



**Department of Veterans Affairs
Office of Inspector General**

Office of Healthcare Inspections

Report No. 14-01785-184

Combined Assessment Program Summary Report

Evaluation of the Controlled Substances Inspection Program at Veterans Health Administration Facilities

June 10, 2014

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections completed an evaluation of the controlled substances (CS) inspection program at Veterans Health Administration (VHA) facilities. The purpose of the evaluation was to determine whether VHA facilities complied with requirements related to CS security and inspections and to follow up on the Office of Inspector General's report *Healthcare Inspection – Review of Selected Pharmacy Operations in Veterans Health Administration Facilities* (Report No. 07-03524-40, December 3, 2009).

We conducted this review at 58 VHA medical facilities during Combined Assessment Program reviews performed across the country from October 1, 2012, through September 30, 2013. We noted high compliance with VHA policy in many areas, including that CS inspectors (CSIs) were sufficiently rotated and had 3-year term limits and that inspections were randomly scheduled and completed on the same day initiated.

We recommended that VHA define in policy acceptable reasons for missed CS area inspections and provide guidance regarding CS Coordinator performance of monthly inspections.

To improve operations, we recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that:

- Pharmacy physical security surveys are conducted and that identified deficiencies are corrected.
- Quarterly CS inspection trend reports of identified discrepancies, problematic trends, and potential areas for improvement are completed and provided to facility Directors.
- Monthly inspections of all non-pharmacy areas with CS are conducted.
- CSIs validate 2 transfers of CS from one storage area to another area, reconcile 1 day's dispensing from the pharmacy to each automated unit, and verify electronic or written orders for 5 randomly selected dispensing activities.
- CSIs perform quarterly physical counts of the emergency drug cache and monthly verification of seals.
- CSIs validate completion of all required drug destruction activities.
- CSIs validate accountability for all prescription pads stored in the pharmacy.
- CSIs conducting outpatient pharmacy inspections verify written prescriptions for 10 percent of (or a maximum of 50) schedule II drugs dispensed.

- CSIs receive annual training regarding problematic issues identified through external surveys and other quality control measures.

Comments

The Under Secretary for Health concurred with the findings and recommendations. (See Appendix A, pages 7–12, for the full text of the comments.) The implementation plans are acceptable, and we will follow up until all actions are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections completed an evaluation of the controlled substances (CS) inspection program at Veterans Health Administration (VHA) facilities. The purpose of the evaluation was to determine whether VHA facilities complied with requirements related to CS security and inspections and to follow up on the OIG report *Healthcare Inspection – Review of Selected Pharmacy Operations in Veterans Health Administration Facilities* (Report No. 07-03524-40, December 3, 2009).

Background

VA requires that managers at VHA facilities ensure that a CS inspection program is implemented and maintained. In 2008, we conducted an inspection of pharmacy operations at 43 VHA medical centers during Combined Assessment Program (CAP) reviews. The review analyzed pharmacy operations, including environment of care, management of CS, and pharmacy security. Overall, pharmacies complied with VHA guidelines for pharmacy security and reporting requirements. However, facility managers needed to reinforce compliance with VHA policy regarding CS inspection programs. VHA Handbook 1108.02 details requirements for facility CS inspections. This follow-up review incorporated selected handbook elements and evaluated whether VHA facility managers implemented and maintained a CS inspection program.

Scope and Methodology

We performed this review in conjunction with 58 CAP reviews of VHA medical facilities conducted from October 1, 2012, through September 30, 2013. The facilities were a stratified random sample of all VHA facilities and represented a mix of facility size, affiliation, geographic location, and Veterans Integrated Service Networks. OIG generated an individual CAP report for each facility. For this report, we summarized the data collected from the individual facility CAP reviews.

We reviewed facility CS policies and inspection documents, CS inspector (CSI) and CS Coordinator (CSC) appointments, training records, and annual pharmacy security surveys. We used 90 percent as the general level of expectation for compliance. The training record and CS area samples within each facility were not a probability sample and thus do not represent the entire population of that facility. Therefore, the summary results presented in this report are not generalizable to the entire VHA.

Inspectors conducted the reviews in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

All 58 facilities we reviewed had established CS inspection programs. We noted high compliance with VHA policy in many areas, including that CSIs were sufficiently rotated and had 3-year term limits and that inspections were randomly scheduled and completed on the same day initiated. However, we identified opportunities for improvement in several areas.

Issue 1: Administrative Program Requirements

Physical Security

VHA requires VA Police to conduct annual physical security surveys of the pharmacy areas and to take corrective actions to resolve deficiencies.¹ Two facilities did not conduct annual physical security surveys. Of the 45 facilities that had identified physical security deficiencies, 13 (29 percent) had not taken actions to fully correct them.

