# Department of Veterans Affairs
# Office of Inspector General

# Review of VA Medical Facility Compliance with Controls over Prescription Drugs

*To prevent and detect thefts of prescription drugs, VA medical facilities need to comply with established VA and VHA controls.*

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**VA Office of Inspector General**
**Washington, DC 20420**

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# Executive Summary

## Introduction

The VA Office of Inspector General (OIG) reviewed compliance with controls intended to account for prescription drugs and to prevent or detect the theft or loss of these drugs at Veterans Health Administration (VHA) medical centers and healthcare systems (hereafter referred to as facilities or medical facilities). The review was conducted at 22 medical facilities between January and September 2005 during OIG Combined Assessment Program (CAP) reviews.

In fiscal year (FY) 2005, VA expended over $3.7 billion for prescription drugs through its Pharmaceutical Prime Vendor[1] program. These drugs include both controlled and noncontrolled substances and are vulnerable to theft. Federal law and VA and VHA policies require stringent controls over controlled substances, which have significant risks for abuse, addiction, or dependency. The controls are intended to prevent and detect thefts of these drugs. VHA policies also require certain other less stringent controls for noncontrolled substances.[2] While these other controls are mainly intended to aid VA pharmacies in managing inventories, they have the added benefit of facilitating detection of thefts of these drugs.

Compliance with controls over prescription drugs are necessary because VA has been vulnerable to thefts, and this risk needs to be mitigated. During FY 2005 and through July of FY 2006, the OIG received referrals or opened investigations involving 129 cases of suspected thefts of prescription drugs by employees at VA medical facilities. To illustrate, an investigation resulted in the arrest and conviction of a VA employee who, on 56 occasions, signed out controlled substances for patients and then used them herself while on duty. In another case, a VA employee manipulated inventories to take drugs from an automated dispensing device, which resulted in the employee's removal and referral to a local district attorney for prosecution.

## Results

Our review of compliance with controls over prescription drugs conducted during CAP reviews at 22 VA medical facilities showed that medical facility staff did not always follow controls intended to deter and detect thefts of drugs. Consequently, vulnerabilities existed that could facilitate drug theft. In addition, we found that some medical facilities

[1] Pharmaceutical Prime Vendor is the title given to VA's contracted supplier of pharmaceuticals and through which VA acquires 90–95 percent of its controlled and noncontrolled prescription drugs.

[2] In this report, the term "prescription drugs" refers to both controlled substances and noncontrolled substances that require prescriptions.

should increase their use of automated inventory management systems to better control prescription drug inventories. Numerous recommendations were made during the 22 CAP review site visits to correct the conditions identified. Those recommendations are not repeated in this report. Also not discussed in this report are identified deficiencies that were minor or unique to the sites where they occurred. For example, at one facility 72-hour inventories and monthly controlled substances inspections did not include controlled substances stored in one particular automated dispensing device. Minor deficiencies identified at only one facility do not, in our opinion, indicate that systemic problems exist, and such cases are not discussed in this report.

However, additional VHA management attention is needed where our tests revealed similar control deficiencies at multiple medical facilities. We found that staff at 16 (73 percent) of the 22 medical facilities visited needed to better comply with controls for detecting, preventing, and reporting drug thefts:

- Eleven (50 percent) of the 22 facilities needed to improve their controlled substances inspection procedures.
- Five facilities (23 percent) needed to improve physical security over controlled substances.
- Three facilities (14 percent) needed to implement procedures for reporting drug thefts to the proper authorities.
- Three (21 percent) of the 14 facilities that operated Research Services needed to improve acquisition, storage, and inspection procedures for controlled substances used by Research Service staff.

Drug inventory management and receiving procedures needed to be improved at 16 (73 percent) of the 22 facilities.

- Ten (45 percent) of the 22 facilities needed to make better use of automated inventory management systems to control drug inventories.
- Eleven facilities (50 percent) needed to improve receiving procedures.
- Six facilities (27 percent) needed to improve procedures for conducting physical inventories.

VHA management needs to ensure that medical facility staff comply with Federal law and VA and VHA policies regarding both controlled and noncontrolled substances. Compliance with accountability controls can decrease vulnerability to undetected theft of both controlled and noncontrolled substances. While occasional lapses in compliance with any control system can occur, this review revealed systemic control weaknesses at a significant number of VA medical facilities. Although we advised medical facility managers of the specific weaknesses identified during our CAP reviews, the weaknesses were sufficiently widespread to warrant additional VHA management attention.

## Recommendations

1. We recommended that the Acting Under Secretary for Health, in conjunction with the Chief Network Officer, ensure that all VA medical facility managers use the findings in this report during their own internal reviews and, at a minimum: (a) assess the adequacy of controlled substances inspection procedures and take actions to improve them where warranted; (b) assess the adequacy of physical security efforts and improve security where needed; (c) enforce theft reporting requirements; and (d) ensure that controlled substances retained by Research Service staff are included in all related internal control procedures.

2. We also recommended that the Acting Under Secretary for Health, in conjunction with the Chief Network Officer, ensure all VA medical facility managers (a) ensure the use of required automated inventory control systems and (b) enforce compliance with controlled substances receiving and physical inventory requirements.

## Acting Under Secretary for Health Comments

The Acting Under Secretary for Health agreed with the report findings and recommendations and provided acceptable implementation plans. (See Appendix C, pages 15–22, for the full text of the Acting Under Secretary's comments.) The Acting Under Secretary reported that corrective actions have been initiated to address the recommendations. We will follow up on planned actions until they are completed.

*(original signed by:)*
JON A. WOODITCH
Deputy Inspector General

# Introduction

## Purpose

The purposes of the review were to determine if medical facilities complied with management controls to deter and detect prescription drug thefts and if procurement and inventory management systems for prescription drugs were effective.

