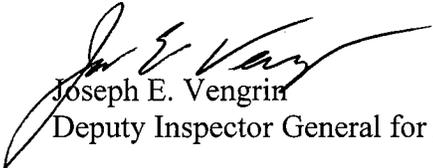




APR 11 2007

TO: Charles W. Grim, D.D.S., M.H.S.A.
Director
Indian Health Service

FROM: 
Joseph E. Vengrin
Deputy Inspector General for Audit Services

SUBJECT: Safeguards Over Controlled Substances at Anadarko Indian Health Center
(A-06-06-00034)

The attached final report provides the results of our review of safeguards over controlled substances at Anadarko Indian Health Center (Anadarko) in Anadarko, Oklahoma.

This review is part of a series of reviews at Indian Health Service (IHS)-operated hospitals and health centers that dispense certain addictive drugs. The Controlled Substances Act of 1970 regulates the possession and use of these drugs, classifies the drugs as controlled substances, and divides them among five schedules based on their medical use and potential for abuse. This report focuses on Schedule II controlled substances (Schedule II substances) because they have the highest potential for abuse among controlled substances with an accepted medical use.

Our objective was to determine whether Anadarko complied with applicable requirements to secure and account for its Schedule II substances.

Anadarko did not always comply with applicable requirements to secure, or have adequate internal controls over, Schedule II substances at its pharmacy. Anadarko appropriately accounted for the Schedule II substances in our review. However, inadequate security and internal controls over these substances made them vulnerable to theft and mismanagement.

We recommend that IHS direct Anadarko to enforce the security and internal controls detailed in our report.

In its written comments on our draft report, IHS concurred with our findings and recommendations and stated that Anadarko had implemented, or was currently implementing, all recommended corrective actions.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Joseph J. Green, Assistant Inspector General for Grants, Internal

Page 2 – Charles W. Grim, D.D.S., M.H.S.A.

Activities, and Information Technology Audits, at (202) 619-1175 or through e-mail at Joe.Green@oig.hhs.gov. Please refer to report number A-06-06-00034.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SAFEGUARDS OVER
CONTROLLED SUBSTANCES AT
ANADARKO INDIAN HEALTH
CENTER**



Daniel R. Levinson
Inspector General

April 2007
A-06-06-00034

Office of Inspector General

<http://oig.hhs.gov>

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OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.



EXECUTIVE SUMMARY

BACKGROUND

The Indian Health Service (IHS), an agency within the Department of Health and Human Services, is the principal Federal health care provider and health advocate for 1.5 million American Indians and Alaska Natives. As part of its health care services, IHS maintains pharmacies that may dispense certain addictive drugs, the possession and use of which are regulated under the Controlled Substances Act (the Act) of 1970. The Act classifies these drugs as controlled substances and divides them among five schedules based on their medical use and potential for abuse. This report focuses on Schedule II controlled substances (Schedule II substances) because they have the highest potential for abuse among controlled substances with an accepted medical use.

The Drug Enforcement Administration (DEA) is the primary Federal agency responsible for enforcing the Act. Consistent with regulations under the Act, IHS requires all of its hospitals and other health care facilities that dispense controlled substances to register with DEA. All DEA registrants must securely store controlled substances and maintain complete and accurate inventories and records of all transactions involving controlled substances in accordance with the Act.

This report addresses safeguards over Schedule II substances at Anadarko Indian Health Center (Anadarko) in Anadarko, Oklahoma. Anadarko is one of 83 IHS-operated hospitals and health centers.

OBJECTIVE

Our objective was to determine whether Anadarko complied with applicable requirements to secure and account for its Schedule II substances.

SUMMARY OF FINDINGS

Anadarko did not always comply with applicable requirements to secure, or have adequate internal controls over, Schedule II substances at its pharmacy. Specifically:

- The safe used to store Schedule II substances was not always locked during pharmacy hours as Federal regulations and IHS policy require, and the pharmacy's main entry door was not always locked. Federal regulations consider control over access to storage areas a factor in determining whether a pharmacy has met the requirement to secure its controlled substances.
- Visitors to the pharmacy were unsupervised, contrary to Anadarko policy.
- An alarm system was not in place to monitor Schedule II substances after pharmacy hours as Federal regulations recommend.