We recommended that managers ensure that physical security surveys are conducted and that identified deficiencies are corrected.

Reporting

CSCs are required to review inspection results and provide facility Directors with monthly summaries of findings and quarterly trend reports of identified discrepancies, problematic trends, and potential areas for improvement.² While facilities met the requirement for monthly summary reports, 10 (17 percent) of the 58 facilities either did not complete the quarterly trend reports or did not include all required elements in the reports.

We recommended that quarterly trend reports of identified discrepancies, problematic trends, and potential areas for improvement be completed and provided to facility Directors.

Issue 2: CS Inspections

Non-Pharmacy CS Inspections

The CSC is responsible for ensuring that required inspections are completed each month in each area that stores CS. VHA specifies that on a rare occasion, a given area may go uninspected as long as the area is inspected in the subsequent month.³ We reviewed inspection documentation for a 6-month period for 544 non-pharmacy areas and found that 109 areas (20 percent) were missing 1 or more monthly CS inspections. We noted multiple reasons for missed inspections, including that some CSIs delayed

¹ VA Handbook 0730, *Security and Law Enforcement*, August 11, 2000.

² VHA Handbook 1108.02, *Inspection of Controlled Substances*, March 31, 2010.

³ VHA Handbook 1108.02.

their assigned inspection until the last day of the month and were then unable to complete the inspection because of illness or other obligations. CSCs were uncertain of acceptable reasons for missed inspections.

VHA does not provide guidance regarding CSC participation in monthly inspections. We found that some CSCs were routinely performing monthly inspections. There is potential the CSC oversight role could be in conflict if the CSC also performs inspections.

If facilities allow CS transfers, CSIs are required to validate two transfers of CS from one storage area to another area.⁴ There were 81 CS areas that had these transfers, and 18 areas (22 percent) did not have the required validations during 1 or more monthly inspections.

As part of the inspection process, VHA requires that CSIs reconcile 1 day's dispensing from the pharmacy to each automated unit.⁵ We found that 127 (24 percent) of 527 applicable inspections did not include this reconciliation.

CSIs are required to verify electronic or written orders for five randomly selected dispensing activities in each CS area. We found that 58 (11 percent) of 545 applicable inspections lacked this verification.

We recommended that monthly inspections of all non-pharmacy CS areas be conducted and that VHA define acceptable reasons for missed inspections and provide guidance on CSC performance of monthly inspections. We also recommended that CSIs validate 2 transfers of CS from one storage area to another area, reconcile 1 day's dispensing from the pharmacy to each automated unit, and verify electronic or written orders for 5 randomly selected dispensing activities.

Pharmacy Inspections

We reviewed inspection documentation for a 6-month period for 72 pharmacy areas.

VHA requires quarterly physical counts of the emergency drug cache and monthly verification of seals.⁶ For the 63 inspections⁷ that included an onsite emergency drug cache, 11 (17 percent) did not include these activities.

⁴ VHA Handbook 1108.02.

⁵ VHA Handbook 1108.02.

⁶ VHA Handbook 1108.02.

⁷ Not all facilities had an onsite emergency drug cache. Additionally, at multi-division facilities, the emergency drug cache was maintained at only one of the division locations.

Drug destruction activities are important components of the pharmacy inspection. We reviewed inspection documentation for 65 areas⁸ and found that documentation for:

- Seven (11 percent) did not include comparison of drugs held for destruction with destruction file holding reports.
- Nine (14 percent) did not include verification that drug destructions were completed at least quarterly.
- Fourteen (22 percent) did not include completed verification of the audit trail for destruction of 10 randomly selected drugs each month.

CSIs are required to validate accountability for all prescription pads stored in the pharmacy.⁹ Eight (11 percent) of 70 applicable inspections did not include this verification. VHA requires that outpatient pharmacy inspections include verification of written prescriptions for 10 percent (or a maximum of 50) of schedule II¹⁰ drugs dispensed.¹¹ Eight (12 percent) of 67 applicable inspections did not include these verifications.

We recommended that CSIs perform quarterly physical counts of the emergency drug cache and monthly verification of the seals and validate completion of all required drug destruction activities and accountability for all prescription pads stored in the pharmacy. We also recommended that in the outpatient pharmacy, CSIs verify written prescriptions for 10 percent of (or a maximum of 50) schedule II drugs dispensed.

Issue 3: Training

VHA requires that CSIs be provided an orientation and annual training that includes problematic issues identified through external survey findings and other quality control measures.¹² Of the 451 CSIs in their positions for more than 1 year, 87 (19 percent) had not received annual training.

We recommended that CSIs receive annual training regarding problematic issues identified through external surveys and other quality control measures.

