers can occur anywhere in a facility where employees have access to controlled substances, and this diversion can pose a risk to veterans—for example, by depriving them of needed medications. Without effective practices to reduce the risk of diversion by employees and to quickly identify it, diversion can remain undetected.

Under its controlled substance inspection program, VHA requires medical facilities to conduct monthly inspections following specified procedures outlined in VHA's inspection program policy. These inspections must be performed in all facility areas that are authorized to have controlled substances—including pharmacies and patient care areas such as operating and emergency rooms.² At each medical facility, the facility's director is primarily responsible for overseeing the inspection program and ensuring that the facility's program adheres to VHA's requirements. The facility director must appoint a coordinator to manage the controlled substance inspection program and the inspectors who conduct the inspections. The coordinator is responsible for ensuring that the inspections are conducted each month and submitting reports summarizing the results from the monthly inspections and trends to the facility director. The Veterans Integrated Service Network (network) that

¹GAO, *VA Health Care: Actions Needed to Ensure Medical Facility Controlled Substance Inspection Programs Meet Agency Requirements*, [GAO-17-242](#) (Washington, D.C.: Feb. 15, 2017).

²As described in our report, we reviewed VHA's controlled substance inspection program policy issued in 2010, which was the most current policy at the time our review. See Department of Veterans Affairs, *Veterans Health Administration Handbook 1108.02, Inspection of Controlled Substances* (Washington, D.C., Mar. 31, 2010). VHA issued an update to its policy in November 2016. See Department of Veterans Affairs, *Veterans Health Administration Directive 1108.02, Inspection of Controlled Substances* (Washington, D.C., Nov. 28, 2016).

oversees the facility is responsible for reviewing the inspection program trend reports annually.

My testimony today summarizes the findings from our report analyzing the implementation and oversight of controlled substance inspection programs at select VA medical facilities. Accordingly, this testimony addresses:

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.

In our report, we recommend several key actions that VA should take to ensure that the facilities' inspection programs meet VHA's requirements, and my testimony summarizes these recommendations and VA's response to them.

To conduct our work, we reviewed VHA policies and interviewed officials from 1) VHA Central Office, 2) a nongeneralizable selection of four VA medical facilities, and 3) the four networks that oversee these facilities. 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. 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 officials from 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 requirements. We reviewed the inspection procedures in place at each of the four facilities as described in the facilities' inspection program policies and other guidance documents, and we compared these procedures to VHA's policy requirements. We also reviewed the monthly and quarterly inspection reports for each of the four selected facilities during our review period and analyzed the contents of VHA's online training courses for coordinators and inspectors. We compared the implementation and oversight of the facilities' controlled substance inspection programs to VHA's policy requirements and to federal standards for internal control related to

control activities, monitoring, and oversight.³ Further details on our scope and methodology are included in our report.⁴ The work this statement is based on was performed in accordance with generally accepted government auditing standards.

Selected VA Medical Facilities Did Not Conduct All Monthly Inspections or Follow All Required VHA Inspection Procedures

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. Further, at both facilities, most of the missed inspections were for patient care areas such as the operating rooms.⁵ At one of the two facilities, inspectors had missed all 14 inspections of the facility's operating rooms during our 14-month review period. The facility's coordinator told us that the operating rooms were not inspected during this time because the assigned inspectors 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.⁶ As a result of missed inspections in the operating rooms and other patient care areas, these medical facilities lack reasonable assurance that their physical inventory of controlled substances matches the recorded inventory, thereby increasing the risk that controlled substances could be stolen. Further, their ability to protect veterans from the harm that can result from diversion, such as depriving them of needed pain medications, is limited. The other two VA medical facilities we reviewed fully adhered to VHA's requirement to conduct monthly inspections in their patient care areas and pharmacies.

³GAO, *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.

⁴See [GAO-17-242](#).

⁵VHA's inspection program policy requires that facilities inspect patient care areas and pharmacies on a monthly basis using specific procedures.

⁶A team of inspectors is assigned from various areas of the medical facility.

We also 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 inspection requirements we reviewed. The fourth facility we reviewed had implemented inspection procedures that followed these nine requirements. For example, inspectors at two facilities did not verify that controlled substances had been properly transferred from their facility pharmacies to the automated dispensing machines in patient care areas.⁷ VHA requires inspectors to verify that all controlled substances transferred by a pharmacy on a selected day were received in patient care areas such as the operating room. However, at one facility, inspectors told us that they did not conduct this required procedure in one of the facility's two pharmacies. At another facility, inspectors verified only a sample of controlled substances dispensed by the pharmacy to confirm that the substances were actually transferred. Without checking that all controlled substances were properly transferred, 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.⁸

We found that several factors contributed to the missed inspections and incorrect implementation of inspection procedures that we identified.