## Background

In FY 2005, VA expended over $3.7 billion to acquire prescription drugs through its Pharmaceutical Prime Vendor program. Through the first 2 quarters of FY 2006, this figure exceeded $1.8 billion.

Prescription drugs include both controlled and noncontrolled substances. The Drug Enforcement Administration (DEA) classifies controlled substances into five schedules on the basis of their medicinal value and potential for abuse, addiction, and dependence. Schedule I drugs—including heroin, marijuana, and hallucinogens—have a high potential for abuse and no currently accepted medical use, although they may be used in approved research studies. Schedule II drugs—including methylphenidate and opiates such as hydrocodone, morphine, and oxycodone—have accepted medical uses but also have high potential for abuse that may lead to severe physical dependence. Drugs on Schedules III through V have medical uses and successively lower potential for abuse and dependence. All controlled substances except Schedule I drugs are legally available to the public by prescriptions. DEA policies require VA and private sector medical facilities and pharmacies to implement strict control systems to account for and protect controlled substances.

Noncontrolled substances include drugs that require prescriptions and those that do not. Noncontrolled substances that require prescriptions include such drugs as Lipitor®, Viagra®, and Zoloft®. While such drugs carry little or no risk of abuse, they are widely used and expensive and are therefore at risk for theft. However, beyond prudent and routine inventory controls and as the phrase itself suggests, there are no special requirements for controlling noncontrolled substances.

During FY 2005 and through July of FY 2006, the OIG Office of Investigations received referrals or opened investigations involving 129 cases of proven or suspected drug thefts from VA medical facilities by VA employees. Many of these thefts were of controlled substances and were detected by medical facility staff as a result of their compliance with required controls.

For example, in February 2005, the OIG opened an investigation into thefts of narcotics from a patient ward. The investigation resulted in the arrest and subsequent conviction of a nurse who, on 56 occasions, signed out narcotics for patients and then used them herself

while on duty. Medical facility staff detected the thefts because they followed procedures by comparing narcotics sign out records to patient records. In January 2005, the OIG opened another investigation involving the theft of controlled substances from an automated narcotics dispensing device. The investigation resulted in the removal of a VA nurse from her position and referral of her case to the local district attorney for prosecution. Medical facility staff detected the thefts during required routine physical inventories of controlled substances.

Although compliance with required controls can be effective in detecting thefts of controlled substances, there are no DEA control requirements for noncontrolled substances. Anecdotal information suggests that there has been a marked rise in thefts of certain high-cost, noncontrolled substances such as Viagra, Lipitor, and other prescription drugs.[3] Such thefts can involve significant quantities of noncontrolled substances. For example, in September 2005 after an OIG investigation a VA pharmacy employee in New York was fired for diverting more than 900 Viagra pills for resale. In another case, the OIG investigated, without resolution, the suspected theft of 60 bottles of Viagra.

## Scope and Methodology

This report summarizes systemic deficiencies related to compliance with controls over prescription drugs identified during CAP reviews conducted at 22 VA medical facilities between January and September 2005 and reported in reports issued between June 2005 and July 2006. (See Appendix B, page 14, for a list of facilities included in the review.) We focused our review on data gathered during CAP reviews at the 22 VA medical facilities. Results were discussed with management at the 22 facilities and, where warranted, individual recommendations were made in the CAP review reports. Management responded with acceptable implementation plans. Systemic issues were cataloged for the purpose of summarization and are contained in this report.

We reviewed applicable laws and facility policies, procedures, and records pertaining to inventory management, procurement, inspection, dispensing, and destruction activities for controlled and noncontrolled substances. We also interviewed pharmacy, acquisition, nursing, and research staff. The review was conducted in accordance with applicable CAP Standard Operating Procedures.

[3] We were unable to identify any consolidated national databases that collect data on thefts of prescription drugs.

# Results and Conclusions

## Issue 1: Inspection Procedures, Physical Security, Reporting Practices, and Control of Research Service Drug Stocks Could Be Improved

### Findings

To prevent, detect, and report the theft of controlled substances, medical facilities needed to better comply with established VA and VHA controls. Sixteen (73 percent) of the 22 facilities reviewed did not comply with 1 or more inspection, physical security, or reporting requirements that are intended to protect controlled substances from theft by VA employees and others.

Controlled Substances Inspection Procedures. Eleven (50 percent) of the 22 facilities needed to improve their controlled substances inspection procedures. VHA policy requires that medical facilities conduct monthly controlled substances inspections and establishes the procedures to be used for these inspections (VHA Handbook 1108.2). The purpose of the inspections is to ensure the safety and control of all inventories of controlled substances, because any weakness in the procedures creates opportunities for medical facility staff or others to divert controlled substances. At the 11 facilities, we found 45 instances of non-compliance with inspection procedures.

*Appointment and Training of Inspectors.* VHA policy requires that inspectors be appointed in writing and trained in inspection procedures.

- At three facilities, inspectors were not appointed in writing (see Appendix A, line 1).
- At two facilities, inspectors did not receive required training in inspection procedures (see Appendix A, line 2).

*Frequency and Scope of Inspections.* VHA policy requires that inspections be performed every month for all controlled substances regardless of where the drugs are located or what medical facility function they serve.

- At two facilities, inspectors did not perform all required monthly inspections during the 6 months preceding our reviews (see Appendix A, line 3).
- At three facilities, inspectors did not include emergency Pharmaceutical Caches[4] in their inspections (see Appendix A, line 4).

[4] The Pharmaceutical Cache program was established to provide emergency medical support to the general public in the event of natural disaster, terrorist attack, or other emergency. The cache is a stockpile of treatment kits, intravenous solutions, medical supplies, and medications, including some controlled substances.