- Key duties and responsibilities for Schedule II substances were not separated among pharmacists as the Office of Management and Budget generally requires.

These deficiencies occurred because Anadarko officials did not enforce applicable policies and procedures.

Anadarko appropriately accounted for the Schedule II substances in our review. Inventory records, invoices, and other documentation showed that Anadarko appropriately ordered, inventoried, administered, and dispensed the Schedule II substances. However, inadequate security and internal controls over these substances made them vulnerable to theft and mismanagement.

RECOMMENDATIONS

We recommend that IHS direct Anadarko to enforce the following security and internal controls at its pharmacy:

- Store Schedule II substances in a locked safe, and lock the door to the pharmacy during pharmacy hours.
- Supervise pharmacy visitors at all times, and ensure that the pharmacy is reserved only for official pharmaceutical business.
- Consider monitoring Schedule II substances with an alarm system after pharmacy hours.

We recognize that Anadarko has only three pharmacists and may not always be able to separate key duties related to Schedule II substances. Therefore, we also recommend that when one pharmacist must perform two or more key duties related to Schedule II substances (ordering, accepting delivery, and recording receipt in inventory records), a different pharmacist review and certify the records for those transactions.

INDIAN HEALTH SERVICE'S COMMENTS

In its written comments on our draft report, IHS concurred with our findings and recommendations and stated that Anadarko had implemented, or was currently implementing, all recommended corrective actions. IHS's comments are included as the Appendix.

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
BACKGROUND	1
The Controlled Substances Act of 1970	1
Anadarko Indian Health Center	1
OBJECTIVE, SCOPE, AND METHODOLOGY	1
Objective.....	1
Scope.....	1
Methodology.....	2
FINDINGS AND RECOMMENDATIONS	3
SECURITY AND INTERNAL CONTROL WEAKNESSES	3
The Safe and Door to the Pharmacy Were Not Always Locked During Pharmacy Hours	3
Visitors to the Pharmacy Were Unsupervised	4
The Pharmacy Was Not Monitored by an Alarm System.....	4
Key Duties and Responsibilities Were Not Separated Among Pharmacists	5
EFFECTIVE ACCOUNTABILITY CONTROLS	5
RECOMMENDATIONS	5
INDIAN HEALTH SERVICE’S COMMENTS	5
APPENDIX	
INDIAN HEALTH SERVICE’S COMMENTS	

INTRODUCTION

BACKGROUND

The Indian Health Service (IHS), an agency within the Department of Health and Human Services, is the principal Federal health care provider and health advocate for 1.5 million American Indians and Alaska Natives. As part of its health care services, IHS maintains pharmacies that may dispense certain addictive drugs, the possession and use of which are regulated under the Controlled Substances Act of 1970 (the Act).

The Controlled Substances Act of 1970

The Act classifies certain federally regulated drugs as controlled substances and divides them among five schedules based on their medical use and potential for abuse and addiction. This report focuses on Schedule II controlled substances (Schedule II substances) because they have the highest potential for abuse among controlled substances with an accepted medical use. Some examples of Schedule II substances include narcotics such as Percodan® and Demerol® and stimulants such as Ritalin®.

The Drug Enforcement Administration (DEA) is the primary Federal agency responsible for enforcing the Act. IHS requires all of its hospitals and other health care facilities that dispense controlled substances to register with DEA. All DEA registrants must securely store controlled substances and maintain complete and accurate inventories and records of all transactions involving controlled substances in accordance with the Act.

Anadarko Indian Health Center

This report addresses safeguards over Schedule II substances at Anadarko Indian Health Center (Anadarko) in Anadarko, Oklahoma. Anadarko is one of 83 IHS-operated hospitals and health centers. It is part of the Lawton service unit, which is under the jurisdiction of the Oklahoma City area office of IHS. Anadarko's pharmacy has a staff of three pharmacists and one pharmacy technician. The chief pharmacist is responsible for procuring, securing, storing, dispensing, and accounting for Schedule II substances in the pharmacy. All of Anadarko's Schedule II substances are stored in a safe in the pharmacy.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Anadarko complied with applicable requirements to secure and account for its Schedule II substances.