Conclusions

All 58 facilities we reviewed during fiscal year 2013 had established CS inspection programs. We noted high compliance (greater than 90 percent) with VHA policy in many areas, including that CSIs were sufficiently rotated and had 3-year term limits and that inspections were randomly scheduled and completed on the same day initiated.

⁸ Not all facilities had drugs held for destruction during the 6-month period.

⁹ VHA Handbook 1108.02.

¹⁰ Those with high potential for abuse and possible psychological or physical dependence.

¹¹ VHA Handbook 1108.02.

¹² VHA Handbook 1108.02.

We identified opportunities for improvement in:

- conducting annual physical security surveys and correcting identified deficiencies
- completing quarterly trend reports and providing them to facility Directors
- conducting monthly CS inspections of non-pharmacy areas
- completing non-pharmacy inspection activities
- performing emergency drug cache quarterly physical counts and monthly verification of seals
- validating completion of required drug destruction activities, accountability of prescription pads stored in the pharmacy, and outpatient pharmacy written prescriptions for schedule II drugs
- providing annual CSI training

VHA can strengthen policy by defining acceptable reasons for missed CS area inspections and providing guidance on CSC performance of monthly inspections.

Recommendations

1. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that pharmacy physical security surveys are conducted and identified deficiencies are corrected and that compliance is monitored.
2. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that quarterly controlled substances inspection trend reports of identified discrepancies, problematic trends, and potential areas for improvement are completed and provided to facility Directors.
3. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that monthly inspections of all non-pharmacy controlled substances areas are conducted and that compliance is monitored.
4. We recommended that the Under Secretary for Health ensures that VHA defines in policy acceptable reasons for missed controlled substances area inspections and provides guidance regarding Controlled Substances Coordinator performance of monthly inspections.
5. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors validate 2 transfers of controlled substances from one storage area to another area, reconcile 1 day's dispensing from the pharmacy to each automated unit, and verify electronic or written orders for 5 randomly selected dispensing activities.
6. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors perform quarterly physical counts of the emergency drug cache and monthly verification of seals and that compliance is monitored.

- 7.** We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors validate completion of all required drug destruction activities.
- 8.** We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors validate accountability for all prescription pads stored in the pharmacy.
- 9.** We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors conducting outpatient pharmacy inspections verify written prescriptions for 10 percent of (or a maximum of 50) schedule II drugs dispensed.
- 10.** We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors receive annual training regarding problematic issues identified through external surveys and other quality control measures.

Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 22, 2014

From: Under Secretary for Health (10)

**Subject: OIG Draft Combined Assessment Program
(CAP) Summary Report – Evaluation of the Controlled
Substances Inspection Program at Veterans
Health Administration Facilities (2014-01785-HI-0435)
(VAIQ 7466184)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the draft CAP Summary Report, Evaluation of the Controlled Substances Inspection Program at Veterans Health Administration (VHA) Facilities. I have reviewed the draft report and concur with the report's recommendations.
2. Attached is the VHA corrective action plan for recommendations one through ten.
3. If you have any questions, please contact Karen M. Rasmussen, M.D., Director, Management Review Service (10AR), at (202) 461-6643 or email VHA10ARMRS2@va.gov.



Robert A. Petzel, M.D.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report, CAP Summary Report – Evaluation of the Controlled Substances Inspection Program at VHA Facilities

Date of Draft Report: March 25, 2014

Recommendations/ Actions	Status	Completion Date
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OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that pharmacy physical security surveys are conducted and identified deficiencies are corrected and that compliance is monitored.

VHA Comments

Concur

The Deputy Under Secretary for Health for Operations and Management will issue a memorandum to reinforce VA Handbook 0730, *Security and Law Enforcement*, including the requirement that the VA Police must conduct annual physical security surveys of the pharmacy areas and take corrective action to resolve deficiencies. The Veterans Integrated Service Network (VISN) Leadership will be responsible for monitoring compliance and corrective actions.

Status: In progress Target Completion Date:
June 30, 2014

Recommendation 2. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that quarterly controlled substances inspection trend reports of identified discrepancies, problematic trends, and potential areas for improvement are completed and provided to facility Directors.

VHA Comments

Concur

The Deputy Under Secretary for Health for Operations and Management will issue a memorandum to reinforce VHA Handbook 1108.02, *Inspection of Controlled Substances*. The Controlled Substance Coordinator (CSC) will provide trend reports of discrepancies, problematic trends, and areas for improvement to the VA Medical Center

Director or Consolidated Mail Outpatient Pharmacy Director. Trend reports will be reviewed by VISN Leadership during the annual Quality Management Oversight visit.

Status: In progress Target Completion Date:
June 30, 2014

Recommendation 3. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that monthly inspections of all non-pharmacy controlled substances areas are conducted and that compliance is monitored.

