



MAY 10 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 Santo Domingo Indian Health Center
(A-06-07-00049)

The attached final report provides the results of our review of safeguards over controlled substances at Santo Domingo Indian Health Center (Santo Domingo) in Santo Domingo, New Mexico.

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 Santo Domingo complied with applicable requirements to secure and account for its Schedule II substances.

Santo Domingo complied with applicable requirements to secure and account for its Schedule II substances. However, Santo Domingo did not institute all recommended security precautions or have adequate internal controls over these substances. As a result, Schedule II substances at Santo Domingo were vulnerable to theft and mismanagement.

We recommend that IHS direct Santo Domingo to:

- consider monitoring its alarm system after pharmacy hours and
- establish a control to compensate for a lack of separation of duties by having another person, in addition to the pharmacist, participate in the receiving and recording functions to ensure that Schedule II substances received are the same as those ordered and that substances received are accurately entered in inventory records.

In its written comments on our draft report, IHS concurred with our findings and recommendations and stated that Santo Domingo 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 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-06-07-00049.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SAFEGUARDS OVER
CONTROLLED SUBSTANCES AT
SANTO DOMINGO INDIAN
HEALTH CENTER**



Daniel R. Levinson
Inspector General

May 2007
A-06-07-00049

Office of Inspector General

<http://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <http://oig.hhs.gov>

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR part 5.)

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 Santo Domingo Indian Health Center (Santo Domingo) in Santo Domingo, New Mexico. Santo Domingo is one of 83 IHS-operated hospitals and health centers.

OBJECTIVE

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

SUMMARY OF FINDINGS

Santo Domingo complied with applicable requirements to secure and account for its Schedule II substances. However, Santo Domingo did not institute all recommended security precautions or have adequate internal controls over these substances. Specifically:

- Neither Santo Domingo nor a private security company monitored the alarm system after pharmacy hours. Federal regulations consider a monitored alarm system as one factor in determining whether a pharmacy has met the requirement to secure its controlled substances.
- Santo Domingo had only one pharmacist and was unable to separate key duties related to Schedule II substances. The pharmacist was the only employee at Santo Domingo authorized to (1) order Schedule II substances for the pharmacy, (2) accept delivery, and (3) record their receipt in the perpetual inventory records. Because these duties could not

be separated at Santo Domingo and Santo Domingo did not have other controls to compensate for this weakness, there was undue risk of fraud and mismanagement.

As a result, Schedule II substances at Santo Domingo were vulnerable to theft and mismanagement.

RECOMMENDATIONS

We recommend that IHS direct Santo Domingo to:

- consider monitoring its alarm system after pharmacy hours and
- establish a control to compensate for a lack of separation of duties by having another person, in addition to the pharmacist, participate in the receiving and recording functions to ensure that Schedule II substances received are the same as those ordered and that substances received are accurately entered in inventory records.

INDIAN HEALTH SERVICE'S COMMENTS

In its written comments on our draft report, IHS concurred with our findings and recommendations and stated that Santo Domingo 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
Santo Domingo Indian Health Center.....	1
OBJECTIVE, SCOPE, AND METHODOLOGY	1
Objective.....	1
Scope.....	2
Methodology.....	2
FINDINGS AND RECOMMENDATIONS	3
SECURITY AND INTERNAL CONTROL WEAKNESSES	3
The Alarm System Was Not Monitored	3
Controls Were Not Implemented To Compensate for a Lack of Separation of Key Duties	4
EFFECTIVE ACCOUNTABILITY CONTROLS	4
RECOMMENDATIONS	4
INDIAN HEALTH SERVICE’S COMMENTS	4
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.

Santo Domingo Indian Health Center

This report addresses safeguards over Schedule II substances at Santo Domingo Indian Health Center (Santo Domingo) in Santo Domingo, New Mexico. Santo Domingo is one of 83 IHS-operated hospitals and health centers. It is part of the Santa Fe service unit, which is under the jurisdiction of the Albuquerque area office of IHS. Santo Domingo's pharmacy has a staff of one pharmacy technician and a chief pharmacist. The chief pharmacist is responsible for procuring, securing, storing, dispensing, and accounting for Schedule II substances in the pharmacy. All of Santo Domingo's Schedule II substances are stored in a wall lockbox in the pharmacy.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Santo Domingo 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 5 of the 12 Schedule II substances that the pharmacy stored and dispensed from April through September 2005. According to the most recent monthly inventory report available during our audit, the five substances were the most frequently dispensed Schedule II substances. In addition to being one of the five most frequently dispensed Schedule II substances, Demerol® was selected because an employee at another IHS hospital had pilfered the substance for personal use. We limited our review of Santo Domingo's internal controls to those related to securing and accounting for Schedule II substances.

We performed our fieldwork at Santo Domingo in September 2005.

Methodology

To perform our audit, we:

- reviewed applicable Federal, IHS, and Santo Domingo requirements;
- evaluated Santo Domingo's controls over the safeguarding and recordkeeping of its Schedule II substances at the pharmacy;
- interviewed Santo Domingo pharmacy and medical staff;
- performed a physical count of the five selected Schedule II substances and compared this count with perpetual inventory records to verify onhand amounts;
- analyzed vendor invoices and perpetual inventory records to determine whether the five selected Schedule II substances were received and recorded as inventory;
- reviewed prescription forms, perpetual inventory records, and medical charts for the five selected Schedule II substances to determine whether the chief pharmacist had dispensed these substances to patients, medical staff had administered them to patients, or the chief pharmacist had returned them to the pharmacy's inventory;
- reviewed medical charts for one of the five selected Schedule II substances to determine whether disposal of the wasted substance was required and 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 Santo Domingo and area office officials.