Scope

We limited our review to Schedule II substances because they have the highest potential for abuse among controlled substances with an accepted medical use.

We selected for review four of the eight Schedule II substances that the pharmacy stored and dispensed from April 2004 through February 2005. According to monthly inventory reports, the four substances were the most frequently dispensed Schedule II substances. In addition to being one of the four most frequently dispensed Schedule II substances, Demerol was selected because an employee at another IHS hospital had pilfered this substance for personal use. We limited our review of Anadarko's internal controls to those related to securing and accounting for Schedule II substances.

We performed our fieldwork at Anadarko during February 2005.

Methodology

To perform our audit, we:

- reviewed applicable Federal requirements and Anadarko policies;
- evaluated Anadarko's controls over the safeguarding and recordkeeping of its Schedule II substances at the pharmacy;
- interviewed Anadarko pharmacy and medical staff;
- performed a physical count of the four selected Schedule II substances and compared this count with the most recent monthly Schedule II inventory report and perpetual inventory logs to verify quantity-on-hand amounts;
- analyzed order forms, vendor invoices, perpetual inventory logs, and monthly inventory reports to determine whether the four selected Schedule II substances were ordered, received, and recorded as inventory at the pharmacy;
- reviewed prescription forms, perpetual inventory logs, and medical charts for the four selected Schedule II substances to determine whether pharmacists had dispensed these substances to patients, medical staff had administered them to patients, or pharmacists had returned them to the pharmacy's inventory;
- reviewed perpetual inventory logs for one of the four selected Schedule II substances to determine whether the disposal of wasted substances was appropriately documented;
- selectively contacted patients to determine whether they had received the controlled substances that were recorded as administered or dispensed; and
- discussed our findings and recommendations with Anadarko and area office officials.

We conducted our audit in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

Anadarko did not always comply with applicable requirements to secure, or have adequate internal controls over, Schedule II substances at its pharmacy. Specifically:

- The safe used to store Schedule II substances was not always locked during pharmacy hours as Federal regulations and IHS policy require, and the pharmacy's main entry door was not always locked. Federal regulations consider control over access to storage areas a factor in determining whether a pharmacy has met the requirement to secure its controlled substances.
- Visitors to the pharmacy were unsupervised, contrary to Anadarko policy.
- An alarm system was not in place to monitor Schedule II substances after pharmacy hours as Federal regulations recommend.
- Key duties and responsibilities for Schedule II substances were not separated among pharmacists as the Office of Management and Budget generally requires.

These deficiencies occurred because Anadarko officials did not enforce applicable policies and procedures.

Anadarko appropriately accounted for the Schedule II substances in our review. Inventory records, invoices, and other documentation showed that Anadarko appropriately ordered, inventoried, administered, and dispensed the Schedule II substances. However, inadequate security and internal controls over these substances made them vulnerable to theft and mismanagement.

SECURITY AND INTERNAL CONTROL WEAKNESSES

Anadarko did not appropriately secure or have adequate internal controls over Schedule II substances at its pharmacy.

The Safe and Door to the Pharmacy Were Not Always Locked During Pharmacy Hours

Consistent with Federal regulations (21 CFR § 1301.75), the "Indian Health Manual," section 3-7.3D(8c)(i)(a), requires IHS pharmacies to keep "Schedule II controlled substances . . . stored in a substantially constructed locked cabinet, safe, or drawer." In addition, although not specifically mandated, Federal regulations (21 CFR § 1301.71) consider control over access to storage areas a factor in determining whether pharmacies have met the requirement to ". . . provide effective controls and procedures to guard against theft and diversion of controlled substances."

During our 1-week survey of Anadarko's pharmacy, we observed that the safe used to store Schedule II substances and the entry door to the pharmacy were not always locked during pharmacy hours. According to the chief pharmacist, these conditions occurred because

pharmacy officials required frequent access to the safe and to the pharmacy. Nevertheless, he believed that the Schedule II substances were secure because a pharmacist was always inside the pharmacy to monitor these substances.