VHA Comments

Concur

The Deputy Under Secretary for Health for Operations and Management will issue a memorandum to reinforce VHA Handbook 1108.02, *Inspection of Controlled Substances*. This memorandum will include the requirement for the CSC to ensure required inspections are completed each month in areas that store Controlled Substances (CS).

Status: In progress Target Completion Date:
June 30, 2014

Recommendation 4. We recommended that the Under Secretary for Health ensures that VHA defines in policy acceptable reasons for missed controlled substances area inspections and provides guidance regarding Controlled Substances Coordinator performance of monthly inspections.

VHA Comments

Concur

VHA will issue a memorandum from the DUSHOM to clarify the updates in VHA Handbook 1108.02, *Inspection of Controlled Substances*. The content of the memorandum will be presented on the Controlled Substance Coordinator's (CSC) bi-monthly learning calls, posted to the CSC National SharePoint, and e-mailed to the CSC National Mailgroup.

Status: In progress Target Completion Date:
September 30, 2014

VHA Handbook 1108.02 is scheduled for revision and will incorporate these changes.

Status: In progress Target Completion Date:
April 1, 2015

This action will be completed when:

1. A copy of the Memorandum is provided;
2. Documentation of the Memorandum posting to CSC National SharePoint, and emailing to the CSC National Mailgroup is provided; and
3. A draft of the VHA Handbook outlining the required elements is provided.

Recommendation 5. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors validate 2 transfers of controlled substances from one storage area to another area, reconcile 1 day's dispensing from the pharmacy to each automated unit, and verify electronic or written orders for 5 randomly selected dispensing activities.

VHA Comments

Concur

A memo from the DUSHOM will be issued to reinforce VHA Handbook 1108.02, Inspection of Controlled Substances. This memo will include the requirement for the Controlled Substance Inspectors to validate two transfers of CS from one storage area to another area, reconcile one day of dispensing from the pharmacy to each automated unit, and verify electronic or written orders for five randomly selected dispensing activities.

Status: In progress Target Completion Date:
June 30, 2014

Recommendation 6. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors perform quarterly physical counts of the emergency drug cache and monthly verifications of seals and that compliance is monitored.

VHA Comments

Concur

The Deputy Under Secretary for Health for Operations and Management will issue a memorandum to reinforce VHA Handbook 1108.02, *Inspection of Controlled Substances*. This memorandum will include the requirement for the Controlled Substance Inspectors to perform quarterly physical counts of the emergency drug cache and monthly verification of seals. Compliance is to be monitored by the CSC.

Status: In progress Target Completion Date:
June 30, 2014

Recommendation 7. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors validate completion of all required drug destruction activities.

VHA Comments

Concur

The Deputy Under Secretary for Health for Operations and Management will issue a memorandum to reinforce VHA Handbook 1108.02, *Inspection of Controlled Substances*. This memorandum will include the requirement for the Controlled Substance Inspectors to validate the completion of all required drug destruction activities and document on the inspection report.

Status: In progress Target Completion Date:
June 30, 2014

Recommendation 8. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors validate accountability for all prescription pads stored in the pharmacy.

VHA Comments

Concur

The Deputy Under Secretary for Health for Operations and Management will issue a memorandum to reinforce VHA Handbook 1108.02, *Inspection of Controlled Substances*. This memorandum will include the requirement for the Controlled Substance Inspectors to verify the accountability of all prescription pads stored in the pharmacy.

Status: In progress Target Completion Date:
June 30, 2014

Recommendation 9. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors conducting outpatient pharmacy inspections verify written prescriptions for 10 percent of (or a maximum of 50) schedule II drugs dispensed.

VHA Comments

Concur

The Deputy Under Secretary for Health for Operations and Management will issue a memorandum that reiterates guidance provided to the field in a prior memorandum

dated July 1, 2013. This memorandum clarified requirements in VHA Handbook 1108.02, *Inspection of Controlled Substances*, with the implementation of e-prescribing for controlled substances. This memorandum will include the requirement for the facility Director to ensure the Controlled Substance Inspectors who conduct outpatient pharmacy inspections verify 50 hand-written prescriptions (or all if less than 50) for schedule II-V drugs dispensed.

Status: In progress Target Completion Date:
June 30, 2014

Recommendation 10. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensures that controlled substances inspectors receive annual training regarding problematic issues identified through external surveys and other quality control measures.

VHA Comments

Concur

The Deputy Under Secretary for Health for Operations and Management will issue a memorandum to reinforce VHA Handbook 1108.02, *Inspection of Controlled Substances*. This memorandum will include the requirement for the VISN/Facility Director to ensure the Controlled Substance Inspectors receive annual training regarding problematic issues identified in this OIG report as well as other quality control measures.

Status: In progress Target Completion Date:
June 30, 2014

OIG Contact and Staff Acknowledgments

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