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

FINDINGS AND RECOMMENDATIONS

Santo Domingo complied with applicable requirements to secure and account for its Schedule II substances. However, Santo Domingo did not institute all recommended security precautions or have adequate internal controls over these substances. Specifically:

- Neither Santo Domingo nor a private security company monitored the alarm system after pharmacy hours. Federal regulations consider a monitored alarm system as one factor in determining whether a pharmacy has met the requirement to secure its controlled substances.
- Santo Domingo had only one pharmacist and was unable to separate key duties related to Schedule II substances. The pharmacist was the only employee at Santo Domingo authorized to (1) order Schedule II substances for the pharmacy, (2) accept delivery, and (3) record their receipt in the perpetual inventory records. Because these duties could not be separated at Santo Domingo and Santo Domingo did not have other controls to compensate for this weakness, there was undue risk of fraud and mismanagement.

As a result, Schedule II substances at Santo Domingo were vulnerable to theft and mismanagement.

SECURITY AND INTERNAL CONTROL WEAKNESSES

Santo Domingo did not monitor its alarm system after pharmacy hours or have adequate internal controls over its Schedule II substances.

The Alarm System Was Not Monitored

The “Security Requirements” section of the “DEA Pharmacist’s Manual” recommends an alarm system for pharmacies. In addition, Federal regulations (21 CFR § 1301.71) consider a monitored 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.”

Santo Domingo routinely activated its alarm system after pharmacy hours, but neither Santo Domingo nor a private security company monitored the alarm so that local authorities could be alerted should a break-in occur. The chief pharmacist initially told us that a private security company monitored the alarm system. However, at our request, she contacted a security company representative who said that the company had not monitored the alarm system for the past 8 months because of a payment dispute with Santo Domingo’s Santa Fe service unit. As a result, Schedule II substances were vulnerable to theft after pharmacy hours because an intrusion could go undetected until the following workday.

Controls Were Not Implemented To Compensate for a Lack of Separation of Key Duties

Santo Domingo had only one pharmacist and was unable to separate key duties related to Schedule II substances. The pharmacist was the only employee at Santo Domingo authorized to (1) order Schedule II substances for the pharmacy, (2) accept delivery, and (3) record their receipt in the perpetual inventory records. Because these duties could not be separated at Santo Domingo and Santo Domingo did not have other controls to compensate for this weakness, there was undue risk of fraud and mismanagement.

Although no IHS, Santo Domingo, 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

Santo Domingo appropriately accounted for the Schedule II substances in our review. Inventory records, invoices, and other documentation showed that Santo Domingo maintained complete and accurate inventories and records of all transactions involving Schedule II substances in accordance with Federal regulations and the “Indian Health Manual.”

RECOMMENDATIONS

We recommend that IHS direct Santo Domingo to:

- consider monitoring its alarm system after pharmacy hours and
- establish a control to compensate for a lack of separation of duties by having another person, in addition to the pharmacist, participate in the receiving and recording functions to ensure that Schedule II substances received are the same as those ordered and that substances received are accurately entered in inventory records.

INDIAN HEALTH SERVICE’S COMMENTS

In its written comments on our draft report, IHS concurred with our findings and recommendations and stated that Santo Domingo 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

APR - 9 2007

Indian Health Service
Rockville MD 20852

TO: Inspector General

FROM: Director

SUBJECT: Response to Office of Inspector General Draft Audit Report, "Safeguards Over Controlled Substances at Santo Domingo Indian Health Center (A-06-07-00049)," issued March 8, 2007

The Indian Health Service (IHS) has reviewed the Office of Inspector General (OIG) draft audit report, "Safeguards Over Controlled Substances at Santo Domingo Indian Health Center," and concurs with all OIG findings and recommendations to implement and enforce security precautions and applicable internal controls for Schedule II controlled substances. The Santo Domingo Indian Health Center (SDIHC) has implemented, or is currently implementing, all recommended corrective actions. The following are specific responses to each OIG recommendation, including implemented corrective actions:

OIG Recommendation: "Consider monitoring its alarm system after pharmacy hours."

IHS Response: Concur. In October 2006 the SDIHC pharmacy relocated to a new building secured by an electronic alarm system that includes motion sensors.

OIG Recommendation: "Establish a control to compensate for a lack of separation of duties by having another person, in addition to the pharmacist, participate in the receiving and recording functions to ensure that Schedule II substances received are the same as those ordered and that substances received are accurately entered in inventory records."

IHS Response: Concur. The SDIHC pharmacy has implemented a policy requiring an alternate person, in addition to the Chief Pharmacist, verify the receiving and recording of Schedule II controlled substances to ensure adequate separation of responsibilities between Schedule II controlled substance procurement and control. The SDIHC pharmacy implemented these changes immediately following the OIG exit interview. In addition, the Area Pharmacy Consultant provided training and instruction to the SDIHC pharmacy staff to submit audits of their Schedule II controlled substances on a monthly basis.

Page 2 – Inspector General

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