



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Review of Selected Pharmacy Operations in Veterans Health Administration Facilities

To Report Suspected Wrongdoing in VA Programs and Operations

**Telephone: 1-800-488-8244 between 8:30AM and 4PM Eastern Time,
Monday through Friday, excluding Federal holidays**

E-Mail: yaoighotline@va.gov

Executive Summary

VA Office of Inspector General, Office of Healthcare Inspections completed an evaluation of select pharmacy processes in Veterans Health Administration (VHA) medical facilities. The purpose of our review was to: (1) evaluate pharmacy controls related to security and management of controlled substances (CS), (2) determine whether medical facilities complied with local and VHA policies regarding pharmacy security and handling of CS, and (3) evaluate whether management controls of deterrence and detection of CS diversion were effective.

We evaluated pharmacy internal physical environments, and we assessed whether pharmacies had processes to evaluate polypharmacy. We also determined whether pharmacies adhered to safety and infection control (IC) standards and whether pharmacy clean rooms complied with United States Pharmacopeia (USP) Chapter <797> guidelines for clean room construction.

We performed this review at 43 VHA medical facilities during Combined Assessment Program reviews conducted across the country from January 1–December 31, 2008.

Overall, pharmacies complied with VHA and IC guidelines, pharmacy physical security, and reporting requirements; however improvement is required to ensure full compliance with VHA regulations regarding CS inspection programs.

We recommended that the Acting Under Secretary for Health, in conjunction with Veterans Integrated Service Network and VHA facility managers, ensure that:

- Compliance with VHA regulations regarding CS inspection programs is reinforced.
- Pharmacies review compliance with USP Chapter <797> guidelines for compounded sterile products.
- Facilities are encouraged to provide guidance for clinical review of polypharmacy in high-risk populations, such as mental health patients and the elderly.



DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Acting Under Secretary for Health (10)

SUBJECT: Healthcare Inspection – Review of Selected Pharmacy Operations in Veterans Health Administration Facilities

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections completed an evaluation of select pharmacy processes in Veterans Health Administration (VHA) medical facilities. The purpose of our review was to: (1) evaluate pharmacy controls related to security and management of controlled substances (CS), (2) determine whether medical facilities complied with local and VHA policies regarding pharmacy security and handling of CS, and (3) evaluate whether management controls of deterrence and detection of CS diversion were effective.

We evaluated pharmacy internal physical environments, and we assessed whether pharmacies had processes to evaluate polypharmacy. We also determined whether pharmacies adhered to safety and infection control (IC) standards and whether pharmacy clean rooms¹ complied with United States Pharmacopeia (USP) Chapter <797> guidelines for clean room construction.²

Background

Controlled Substances

Based in part on a past report published by the OIG, the Deputy Under Secretary for Health for Operations and Management (DUSHOM) identified pharmacy security and CS management as material weaknesses.³ Consequently, the DUSHOM required that facilities either conduct a self-assessment of the physical security in pharmacies to

¹ A clean room is where patients' intravenous medications and solutions are compounded.

² VHA Handbook 1108.06, *Inpatient Pharmacy Services*, June 27, 2006.

³ *Review of VA Medical Facility Compliance with Controls over Prescription Drugs*, Report No. 05-00877-17, November 1, 2006.

safeguard CS or describe progress in meeting previous OIG or System-wide Ongoing Assessment and Review Strategy team recommendations.⁴ In 2007, the DUSHOM required pharmacies to conduct a self-assessment of CS management.⁵ This review assessed compliance with VHA guidelines for CS inspection programs.

Infection Control Standards

The International Organization for Standardization (ISO) classifies a clean room as an area where the concentration of airborne particles is controlled. A clean room is constructed and used to minimize the introduction, generation, and retention of particles inside the room. Temperature, humidity, and pressure in the room should be monitored.⁶ The use of alternative systems, such as a Laminar Airflow Workbench (LAFW)⁷ or biosafety cabinets⁸ that have been verified to achieve an ISO Class 5 environment, may be utilized.⁹ In 2004, the USP published guidelines for clean rooms, and compliance became mandatory on January 1, 2008.¹⁰ The guidelines, known as USP Chapter <797>, are enforceable through the U.S. Food and Drug Administration. VHA has adopted policies that acknowledge the USP as an authority in pharmaceutical practice and requires adherence to its guidelines.