However, on one occasion, we observed a child entering the pharmacy alone through its unlocked entry door without detection by pharmacy officials. The child walked past shelves of medications, including working stocks of controlled substances, until she gained the attention of a pharmacy technician who quickly escorted her out.

We believe that this occasion underscores the need for pharmacists to ensure that the pharmacy's entry door is always locked to prevent unauthorized access. Additionally, pharmacists should strictly adhere to the requirement to keep Schedule II substances stored in a locked safe because these substances are vulnerable to theft from a pharmacy technician who works inside the pharmacy but is not supposed to have access to the safe. Locking the safe and the door to the pharmacy would add a significant security control over these substances during pharmacy hours.

Visitors to the Pharmacy Were Unsupervised

Anadarko's pharmacy "Policy Procedure Manual," section 1.4.6, states that visitors to the pharmacy must be supervised ". . . by the Chief Pharmacist or whomever he assigns this duty." In addition, the area pharmacy officer told us that anyone entering the pharmacy, other than a pharmacist, should always be in the direct line of sight of a pharmacist while the pharmacy is open. On two occasions, however, pharmacists allowed medical personnel to enter the pharmacy without appropriate supervision to heat food in a microwave oven close to the unlocked safe that contained Schedule II substances. We observed that these personnel, who were not supposed to have access to the safe, were not always within sight of a pharmacist who could ensure that they did not pilfer substances from the safe.

The Pharmacy Was Not Monitored by an Alarm System

Electronic alarm systems are not specifically mandated. However, Federal regulations (21 CFR § 1301.71) consider an alarm system as one factor in determining whether the overall security environment has met the requirement to ". . . provide effective controls and procedures to guard against theft and diversion of controlled substances." In addition, the "Security Requirements" section of the "DEA Pharmacist's Manual" recommends an alarm system for pharmacies.

A pharmacist told us that the pharmacy was not equipped with an alarm system to monitor Schedule II substances after pharmacy hours. We confirmed this with Anadarko's area pharmacy officer, who added that the pharmacy should install an alarm system. Without an alarm system, Schedule II substances were vulnerable to theft after pharmacy hours, and intrusion into the pharmacy could go undetected until the following workday. An alarm system would significantly strengthen security over these substances.

Key Duties and Responsibilities Were Not Separated Among Pharmacists

A pharmacist told us that all three pharmacists at Anadarko were authorized to (1) order Schedule II substances, (2) accept delivery of those substances, and (3) record the receipt of those substances in the perpetual inventory records. However, these duties should be separated to mitigate the risk of fraud or mismanagement; specifically, the risk that a pharmacist with authority to order a Schedule II substance, accept delivery, and record its receipt in inventory records could pilfer the substance.

Although no IHS, Anadarko, or other Federal policy specifically mandates the separation of these duties in the context of a pharmacy operation, this practice is consistent with a requirement in Office of Management and Budget Circular A-123. Attachment II of the circular states: “Key duties and responsibilities in authorizing, processing, recording, and reviewing official agency transactions should be separated among individuals.”

EFFECTIVE ACCOUNTABILITY CONTROLS

Anadarko had adequate recordkeeping controls in place to account for the Schedule II substances in our review. Inventory records, invoices, and other documentation showed that Anadarko appropriately ordered, inventoried, administered, and dispensed the Schedule II substances in accordance with Federal regulations and the “Indian Health Manual.”

RECOMMENDATIONS

We recommend that IHS direct Anadarko to enforce the following security and internal controls at its pharmacy:

- Store Schedule II substances in a locked safe, and lock the door to the pharmacy during pharmacy hours.
- Supervise pharmacy visitors at all times, and ensure that the pharmacy is reserved only for official pharmaceutical business.
- Consider monitoring Schedule II substances with an alarm system after pharmacy hours.

We recognize that Anadarko has only three pharmacists and may not always be able to separate key duties related to Schedule II substances. Therefore, we recommend that when one pharmacist must perform two or more key duties related to Schedule II substances (ordering, accepting delivery, and recording receipt in inventory records), a different pharmacist review and certify the records for those transactions.