First, the two VA medical facilities that missed inspections lacked an additional control procedure, such as designating an alternate coordinator or appointing additional inspectors, to help prevent missed inspections when the assigned inspectors could not conduct them. Both of the 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. In addition, the alternate coordinator at one of these facilities conducted inspections when inspectors had unforeseen circumstances that prevented them from completing the assigned inspections. In contrast, the two medical facilities that missed inspections did not have an additional control procedure,

⁷Automated dispensing machines are computerized drug storage and dispensing medication cabinets.

⁸The VA Office of the Inspector General also found in 2009—and again in 2014—that VA medical facilities did not always conduct required inspections or follow VHA's required procedures. For example, see VA Office of the Inspector General, *Combined Assessment Program Summary Report: Evaluation of the Controlled Substances Inspection Program at Veterans Health Administration Facilities* (Washington, D.C.: June 10, 2014).

such as the use of an alternate coordinator. Without coordinators ensuring that the monthly inspections are conducted, VA medical facilities lack assurance that the inspection programs are meeting the objective to reduce the risk of diversion of controlled substances.

Second, three of the four VA medical facilities in our review did not have written inspection procedures that were fully consistent with VHA's policy requirements. This likely contributed to their inspections not following certain VHA policy requirements. (See figure 1.)

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-17-442T

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 the 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 written inspection procedures that were consistent with VHA's policy requirements has an ongoing process to conduct comprehensive reviews of its procedures. At this facility, the coordinators had conducted separate reviews of the facility's procedures

in coordination with two pharmacy managers, according to a facility official. In contrast, at the other three selected VA medical facilities, the coordinators' reviews of the facilities' procedures were not as comprehensive. For example, the coordinator at one facility told us he had compared the facility's procedures to the VHA requirements but did not involve other facility officials to verify the accuracy of his review.

Third, while VHA relies on coordinators to ensure that the inspections are conducted correctly, we found that VHA's training course for coordinators lacks substantive information about VHA's required inspection procedures. VHA's training course for inspectors, in comparison, includes substantive information about the required inspection procedures. 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 our report we noted that missed inspections and gaps in facilities' local inspection procedures and coordinator training are inconsistent with federal internal control standards, which state that management should periodically review their procedures for effectiveness and provide proper training to achieve results. We concluded that missed inspections and gaps in inspection procedures and training could significantly limit VHA's ability to reduce the risk of diversion of controlled substances. To address these shortcomings, we recommended that VA ensure that VA medical facilities establish an additional control procedure, such as an alternate coordinator, to help prevent missed inspections as well as a process in which coordinators and other stakeholders compare facility inspection procedures to VHA's policy requirements and modify facility procedures, as appropriate. We also recommended that VA improve its coordinator training by ensuring that the training includes the inspection procedures that VHA requires. VA agreed with these recommendations and said it plans to take steps to implement them by October 2017.

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

We found inconsistent oversight of the controlled substance inspection programs at selected VA medical facilities by facility directors and by the networks to which the facilities report. Directors at two of the four facilities

had not implemented corrective actions to address missed inspections identified by coordinators in the monthly inspection reports that the directors had reviewed. In addition, one of four facility directors did not receive quarterly trend reports during our review period as required by VHA policy and did not implement a corrective action to ensure that he receives future reports. Further, we found that two of the four networks did not review their facilities' quarterly trend reports as required by VHA policy. Officials at one of these two networks told us that they were unaware of the requirement, while an official in the other network told us the officials responsible for reviewing the reports did not realize it was a requirement.⁹ One network that had reviewed the quarterly trend reports did not follow up with a facility in our review to ensure that the coordinator had submitted missed trend reports to the facility's director. We also found that this coordinator had not completed other quarterly trend reports, and the facility's director did not develop a corrective action plan to ensure the completion of these reports in the future.

In our report, we pointed out that the inconsistent oversight by the directors and networks is contrary to federal internal control standards, which call for oversight to be ongoing to assess performance, promptly remediate deficiencies, and hold individuals accountable for their responsibilities. We concluded in our report that without ongoing monitoring by facility directors and networks—including holding facilities accountable for correcting nonadherence to program requirements—VHA lacks reasonable assurance that facilities will correct deficiencies on a timely basis. To address these oversight problems, we recommended that VA ensure that medical facility directors have a process in place to document and correct nonadherence with program requirements. We also recommended that VA ensure that the networks review their facilities' quarterly trend reports and ensure that facilities take corrective actions when program nonadherence is identified. VA agreed with our recommendations and said it plans to take steps to implement them by October 2017.

⁹VHA included this network requirement in a 2014 memo that it issued in response to the VA Office of the Inspector General findings on weaknesses in the inspection programs. See VA, *Memorandum on Controlled Substance Inspection Program Requirement, VA Office of Inspector General-Combined Assessment Program Findings* (Washington, D.C.: July 9, 2014).

Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee, this concludes my statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contacts & Staff Acknowledgments

If you or your staff members have any questions concerning this testimony, please contact me at (202) 512-7114 (williamsonr@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Other individuals who made key contributions to this testimony include Marcia A. Mann, Assistant Director; Pamela Dooley (Analyst-in-Charge); Krister Friday; and Carmen Rivera-Lowitt.

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