Though packaged medications are rarely contaminated, medication bins, storage areas, or the exteriors of individual medication packages can harbor nosocomial pathogens and be indirect sources of contamination.¹¹ This review assessed compliance with VHA guidelines for cleanliness and safety in day-to-day pharmacy operations.¹²

Polypharmacy

Polypharmacy is more complex than just the number of drugs that a patient takes. The use of multiple medications is particularly prevalent among the elderly population, leading to complex drug regimens and the risk of further complications.¹³ Although drug therapy is often necessary for the maintenance and prevention of disease states, excessive

⁴ Deputy Under Secretary for Health for Operations and Management, *FY 2006 Monitors and Guidelines*.

⁵ Deputy Under Secretary for Health for Operations and Management, *FY 2007 Monitors and Guidelines*.

⁶ Department of Veterans Affairs, Office of Facilities Management, *Design Alert: Pharmacy Design Compliance with U.S. Pharmacopeia chapter <797>*, February 23, 2006.

⁷ An LAFW is a work area that contains a system of circulating filtered air in parallel flowing planes. The system reduces the risk of airborne contamination and exposure in hospital pharmacies.

⁸ Ventilated cabinets for personnel and environmental protection that have an un-recirculated inward airflow away from the operator that exhausts all air to the atmosphere after filtration through a HEPA filter.

⁹ A Class 5 environment is used when a bacteria-free or particulate-free environment is required in the manufacture of aseptically produced injectable medicines.

¹⁰ An additional USP Chapter <797> revision bulletin became final on June 1, 2008.

¹¹ Nosocomial infections are infections that are a result of treatment in a hospital or a health care service unit but are secondary to the patient's original condition.

¹² VHA Handbook 1108.05, *Outpatient Pharmacy Services*, May 30, 2006; VHA Handbook 1108.06.

¹³ Yvette C. Terrie, BS PharmD, RPh, "Understanding and Managing Polypharmacy in the Elderly," *Pharmacy Times*, December 2004.

use of medications can result in adverse reactions. Clinically, the criteria utilized for identifying polypharmacy involve the following:

- Taking medications that have no apparent indication.
- Using therapeutic equivalents to treat the same illness.
- Concurrently using interacting medications.
- Using inappropriate dosages.
- Using additional medications solely to treat adverse drug reactions.

Polypharmacy in psychiatry is becoming the norm rather than the exception.¹⁴ Some instances of polypharmacy may not be justifiable, such as when a clinician neglects to review medications regularly or to discontinue one antipsychotic medication when starting another. This review assessed whether facilities had processes to evaluate polypharmacy in order to intervene when appropriate.