- At three facilities, controlled substances inspections did not include stocks of Research Service controlled substances (see Appendix A, line 5). (See the Research Services section, page 6, for this and other issues related to Research Services.)
- At one facility, inspectors did not include drugs held for destruction in their inspections (see Appendix A, line 6).

*Inspection Procedures*. VHA policy requires that inspectors follow certain procedures when conducting inspections. The procedures, if followed, help ensure that all controlled substances can be accounted for and help ensure that pharmacy and medical staff with access to controlled substances also comply with requirements for controlled substances.

- At four facilities, inspectors did not verify orders for five randomly selected dispensing activities (see Appendix A, line 7).
- At three facilities, inspectors did not verify that drug destructions occurred at least quarterly (see Appendix A, line 8).
- At 3 facilities, inspectors did not test accountability for 10 randomly selected drugs awaiting destruction (see Appendix A, line 9).
- At three facilities, inspectors did not ensure that medical staff on wards and in clinics that did not have automated dispensing devices had conducted required change-of-shift counts of controlled substances (see Appendix A, line 10).
- At two facilities, inspectors did not account for prescription pads (see Appendix A, line 11).
- At two facilities, inspectors did not verify the weight of unsealed containers containing powders (see Appendix A, line 12).
- At two facilities, inspectors did not measure the contents of unsealed containers containing liquids (see Appendix A, line 13).
- At two facilities, inspectors did not verify that pharmacy staff had conducted required 72-hour physical inventories (see Appendix A, line 14).
- At two facilities, inspectors did not ensure that newly received controlled substances had been properly placed into inventory by comparing monthly vendor invoice reports against pharmacy drug receipt history reports (see Appendix A, line 15).
- At two facilities, inspectors did not verify the existence of hard copy prescription forms for the required 10 percent of Schedule II drugs dispensed to outpatients (see Appendix A, line 16).
- At two facilities, inspectors did not reconcile 1 day's dispensings from the pharmacy to automated dispensing devices to validate the accuracy of pharmacy dispensing records and automated dispensing device inventory records (see Appendix A, line 17).
- At one facility, inspectors did not validate two transfers of controlled substances between dispensing areas to ensure proper documentation (see Appendix A, line 18).

*Reporting Inspection Results*. VHA policy requires that the Controlled Substances Coordinator report to medical facility management any unresolved discrepancies and discrepancy trends identified by inspections. The policy also requires that management take appropriate remedial action.

- At two facilities, follow-up by management on discrepancies reported in Controlled Substances Coordinator reports was not adequate (see Appendix A, line 19).

- At one facility, Controlled Substances Coordinator reports to management did not report identified discrepancies and discrepancy trends (see Appendix A, line 20).

Physical Security. Five (23 percent) of the 22 facilities needed to improve physical security over controlled substances. VA and VHA policies require that controlled substances be securely stored and protected against theft (VA Handbook 0730; VHA Handbook 1108.1; and VHA Manual M-2, Part VII, Chapter 1). VA policy also requires that medical facility police staff conduct annual surveys to assess physical security vulnerabilities (VA Handbook 0730).

- At two facilities, security weaknesses previously identified by medical facility police during physical security surveys (lack of motion sensors and an improperly secured dispensing window) were not corrected by the time of our reviews (see Appendix A, line 21).
- At one facility, pharmacy windows and doors were not properly secured (see Appendix A, line 22).
- At two facilities, intrusion detection systems were not installed (see Appendix A, line 23).
- At two facilities, drugs stored on wards and in clinics were not secured (see Appendix A, line 24).
- At one facility, our auditor was admitted to the outpatient pharmacy without challenge or escort on three separate occasions (see Appendix A, line 25).
- At one facility, serially numbered security seals for the Pharmaceutical Cache were not properly controlled (see Appendix A, line 26).

Theft Reporting. VHA policy requires that any theft, suspected theft, or suspicious loss of drugs be reported immediately to the facility director, who is then responsible for reporting the loss to medical facility police and to the OIG Office of Investigations (VHA Handbook 1108.1). Three facilities (14 percent) did not properly comply with this requirement because they waited from 2 to 8 months before reporting possible thefts to the OIG (see Appendix A, line 27). These delays potentially compromised any follow-up investigations and represented, in our opinion, a significant vulnerability.

Research Services. Research Services often maintain stocks of prescription drugs for use in animal and human research projects. VHA policy requires the same controls for the use and storage of Research Service controlled substances as are required for other medical facility operations (VHA Handbook 1108.1). Fourteen of the 22 medical facilities reviewed operated Research Services. Eleven of these 14 facilities maintained adequate controls over these drugs, but 3 facilities (21 percent) needed to improve controls.

At two facilities, Research Service stocks of controlled substances drugs were not obtained through VA pharmacies as required by VHA policy (see Appendix A, line 28). At one facility, Research Service staff had obtained about 900 ml of Ketamine® directly from a supplier. Ketamine is a Schedule III drug used as a human and an animal anesthetic, but it can be abused and has reportedly been used as a date-rape drug. At another facility, Research Service staff had obtained 10 ml of Euthasol® from an affiliated university hospital. Euthasol contains pentobarbital, a Schedule II drug, and is used to euthanize animals. Because research staff had not acquired these drugs through VA pharmacies, the drugs were effectively outside VA control.

At one facility, Research Service controlled substances were stored in unlocked cabinets, in cabinets that were not properly anchored, and in cabinets with glass doors (see Appendix A, line 29). These conditions were not in compliance with VA policy, which requires that only locked, securely anchored, glassless steel cabinets be used to store small quantities of controlled substances (VA Handbook 0730).

At three facilities, controlled substances inspections did not include stocks of Research Service controlled substances (see Appendix A, line 5). VHA policy specifically includes research laboratories in controlled substances inspections procedures (VHA Handbook 1108.2). At one of the three facilities, inspectors had not been trained in Bio-Safety Level 2[5] laboratory safety procedures and, therefore, could not conduct required controlled substances inspections in those laboratory areas.