INDIAN HEALTH SERVICE’S COMMENTS

In its written comments on our draft report, IHS concurred with our findings and recommendations and stated that Anadarko had implemented, or was currently implementing, all recommended corrective actions. IHS’s comments are included as the Appendix.

APPENDIX



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Indian Health Service
Rockville MD 20852

MAR 23 2007

TO: Inspector General

FROM: Director

SUBJECT: Response to Office of Inspector General Draft Audit Report, "Safeguards Over Controlled Substances at Anadarko Indian Health Center (A-06-06-00034)," issued January 24, 2007

The Indian Health Service (IHS) has reviewed the Office of Inspector General (OIG) draft audit report, "Safeguards Over Controlled Substances at Anadarko Indian Health Center," and concurs with all OIG findings and recommendations to enforce all applicable security, internal, and accountability controls for Schedule II substances. The Oklahoma City Area IHS will issue an appropriate directive to enforce adherence to identified security and internal controls only if deemed necessary, because the Anadarko Indian Health Center has implemented, or is currently implementing, all recommended corrective actions. The following are specific responses to each recommendation, including corrective actions that have been implemented:

OIG Recommendation: "Store Schedule II substances in a locked safe, and lock the door to the pharmacy during pharmacy hours."

IHS Response: Concur. The Anadarko Indian Health Center pharmacy staff received training and instruction from the Area Pharmacy Consultant to keep all Schedule II substances in a locked narcotic safe at all times. Only Schedule II substances that are currently being dispensed will be removed from the narcotic safe. The narcotic safe is to be locked at all times regardless whether the pharmacy is open to the public or not. This requirement has been strengthened and audited onsite by the Area Pharmacy Consultant on two occasions since the OIG audit and found to be in compliance. The new narcotic procedures are in compliance with Federal regulations at Title Code of Federal Regulations Section 1301.75, and a new local policy is in place that requires continually locked narcotics in compliance with the Indian Health Manual [Section 3-7.3D (8c)(i)(a)].

OIG Recommendation: "Supervise pharmacy visitors at all times, and insure that the pharmacy is reserved only for official pharmaceutical business."

IHS Response: Concur. Anadarko Indian Health Center pharmacists are responsible for taking the lead in controlling Schedule II substances in accordance with the Controlled Substance Act of 1970 and the Indian Health Manual, Part 3, Chapter 7. The only way this can be accomplished is to have direct sight of all unauthorized personnel and visitors. Anadarko pharmacists received training and instruction from the Area Pharmacy Consultant to directly

Page 2—Inspector General

supervise and monitor unauthorized personnel and pharmacy visitors at all times. Also, only visitors on official pharmacy business are allowed in the main pharmacy storage area. This requirement has been strengthened and audited onsite by the Area Pharmacy Consultant on two occasions since the OIG audit and found to be in compliance. A door lock was installed on the entrance to the pharmacy that remains closed and locked at all times.

OIG Recommendation: "Consider monitoring Schedule II substances with an alarm system after pharmacy hours."

IHS Response: Concur. There is currently no electronic alarm system in place in the main pharmacy of the Anadarko Indian Health Center. The Area Pharmacy Consultant has recommended that the Chief Pharmacist and Facility Manager install an electronic alarm system for the outpatient pharmacy department when funding and resources become available.

OIG Recommendation: "During Schedule II substances ordering when one pharmacist must perform two or more key duties related to Schedule II substance (ordering, accepting delivery, and recording receipt in inventory records), a different pharmacist review and certify the records for those transactions."

IHS Response: Concur. The Anadarko Indian Health Center pharmacy has implemented a new policy that ensures separation of responsibilities for controlled substance procurement and control. At this time, authorized personnel are not allowed to order and receive the same shipment of controlled substances.

If you have any questions concerning this response, please contact Mr. Darryl Drapeaux, Director, IHS Office of Management Services, Management Policy and Internal Control Staff, at (301) 443-2650.

Charles W. Grim, DDS

Charles W. Grim, D.D.S., M.H.S.A.
Assistant Surgeon General