Scope and Methodology

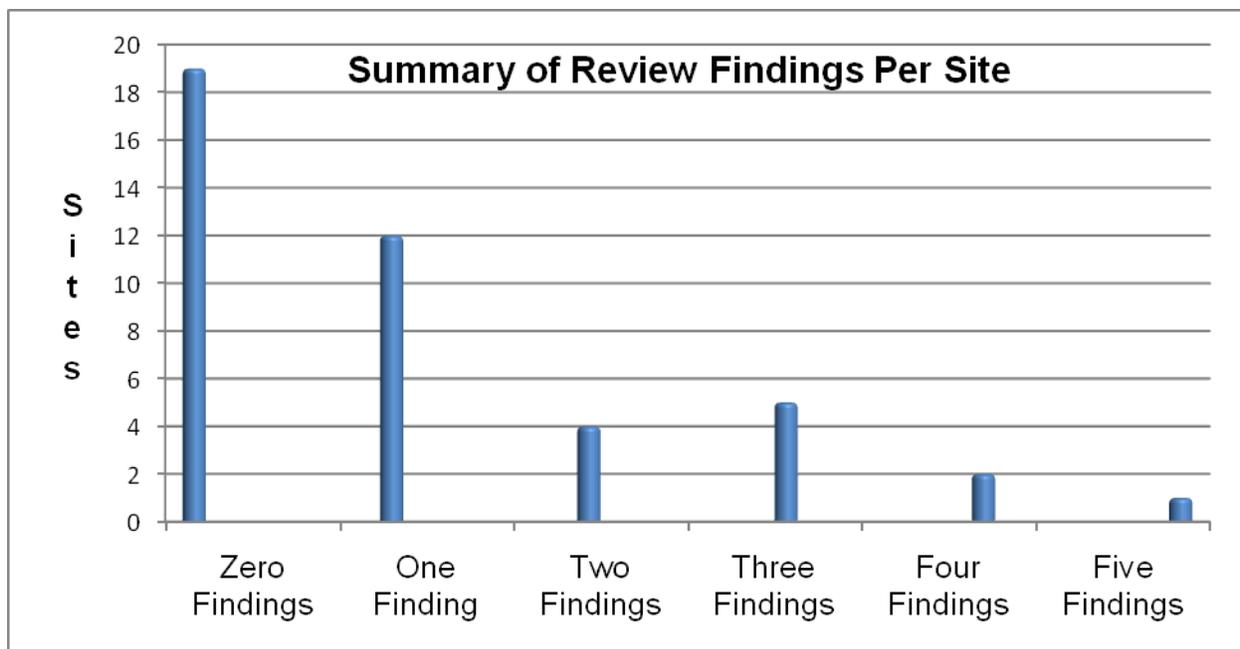
We conducted the review at 43 VHA medical facilities during Combined Assessment Program (CAP) reviews conducted from January 1–December 31, 2008. We analyzed results and reported deficiencies in each facility CAP review report.

Our evaluation included reviewing policies and procedures prior to site visits. The majority of the review was conducted onsite in the form of tours of the inpatient and outpatient pharmacies, pharmacy clean rooms, and CS vaults. We conducted interviews with pharmacy staff, CS Coordinators and inspectors, and VA Police personnel. The review analyzed pharmacy operations, including environment of care (EOC), IC, management of CS, and pharmacy security, and assessed whether pharmacies had processes to address polypharmacy.

We reviewed VHA regulations¹⁵ governing pharmacy and CS security, and we assessed whether each facility's policies and practices were consistent with VHA regulations. We inspected inpatient and outpatient pharmacies for security, EOC, and IC issues, and we interviewed managers from Pharmacy Service and VA Police Service when indicated. We reviewed policies and processes to determine whether each facility took action to monitor and avoid inappropriate use of multiple medications. In the 43 CAP reports, we made 48 recommendations related to pharmacy operations. (See summary on next page.)

¹⁴ Vijayalakshmy Patrick, M.D., et al., "Best Practices: An Initiative to Curtail the Use of Antipsychotic Polypharmacy in a State Psychiatric Hospital," *Psychiatric Services*, 57:21–23, January 2006.

¹⁵ VHA Handbook 1108.1, *Controlled Substances (Pharmacy Stock)*, October 4, 2004; VHA Handbook 1108.05; VHA Handbook 1108.06.



We conducted the review in accordance with the *Quality Standards for Inspections* published by the President’s Council on Integrity and Efficiency.