## Conclusion

To prevent and detect thefts of controlled substances, medical facilities need to comply more fully with Federal law and VA and VHA policies. While most facilities complied with many of the control requirements for controlled substances, noncompliance was sufficiently widespread to represent a significant and unacceptable vulnerability. (See Appendix A, pages 11–13, for the distribution of compliance deficiencies by facility.) Although we advised medical facility managers of the instances of noncompliance

[5] Bio-Safety Level 2 is a Centers for Disease Control designation for laboratories that work with certain pathogenic organisms associated with human diseases. Centers for Disease Control recommendations for such laboratories include limiting access.

observed during our CAP reviews, noncompliance was sufficiently widespread to warrant additional attention from VHA officials.

**Recommendation 1.** We recommended that the Acting Under Secretary for Health, in conjunction with the Chief Network Officer, ensure that all VA medical facility managers use the findings in this report during their own internal reviews and, at a minimum: (a) assess the adequacy of controlled substances inspection procedures and take actions to improve them where warranted; (b) assess the adequacy of physical security efforts and improve security where needed; (c) enforce theft reporting requirements; and (d) ensure that controlled substances retained by Research Service staff are included in all related internal control procedures.

## Acting Under Secretary for Health Comments

The Acting Under Secretary for Health agreed with the finding and recommendations.

## Implementation Plan

The Acting Under Secretary for Health reported the development of several ongoing initiatives that will address the findings. These include:

- Development of a self-assessment tool to evaluate medical facilities' controlled substances management programs.
- Production of a comprehensive training video dealing with controlled substances accountability and inspection program.
- Inclusion of issues raised in this report during regular monthly pharmacy conference calls with Veterans Integrated Service Network (VISN) staff and Chiefs of Pharmacy.
- Continuation of Systematic Ongoing Assessment and Review Strategy focused reviews of compliance with drug accountability requirements.
- Inclusion of a discussion and re-emphasis of theft reporting requirements during the November 2006 conference call with VISN staff and Chiefs of Pharmacy.
- Issuance of a reminder memorandum, by October 31, 2006, from the Chief Research and Development Officer to field research staff to re-emphasize drug accountability requirements.

## Office of Inspector General Comment

The implementation plans are acceptable. We will follow up on the planned actions until they are implemented.

# Issue 2: VA Medical Facilities Needed To Improve Prescription Drug Inventory Management and Receiving Procedures

## Findings

Sixteen (73 percent) of the 22 medical facilities reviewed needed to improve their use of automated prescription drug inventory management systems or to improve their controlled substances receiving procedures.

Inventory Management. In our report of *Audit of VA Medical Center Management of Pharmaceutical Inventories* (Report No. 99-00186-86, June 30, 2000), we recommended that medical facilities use automated inventory management systems to manage drug inventories and control costs. All VA medical facilities have available for their use three automated systems that they can use to control drug inventories. Medical facilities can use automated inventory analysis tools available through the proprietary ordering system operated by VA's Pharmaceutical Prime Vendor. Facilities can also use controlled substances software contained in VA's automated Veterans Health Information Systems and Technology Architecture (VistA) to maintain perpetual inventories of controlled substances. In addition, they can use VistA's drug accountability software, which interfaces with the Prime Vendor system, to maintain perpetual inventories of all prescription drugs, including noncontrolled substances.

VHA policy requires that pharmacies follow inventory management practices that include using automated inventory management systems to facilitate calculating economic order quantities, forecasting demand, establishing safety stock levels, and determining the frequency of inventory turns (VHA Handbook 1761.2). The purpose is to minimize drug replenishment costs, including inventory carrying costs and labor costs associated with stocking drugs. In addition, VHA policy requires that pharmacies use VistA's controlled substances software to maintain perpetual inventories of controlled substances (VHA Handbook 1108.1).

While most of the facilities we visited had implemented our recommendation to use automated inventory management systems, 10 facilities (45 percent) did not use all of the required functionalities of these systems (see Appendix A, line 30). Three of the 22 facilities did not use the Pharmaceutical Prime Vendor's inventory management software to manage drug inventories. In addition, four facilities that did use the system had not adopted some of its inventory management tools such as demand forecasting, inventory turn calculations, or ABC inventory analysis.[6] Four facilities did not use VistA's drug

[6] ABC inventory analysis uses tiered costs to monitor and manage inventories. "A" items, representing the greatest percentage of inventory costs, are monitored closely. "B" items, representing a middle percentage of inventory costs, are monitored correspondingly less closely, and "C" items, representing the smallest percentage of inventory costs, are monitored least aggressively.

accountability software to maintain perpetual inventories of noncontrolled substances. By not using these automated inventory management tools, pharmacy staff at these facilities handicapped their ability to economically manage their drug inventories.

Receiving Procedures. Eleven (50 percent) of the 22 facilities needed to improve procedures for receiving controlled substances and needed to improve inventory procedures. VHA and DEA policies establish certain procedural and physical controls designed to ensure that controlled substances are protected against theft.

VA and VHA policies require that certain actions related to the ordering, receiving, posting, and verifying of controlled substances be performed in the presence of two organizationally independent staff, a designated Acquisition and Materiel Management Service (A&MMS) accountable officer and a designated Pharmacy Service employee (VA Handbook 7127 and VHA Handbook 1108.1). The purpose is to provide added assurance of accuracy to the verification and recording of newly received controlled substances. Five of the 22 facilities did not fully comply with accountable officer requirements.