Inspection Results

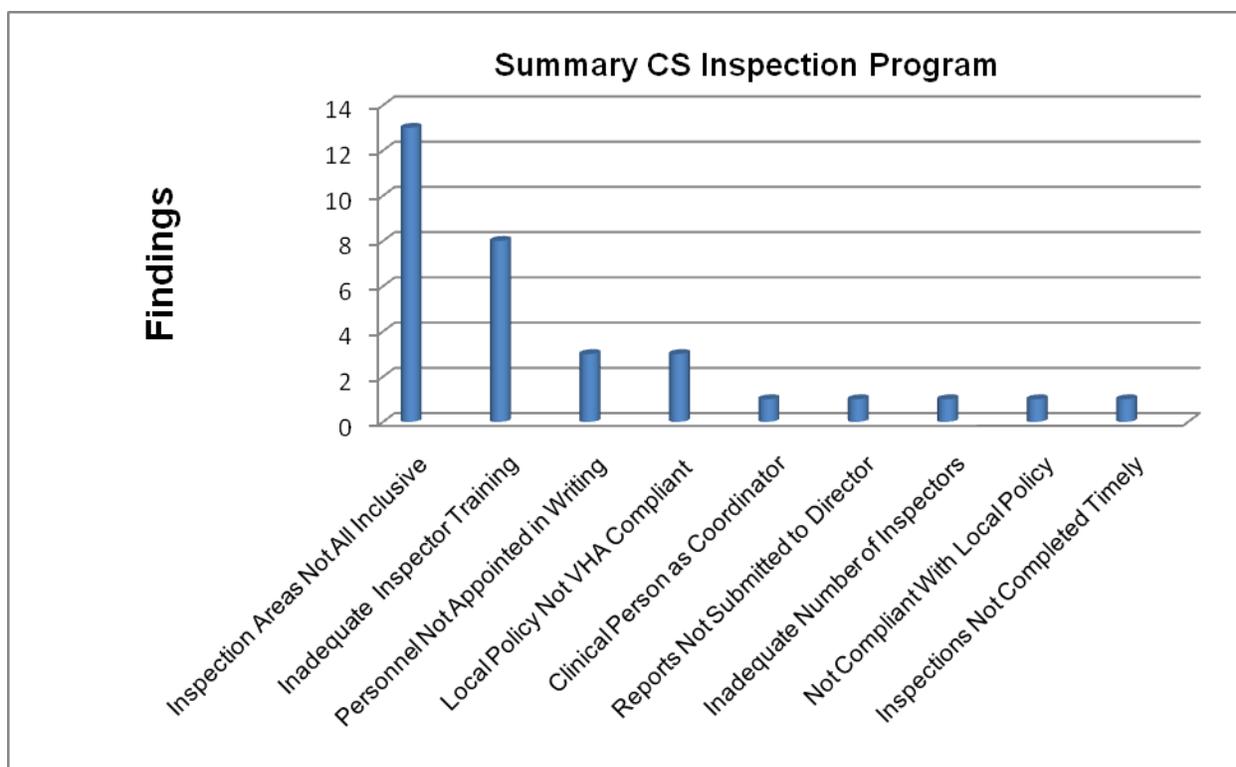
A. Controlled Substance Inspections

We determined that 33 (77 percent) of the 43 facilities experienced suspected drug diversions during the previous year. All but one facility reported suspected diversions to appropriate authorities, including the OIG Office of Investigations. We recommended that this one facility’s local policy include internal and external notification procedures.

We evaluated whether CS inspections were conducted according to VHA regulations.¹⁶ The CS inspection program accounted for 32 (67 percent) of the 48 recommendations. CS inspectors at 13 (30 percent) facilities did not conduct inspections in all areas within the facility where CS were held.

Although all CS Coordinators received appropriate training, eight (19 percent) facilities lacked documentation that all CS inspectors received annual CS inspection training. In addition, at three (7 percent) facilities, the Director did not appoint the CS Coordinator or inspectors in writing, as required by VHA policy. The remaining findings included findings such as the absence of quarterly reports from CS Coordinators to facility Directors and the appointment of an inadequate number of inspectors for the facility’s size and CS inspection scope. (See summary on next page.)

¹⁶ VHA Handbook 1108.2, *Inspection of Controlled Substances*, August 29, 2003.



B. Environment of Care

Pharmacies were generally clean and adhered to IC guidelines, and only four (9 percent) facilities received recommendations in this area. Drug processing areas were free from food and drink, floors and sinks were clean, and soap and alcohol-based antibacterial hand rubs were readily available. Medication storage areas were designed for maximum cleanliness, and medication transport carts were free from spills and liquid medication build-up. Pharmacies disposed of personally identifiable patient information in a secure manner. We cited four facilities for EOC issues due to cleanliness or inconsistent monitoring of temperatures in medication refrigerators.

Physical Security

Facilities had appropriate policies and processes to ensure the security of their pharmacies and CS. VA Police conducted annual physical assessments of pharmacies, identified security weaknesses, and made recommendations when appropriate. We made recommendations regarding pharmacy physical security at 2 (5 percent) of the 43 facilities visited. We recommended installing ballistic glass in a pharmacy outpatient prescription-dispensing window and improving security in an outpatient cabinet for CS prescriptions awaiting pick-up by patients.¹⁷

¹⁷ VA Handbook 0730/1, *Security and Law Enforcement*, August 20, 2004.

Controlled Substances Vault Security

We inspected 45 CS vaults. Generally, vault security complied with VA requirements.¹⁸ All facilities had a process for reviewing vault access by either security access card or personnel specific access codes or combinations. Although not a requirement, 33 (73 percent) of the 45 vaults had a surveillance system in place. However, four vaults lacked a steel outer door; two vaults lacked a self-closing day-gate; and one vault lacked a steel outer door, a self-closing gate, and an emergency release function.

C. Infection Control

Clean Room

USP Chapter <797>¹⁹ describes the procedures and requirements for compounding sterile preparations and sets the standards that apply to all settings in which compounded sterile products (CSP) are prepared. Clean rooms are commonly utilized to manufacture CSP and were developed to mitigate the presence of bacteria and minimize infection rates in hospitals. The environment needed to manufacture CSP is influenced by the complexity and risk level. Risk levels refer to microbial risk levels and not the hazardous or radioactive nature of CSP. USP Chapter <797> requires a minimum of a Class 5 primary engineering control, such as an LAFW and/or a biological safety cabinet, to which sterile ingredients and components of CSP are directly exposed, regardless of risk level. Via self-assessment, pharmacy managers rated the level of compounding at their facility as high risk, medium risk, or low risk.²⁰ Of the 43 facilities, 2 manufactured high-risk CSP, 34 medium-risk, and 7 low-risk.

Facilities also self-reported on the type of compounding environment in place for the manufacture of CSP. Facility self-assessments indicated that 12 (28 percent) utilized a Class 5 clean room for sterile compounding. Other methods are acceptable for assuring sterility of CSP and include appropriately placed biosafety cabinets and LAFWs. These alternate methods were utilized by 31 (72 percent) of the facilities. Of the 12 facilities that utilized a clean room, 4 indicated that the clean room was not USP Chapter <797> compliant. In order to be compliant, the first facility had construction plans to build a new pharmacy, the second planned to remodel the clean room, the third was constructing a clean room, and the fourth had resolved an environmental issue to become compliant.

We identified clean room violations at two facilities. At both facilities, clean room door controls were not sufficient to ensure cleanliness of personnel entering the room. At one

¹⁸ VA Handbook 0730, *Security and Law Enforcement*, August 11, 2000; VA Handbook 0730/1.

¹⁹ *Pharmaceutical Compounding: Sterile Preparations*, Chapter <797>, is the first set of enforceable sterile compounding standards issued by the USP.

²⁰ The June 2008 revision of USP Chapter <797> contained changes in assessment of risk levels and added two additional risk levels—Immediate-Use Category and Low-Risk Level with <12-hour beyond use date (BUD).

facility, we also found unsealed ceiling seams, allowing for potential microbial accumulation and contamination.

D. Polypharmacy

The mentally ill and the elderly are at high risk for polypharmacy. We determined whether facilities had policies regarding the identification of polypharmacy and whether the policies specifically addressed mental health patients and the elderly. Twenty-nine (67 percent) of the 43 facilities had a local policy or procedure that addressed assessment of polypharmacy, and 17 (40 percent) had a policy or procedure that addressed both high-risk populations.

Conclusions

Overall, pharmacies complied with VHA guidelines for IC, pharmacy physical security, and reporting requirements; however, improvement in CS inspection programs is required to ensure full compliance with VHA regulations.

Our review was not intended to be an intensive review of clean room and CSP compounding environments, but we found variability with progress towards USP Chapter <797> compliance. Since USP Chapter <797> revisions were published in June 2008, it may be advantageous for facilities to perform a gap analysis and, where the need is identified, develop an action plan for compliance.

Recommendations

Recommendation 1: We recommended that the Acting Under Secretary for Health ensure that Veterans Integrated Service Network (VISN) and VHA facility managers reinforce compliance with VHA regulations regarding CS inspection programs.

Recommendation 2: We recommended that the Acting Under Secretary for Health require that VISN and VHA facility managers ensure that pharmacies comply with USP Chapter <797> guidelines for CSP.