- At three facilities, accountable officers had not been appointed in writing as required by VHA policy (see Appendix A, line 31).
- At four facilities, staff did not open newly received cartons containing controlled substances in the presence of accountable officers (see Appendix A, line 32).
- At four facilities, pharmacy staff and accountable officers did not properly annotate controlled substances receiving reports (see Appendix A, line 33).
- At two facilities, pharmacy staff did not reconcile apparent discrepancies with accountable officers before placing newly received controlled substances into inventories (see Appendix A, line 34).

Two facilities did not have written procedures for ordering and receiving controlled substances as required by VHA policy (VHA Handbook 1108.1) (see Appendix A, line 35). In addition, staff at two facilities did not reconcile Schedule II controlled substances with required DEA forms (see Appendix A, line 36), staff at two facilities did not properly verify orders when they were received (see Appendix A, line 37), staff at two facilities did not properly post controlled substances into inventory through the VistA controlled substances software (see Appendix A, line 38), and staff at five facilities did not promptly update inventories when shipments arrived (see Appendix A, line 39).

Physical Inventory Procedures. Six (27 percent) of the 22 facilities needed to improve physical inventory procedures. VHA policy requires that pharmacy staff conduct physical inventories of all controlled substances every 72 hours (VHA Handbook 1108.1). This policy also requires that a complete physical inventory be conducted when there is a permanent change in the appointment of a Chief of Pharmacy. Six facilities did not conduct all required 72-hour physical inventories (see Appendix A, line 40), and one

of those facilities also did not conduct a physical inventory when the Chief of Pharmacy changed (see Appendix A, line 41).

## Conclusion

To minimize costs associated with procuring and stocking drugs, medical facilities need to utilize automated inventory management system capabilities to the fullest extent required. While most facilities had implemented a prior OIG recommendation to use these systems, the use of these systems needs to be reemphasized. In addition, to provide information necessary to detect drug thefts, medical facilities need to improve compliance with controlled substances receiving and physical inventory procedures. (See Appendix A, pages 11–13, for the distribution of compliance deficiencies by facility.)

**Recommendation 2.** We recommended that the Acting Under Secretary for Health, in conjunction with the Chief Network Officer, ensure that all VA medical facility managers (a) ensure the use of required automated inventory control systems and (b) enforce compliance with controlled substances receiving and physical inventory requirements.

## Acting Under Secretary for Health Comments

The Acting Under Secretary for Health agreed with the finding and recommendations.

## Implementation Plan

The Acting Under Secretary for Health reported that training was provided on the required use of automated inventory control systems during the September 2006 National Pharmacy Conference and is included in a video that will be distributed to all medical facilities. In addition, aggregated Pharmaceutical Prime Vendor data will be provided to Pharmacy Benefits Management Strategic Healthcare Group officials during the third quarter of FY 2007, which will permit assessments of and, if necessary, follow-up consultations regarding compliance by medical facilities. In addition, controlled substances receiving and inventory requirements have been included in a self-assessment tool and in a training video.

## Office of Inspector General Comment

The implementation plans are acceptable. We will follow up on the planned actions until they are implemented.

**Appendix A**

# Distribution of Compliance Deficiencies among Medical Facilities

| Finding | Medical Facility (See Appendix B for Key) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V |
| *Inspection procedure deficiencies observed at 11 facilities:* | → | | → | → | | → | → | → | → | | | | | | | → | → | → | | | → | |
| 1. Inspectors not appointed in writing | | | | | | | X | X | X | | | | | | | | | | | | | |
| 2. Inspectors not trained | | | | | | | X | | | | | | | | | | | | | | X | |
| 3. Inspectors did not perform all inspections | | | | | | | X | | | | | | | | | X | | | | | | |
| 4. Inspectors did not include Pharmaceutical Cache | | | X | X | | X | | | | | | | | | | | | | | | | |
| 5. Research Service drugs not included in inspections | | | X | | | X | | | | | | | | | | | | X | | | | |
| 6. Inspectors did not include drugs held for destruction | | | | | | | | | X | | | | | | | | | | | | | |
| 7. Inspectors did not verify orders for five dispensing activities | | | X | | | | | | X | | | | | | | | X | | | | X | |
| 8. Inspectors did not verify quarterly drug destructions | X | | | | | | | | X | | | | | | | | | | | | X | |
| 9. Inspectors did not test accountability for 10 drugs awaiting destruction | | | | | | | | X | X | | | | | | | | | | | | X | |
| 10. Inspectors did not ensure change-of-shift counts were conducted | | | X | | | | | X | | | | | | | | X | | | | | | |
| 11. Inspectors did not attempt to account for prescription pads | | | | | | | | | | | | | | | | X | | | | | X | |
| 12. Inspectors did not weigh unsealed powders | | | X | | | | | | | | | | | | | X | | | | | | |
| 13. Inspectors did not measure unsealed liquids | | | X | | | | | | | | | | | | | X | | | | | | |
| 14. Inspectors did not verify 72-hour inventories | X | | | | | | | | | | | | | | | | | | | | X | |
| 15. Inspectors did not compare invoices with receiving reports | | | | | | | | | X | | | | | | | | | | | | X | |
| 16. Inspectors did not verify prescriptions for 10 percent of Schedule II drugs dispensed to outpatients | | | | | | | | | | | | | | | | X | | | | | X | |
| 17. Inspectors did not reconcile 1 day's dispensings to automated dispensing devices | | | | | | X | | X | | | | | | | | | | | | | | |
| 18. Inspectors did not validate two transfers of controlled substances | | | | | | | | | | | | | | | | X | | | | | | |
| 19. Follow-up on reported discrepancies not adequate | | | X | X | | | | | | | | | | | | | | | | | | |
| 20. Controlled Substances Coordinator reports to management did not report identified discrepancies and trends | X | | | | | | | | | | | | | | | | | | | | | |