Recommendation 3: We recommended that the Acting Under Secretary for Health require that VISN and VHA facility managers encourage facilities to provide guidance for clinical review of polypharmacy in high-risk populations, such as mental health patients and the elderly.

Acting Under Secretary for Health Comments

The Acting Under Secretary for Health concurred with the recommendations and provided implementation plans. Pharmacy Benefits Management (PBM) staff will assist the DUSHOM to reinforce VISN and VHA facility managers' compliance with VHA regulations regarding CS inspection programs. PBM has developed an educational

program for pharmacy personnel on meeting USP Chapter <797> compliance standards. VHA provided selected facilities resources for clean room construction. PBM staff will help to ensure that VHA and VISN managers are aware of any USP Chapter <797> non-compliance issues and will certify that action plans are in place to address deficiencies. Additionally, VHA has provided polypharmacy guidance to facilities for selected high-risk patients in 2008 and 2009. The full text of the comments is shown in Appendix A (beginning on page 9).

Assistant Inspector General for Healthcare Inspections Comments

The Acting Under Secretary for Health's comments and implementation plans are responsive to the recommendations. We will continue to follow up until all actions are complete.

(original signed by:)

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

Acting Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: November 6, 2009

From: Acting Under Secretary for Health (10)

Subject: **OIG Draft Report, Healthcare Inspection – Review of Selected Pharmacy Operations, (WebCIMS 441810)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report, and I concur with the findings and recommendations. I am pleased that the Office of Inspector General found that Veterans Health Administration (VHA) pharmacies comply with VHA and Infection Control (IC) guidelines, pharmacy physical security, and reporting requirements. The report also highlights where additional attention is needed overall to comply with the requirements of the Controlled Substances (CS) Inspection Programs and to reduce variability in compliance with United States Pharmacopeia (USP) Chapter <797> guidelines for clean room requirements where compounded sterile products are prepared.

2. VHA's Pharmacy Benefits Management Services (PBM) has worked to provide specific guidance for Facility Directors concerning VHA regulations for their oversight of the CS Inspection Programs. Such guidance has included web-based training for CS inspectors, which is required before and during mandatory annual facility based training. PBM also developed an inspection checklist for use by System-wide Ongoing Assessment and Review Strategy (SOARS) reviewers. VHA guidance provides stricter requirements for managing controlled substances than those in the Controlled Substance Act of 1970. PBM staff will work with the Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) to reinforce VISN and VHA facility managers' compliance with VHA regulations regarding CS Inspection Programs. The Office of the DUSHOM will request certification from VISN directors that all sites are in compliance.

3. All Department of Veterans Affairs medical centers (VAMCs) that perform sterile compounding must comply with USP Chapter <797>. Since 2006, VHA's PBM has regularly provided technical guidance to facility pharmacy personnel regarding USP <797> compliance. To ensure that VHA and Veterans Integrated Service Network (VISN) managers are aware of issues of non-compliance with USP Chapter <797>, PBM conducted two surveys for 141 VAMCs (November 2008 and February 2009) to assess compliance and time-frames for construction of required environmentally clean rooms for USP <797> pharmaceutical drug compounding. PBM staff will provide technical assistance to the Office of the DUSHOM to obtain VISN Directors' certifications that action plans are in place to become compliant with USP Chapter <797>.

4. While VHA supports the concept of poly-pharmacy reviews for high-risk patients, separate reviews are not currently a VHA policy requirement. Rather, these types of reviews are expected to be conducted in an integrated manner as part of routine medication reconciliation and drug therapy management activities. Even so, VHA has provided poly-pharmacy guidance to facilities through PBM for selected high-risk patients in 2008 and 2009. These activities are expected to continue in 2010.

5. Thank you for the opportunity to review the report and provide comments. I would be pleased to discuss any concerns or comments you may have about this response. If you have any questions, please have a member of your staff contact Margaret Seleski, Director, Management Review Service (10B5) at (202) 461-7245.

(original signed by:)

Gerald M. Cross, MD, FAAFP

Attachment

**VETERANS HEALTH ADMINISTRATION
Additional Comments Related to Recommendations in OIG Draft
Report, Healthcare Inspection, Review of Selected Pharmacy
Operations, WebCIMS441810)**

Date of Report: October 6, 2009

Recommendations/ Actions	Status	Completion Date
-----------------------------	--------	--------------------

OIG Recommendations

Recommendation 1: We recommended that the Acting Under Secretary for Health ensure that VISN and VHA facility managers reinforce compliance with VHA regulations regarding CS Inspection Programs.

VHA Comments

Concur

Pharmacy Benefits Management staff will assist the office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) to reinforce VISN and VHA facility managers' compliance with VHA regulations regarding CS Inspection Programs. The DUSHOM office will request certification from VISN directors that all sites are in compliance.

In process

December 30, 2009

Recommendation 2: We recommended that the Acting Under Secretary for Health require that VISN and VHA facility managers ensure that pharmacies comply with USP Chapter <797> guidelines for CSP.

VHA Comments

Concur

All Department of Veterans Affairs medical centers (VAMCs) that perform sterile compounding must comply with USP Chapter <797>. In 2006, Pharmacy Benefits Management Services (PBM) developed a USP <797> Educational Program in video format for use by VHA pharmacy service personnel on competency training modules to meet USP <797> compliance standards. Since 2006, PBM has regularly provided technical guidance to facility pharmacy personnel regarding

USP <797> compliance. This guidance is also located on PBM's website in the form of Frequently Asked Questions (FAQs) and technical guidance documents.

Additionally, in 2006 and 2008, PBM and the VA Office of Construction and Facilities Management (OCFM) jointly published a Pharmacy Design Guidance document on various options and approaches for construction of mechanical and architectural systems related to both the Controlled Substance Program (CSP) and hazardous drugs. VAMC facilities were also provided resources by PBM and OCFM to select suitable vendors for clean room construction.

The USP published new USP Chapter <797> revisions that were finalized in December 2007 with a provision that The Joint Commission will expect hospitals to have at least an action plan with time-lines to ensure structures and processes are in place to conduct safe practices for CSPs. These revised standards were disseminated by PBM to VAMCs. PBM conducted two surveys for 141 VAMCs (November 2008 and February 2009) through the VISN network offices to assess compliance and timeframes for construction of required environmentally clean rooms for USP Chapter <797> pharmaceutical drug compounding.

Pharmacy Benefits Management staff will provide technical assistance to the office of the DUSHOM to ensure that VHA and VISN managers are aware of non-compliance issues with United States Pharmacopeia (USP) Chapter <797> as indicated by the survey results, and certify they have action plans in place to become compliant with the requirements.

In process

November 2009 to notify VISN and Facility managers; July 2011 for full compliance with USP Chapter <797>

Recommendation 3: We recommended that the Acting Under Secretary for Health require that VISN and VHA facility managers encourage facilities to provide guidance for clinical review of polypharmacy in high-risk populations, such as mental health patients and the elderly.

VHA Comments

Concur

While VHA supports the concept of poly-pharmacy reviews for high-risk patients, separate reviews as recommended in the report are not currently a

VHA policy requirement. Rather, these types of reviews are expected to be conducted in an integrated manner as part of routine medication reconciliation and drug therapy management activities.

Despite there not being an existing VHA policy requirement, VHA has provided poly-pharmacy guidance to facilities through its Pharmacy Benefits Management Services group. This was done for selected high-risk patients in 2008 and 2009 and is expected to continue in 2010.

Completed 2008 and 2009

Ongoing

Veterans Health Administration
November 2009

OIG Contact and Staff Acknowledgments

OIG Contact	Jeanne Martin, PharmD Bedford Regional Office of Healthcare Inspections (603) 222-5872
-------------	--

Acknowledgments	Annette Acosta Daisy Arugay Gail Bozzelli Shirley Carlile Paula Chapman Victoria Coates Audrey Collins-Mack Melanie Cool Dorothy Duncan David Griffith Wachita Haywood Katherine Owens Reba Ransom Wilma Reyes Annette Robinson Christa Sisterhen Virginia Solana Toni Woodard
-----------------	---

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
Office of General Counsel
Veterans Integrated Service Network Directors (1–23)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and
Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and
Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget

This report is available at <http://www.va.gov/oig/publications/reports-list.asp>.