| Finding | Medical Facility (See Appendix B for Key) | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V |
| *Physical security deficiencies observed at 5 facilities:* | | → | → | | | | | → | | → | | | | | → | | | | | | | |
| 21. Security weaknesses identified by VA police not corrected | | | | | | | | X | | X | | | | | | | | | | | | |
| 22. Pharmacy windows and doors not secured | | | | | | | | | | X | | | | | | | | | | | | |
| 23. Intrusion detection systems not installed | | | | | | | | | | X | | | | | X | | | | | | | |
| 24. Drugs stored on wards and in clinics not secured | | X | | | | | | | | | | | | | X | | | | | | | |
| 25. Auditor admitted to pharmacy without challenge | | | | | | | | X | | | | | | | | | | | | | | |
| 26. Pharmaceutical Cache security seals not properly controlled | | | X | | | | | | | | | | | | | | | | → | | | |
| *Reporting deficiencies observed at 3 facilities:* | | | | → | | | | | | | | | | | | | | | | | | |
| 27. Suspected drug thefts not reported promptly | | | | X | | | | | | | | | | | | | | | X | | | |
| *Research Service deficiencies observed at 3 facilities:* | | → | | | | → | No Research Service | | | | | | | | | | | → | No Research Service | No Research Service | No Research Service | |
| 28. Research Service drugs not obtained through VA pharmacy | | | | | | X | | | | | | | | | | | | X | | | | |
| 29. Research Service drugs not properly secured | | | | | | | | | | | | | | | | | | X | | | | |
| (5.) Research Service drugs not included in inspections (See line 5 on preceding page.) | | | X | | | X | | | | | | | | | | | | X | | | | |

| Finding | Medical Facility (See Appendix B for Key) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V |
| *Automated inventory systems not fully utilized at 10 facilities* | | ↓ | | ↓ | | | ↓ | ↓ | ↓ | | | | ↓ | | | ↓ | ↓ | | ↓ | ↓ | | |
| 30. Automated inventory systems not fully utilized | | X | | X | | | X | X | X | | | | X | | | X | X | | X | X | | |
| *Ordering and receiving deficiencies observed at 11 facilities:* | ↓ | ↓ | ↓ | ↓ | | ↓ | | ↓ | ↓ | | | ↓ | ↓ | | | | | ↓ | ↓ | | | |
| 31. Accountable officers not appointed in writing | | X | | | | | | | | | | | X | | | | | X | | | | |
| 32. Controlled substances cartons not opened in the presence of accountable officer | | X | | | | | | | X | | | | X | | | | | X | | | | |
| 33. Pharmacy staff and accountable officer did not properly annotate receiving reports | | X | X | | | | | | X | | | | X | | | | | | | | | |
| 34. Pharmacy staff did not reconcile discrepancies with accountable officer | | X | X | | | | | | | | | | | | | | | | | | | |
| 35. No written procedures for ordering and receiving controlled substances | | | | | | | | | | | | X | | | | | | X | | | | |
| 36. Schedule II controlled substances not reconciled with DEA forms | | | X | | | | | | X | | | | | | | | | | | | | |
| 37. Orders not properly verified upon receipt | X | | | | | | | | X | | | | | | | | | | | | | |
| 38. Controlled substances not properly posted into inventory | | | | | | | | | X | | | | X | | | | | | | | | |
| 39. Inventories not promptly updated when shipments arrived | | | | X | | X | | X | X | | | | | | | | | | X | | | |
| *Physical inventory deficiencies observed at 6 facilities* | ↓ | ↓ | ↓ | ↓ | ↓ | ↓ | | | | | | | | | | | | | | | | |
| 40. Not all required 72-hours physical inventories conducted | X | X | X | X | X | X | | | | | | | | | | | | | | | | |
| 41. Physical inventory not conducted when Chief of Pharmacy changed | X | | | | | | | | | | | | | | | | | | | | | |

**Appendix B**

# VA Medical Facilities Included in Review

Data presented in this report was collected during CAP reviews conducted at the 22 VA medical facilities listed in the table below.

| VA Medical Facility | Dates of CAP Review | Key to App. A |
|---|---|---|
| Harry S. Truman Memorial Veterans' Hospital Columbia, MO | 1/24–28/05 | A |
| Central Iowa Health Care System | 2/28–3/4/05 | B |
| John D. Dingell VA Medical Center Detroit, MI | 4/25–29/05 | C |
| Medical Center Coatsville, PA | 5/16–20/05 | D |
| Central Arkansas Veterans Healthcare System | 5/23–27/05 | E |
| William S. Middleton Memorial Veterans Hospital Madison, WI | 6/6–10/05 | F |
| Medical Center West Palm Beach, FL | 6/6–10/05 | G |
| Southern Arizona Health Care System | 6/20–24/05 | H |
| Edith Nourse Rogers Memorial Veterans Hospital Bedford, MA | 6/13–17/05 | I |
| Medical Center Oklahoma City, OK | 6/20–24/05 | J |
| Medical Center Wilmington, DE | 6/6–10/05 | K |
| Medical Center Butler, PA | 7/11–15/05 | L |
| Medical Center Togus, ME | 7/18–22/05 | M |
| Tennessee Valley Healthcare System | 7/18–22/05 | N |
| Medical Center Kansas City, MO | 8/1–5/05 | O |
| Medical Center Fayetteville, NC | 8/15–19/05 | P |
| Medical Center White River Junction, VT | 8/22–26/05 | Q |
| Medical Center San Francisco, CA | 8/22–26/05 | R |
| John J. Pershing VA Medical Center Poplar Bluff, MO | 9/12–16/05 | S |
| Medical Center Lebanon, PA | 9/12–16/05 | T |
| Medical Center Northampton, MA | 9/26–30/05 | U |
| Medical Center Birmingham, AL | 9/19–23/05 | V |

**Appendix C**

# Acting Under Secretary for Health Comments

**Department of Veterans Affairs** **Memorandum**

**Date:** October 17, 2006

**From:** Acting Under Secretary for Health (10)

**Subject:** **Review of VA Medical Facility Compliance with Controls over Prescription Drugs**

**To:** Assistant Inspector General for Auditing (52)

1. I have reviewed your draft report and concur with the findings and recommendations. I am pleased to note that with a more than 88 percent overall compliance rate, Veterans Health Administration (VHA) is making systematic progress in implementing the stringent drug inventory control mandates that we have established, requirements that provide innumerable opportunities for occasional compliance lapses. Nevertheless, I also acknowledge what your findings confirm: that inconsistency among facilities in fully implementing all requirements still continues. While it seems unrealistic in a system as large as ours to demand 100 percent compliance at all times with policies that actually exceed requirements of the U.S. Drug Enforcement Administration and private sector pharmacy practices, that is what we strive for, and we consider each of the issues you specify as an opportunity for further improvement in our control systems. As detailed in the attached action plan, VHA's Pharmacy Benefits Management Strategic Healthcare Group (PBMSHG), in conjunction with the Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM), is actively addressing identified concerns, and will continue on an ongoing basis to prioritize the importance of drug control compliance by all facilities.

2. I agree with your conclusion that regular internal reviews by facilities at the local level are key to assuring consistent compliance with requirements. In this regard, PBM has

collaborated with VHA's Systematic Ongoing Assessment and Review Strategy (SOARS) program managers to devise a standardized drug accountability self-assessment tool that was applied nationally in the first quarter of Fiscal Year 2006 as a special quality performance monitor and completed by almost all facilities. The few remaining facilities either utilized a different self-assessment tool or had already undergone a focused external review. This same assessment guide is used by SOARS teams during their facility site visits. On September 13, 2006, the DUSHOM provided a roll-up of monitor findings to all Veterans Integrated Service Network (VISN) Chief Medical Officers and Quality Management Officers for follow-up oversight. Most facilities indicated that deficiencies were identified and that corrective action plans are being implemented. A copy of the self-assessment summary is included as an attachment to this response.

3. The SOARS teams will continue to assess facility compliance with drug accountability requirements, and will provide bi-monthly progress updates to PBM in order to determine improvement trends. Each update report will reflect activities at eight to ten facilities, encompassing approximately one-third of all VHA facilities annually. To further enhance SOARS expertise in this area, PBM has arranged for their recently appointed Associate Chief Consultant for Pharmacy Compliance and Efficiency to participate as a SOARS team member at selected sites, providing on-site consultation and training. This individual also administers VHA's national training efforts in controlled substance management, and provides facility-specific consultation when required.

4. Another PBM/SOARS cooperative venture was the design of a comprehensive training video on the controlled substance accountability and inspection program that will soon be widely distributed throughout the system. The video, which addresses issues identified in your report, was also highlighted during a workshop on controlled substances policy compliance that was conducted in conjunction with VHA's recent National Pharmacy Conference

(September 11-15, 2006). The conference agenda also included other sessions devoted to related accountability

control issues, many of which reflected issues raised in your report. For example, the Director of the SOARS program provided a refresher course on the use of the self-assessment guide, and participants were encouraged to re-apply the guide at their own facilities to determine compliance improvement following expanded training efforts. More than 175 VA pharmacists attended the conference.

5. The National Pharmacy Conference also included training sessions dealing with management of controlled substances by Research Service and use of the required automated inventory control system, issues also highlighted in your report. I was pleased that your findings reflect considerable improvement from previous reports in the management of controlled substances maintained in field research programs. Our action plan provides more detail about initiatives undertaken by the Office of Research and Development to assure compliance in this area.

6. Though not directly related to the medical facility focus of your report, another aspect of VHA's drug control efforts is noteworthy. Approximately 80 percent of VA outpatient prescriptions are dispensed through the Consolidated Mail Outpatient Pharmacies (CMOP). CMOP inventory controls differ significantly from medical facility controls, and recent data indicate that the controls are very effective in preventing inventory loss. CMOP inventory shrinkage was found to be less than 0.1 percent, with a large portion of that small amount due to spillage from the automated equipment. As a benchmark, shrinkage from general warehouse operations is estimated to be in the range of 1 percent to 3 percent, with a mean of 1.7 percent.

7. In summary, I believe that VHA's ongoing efforts to assure medical facility compliance with drug control requirements are resulting in steady improvement. We are committed to maintaining this trend. I am convinced that we are better served by having stringent inventory control requirements that are difficult to meet than by having less demanding mandates, but more consistent compliance outcomes.

8. Thank you for your helpful observations and recommendations. A copy of your report will be provided to the Network Directors for subsequent distribution to all medical facilities. If additional information is required, please contact Margaret M. Seleski, Director, Management Review Service (10B5), at 565-7638.

*(original signed by:)*
Michael J. Kussman, MD, MS, MACP

Attachment

## Acting Under Secretary for Health Comments to Office of Inspector General's Report

The following comments are submitted in response to the recommendation(s) in the Office of Inspector General's Report:

**OIG Recommendation(s)**

**Recommendation 1:** We recommend that the Acting Under Secretary for Health, in conjunction with the Chief Network Officer, ensure that all VA medical facility managers use the findings in this report during their own internal reviews and, at a minimum:

(a) Assess the adequacy of controlled substances inspection procedures and take action to improve them where warranted.

Concur **Target Completion Date:** Ongoing

The Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) will forward a copy of this report to all Network offices for distribution to medical facility managers. During the first quarter of Fiscal Year (FY) 2006, all facilities completed a self-assessment of their controlled substance management programs, with most using a standardized self-assessment tool jointly developed by the Pharmacy Benefits Management Strategic Healthcare Group (PBMSHG) and the Systematic Ongoing Assessment and Review Strategy (SOARS) program. This evaluative tool is also used by the SOARS teams in their focused reviews of controlled substance management, and addresses all of the issues highlighted in report recommendations. Findings from the assessment were aggregated by facility and distributed to all Network offices by the DUSHOM for follow-up oversight of corrective actions by the facilities. Facilities will be strongly encouraged to use this self-assessment tool to re-evaluate improvement progress in their drug control programs.

In addition, PBMSHG and SOARS program managers worked in coordination with the Employee Education System to develop a comprehensive training video dealing with the controlled substance accountability and inspection program. This video was featured during VHA's September 2006 National Pharmacy Conference and will soon be widely distributed to all Network offices and field facilities. Again, the video addresses issues raised by OIG, including inspection procedures, physical security, and other internal control and reporting requirements.

Issues identified in the report will also be included as agenda items for discussion during the regular monthly pharmacy conference calls for all VISN Formulary/facility Chiefs of Pharmacy.

The SOARS teams will also continue their focused reviews of facility compliance with drug accountability requirements and provide bi-monthly briefings to the PBMSHG of trended findings. PBMSHG has also recently appointed an Associate Chief Consultant for Pharmacy Compliance and Efficiency to direct national training efforts in controlled substance management and to provide individualized on-site consultation to facilities, as needed.

(b) Assess the adequacy of physical security efforts and improve security where needed.

Concur **Target Completion Date:** Ongoing

See response under 1(a).

In addition, security of pharmacy operations is also included as part of the annual security reviews that are randomly conducted at all sites by facility police and security officers. In a written report to medical facility management, the police report any security deviations observed. All facilities will be re-reviewed by the end of FY 2007.

(c) Enforce theft reporting requirements.

Concur **Target Completion Date:** 11/30/06

PBMSHG will include discussion of theft reporting requirements on the agenda of the November 2006 monthly conference call with all VISN formulary leaders and facility Chiefs of Pharmacy. The importance of timely and complete reporting will be stressed. Compliance with theft reporting requirements is also included as part of the SOARS team focused reviews.

(d) Ensure that controlled substances retained by Research Service staff are included in all related internal control procedures.

Concur **Target Completion Date:** 10/31/06

Requirements for maintenance of controlled substances by Research Service were included among the agenda items at the recently convened National Pharmacy Conference. The SOARS teams focused reviews also encompass compliance assessment by field research programs.

In March 2004, the Chief Research and Development Officer (ORD) issued a memorandum to all field research programs emphasizing that research investigators are obligated to comply with all Pharmacy Service requirements and DEA regulations regarding obtaining, using, tracking and storing controlled substance drugs. Specifically, it discussed the requirement that all controlled substances must be ordered by the VA pharmacy and received by the pharmacy for disbursement to research personnel. It further stated that all controlled substances used and stored in research areas must be included in the medical center controlled substance inspection program. By October 31, 2006, ORD will again issue a reminder memorandum to the field research programs, re-emphasizing compliance requirements.

In addition, the Office of Research Oversight (ORO) will continue to review issues identified in the report, and during ORO site visits, will incorporate drug security compliance checks as part of their reviews.

**Recommendation 2:** We recommend that the Acting Under Secretary for Health, in conjunction with the Chief Network Officer, ensure that all VA medical facility managers:

(a) Ensure the use of required automated inventory control systems.

Concur **Target Completion Date:** 6/30/07

Training on the use of the automated inventory control systems was provided during the September 2006 National Pharmacy Conference, and the requirement is also addressed in the referenced SOARS training video that will soon be distributed to all medical facilities. Facility Chiefs of Pharmacy will be reminded of the requirement during upcoming monthly national conference calls. Representatives from VA's pharmaceutical prime vendor have also provided training on use of the systems at VISN pharmacy leadership meetings. In addition, during the third quarter of FY 2007, the prime vendor will aggregate procurement data from each facility. The generated inventory turns will be monitored nationally by PBMSHG to assess implementation compliance. Follow-up consultation with any outlier facilities will be provided as necessary. We note, however, that VHA does not require use of all available features on the control systems to achieve compliance with established policy.

(b) Enforce compliance with controlled substances receiving and physical inventory requirements.

Concur **Target Completion Date:** Ongoing

Controlled substance receiving and physical inventory requirements are also addressed in the SOARS assessment tool and in the national training video that will be distributed to all facilities. Training on these requirements was included in workshop presentations during the recent National Pharmacy Conference. Controlled substance coordinators, inspectors and pharmacy managers have been requested to review the training video and to utilize the self-assessment tool to monitor the effectiveness of their compliance efforts on a routine basis.

**Appendix D**

# OIG Contact and Staff Acknowledgments

| | |
|---|---|
| OIG Contact | William J. Gerow, Jr. (708) 202-2344 |
| Acknowledgments | Julio Arias<br>Verena Briley-Hudson<br>Paula Chapman<br>Melissa E. Colyn<br>Kevin F. Gibbons<br>Gregory Gladhill<br>Wachita Haywood<br>Freddie Howell, Jr.<br>Gary G. Humble<br>Tae T. Kim<br>Claire McDonald<br>Patricia E. McGauley<br>Henry J. Mendala<br>Jennifer Reed<br>Annette Robinson<br>Jennifer S. Roberts<br>Joel A. Snyderman<br>Vishala Sridhar<br>Joseph Vivolo<br>Jeff B. Wieters<br>Wilma Wong |

**Appendix E**

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## VA Distribution

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## Non-VA Distribution

House Committee on Veterans' Affairs
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Senate Committee on Veterans' Affairs
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Senate Committee on Homeland Security & Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget

This report will be available in the near future on the OIG's Web site at http://www.va.gov/oig/52/reports/mainlist.htm. This report will remain on the OIG Web site for at least 2 fiscal years after it is issued.