DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

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 Santa Fe Indian Hospital (A-06-06-00032)

The attached final report provides the results of our review of safeguards over controlled substances at Santa Fe Indian Hospital (Santa Fe) in Santa Fe, 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 Santa Fe complied with applicable requirements to secure and account for its Schedule II substances.

Santa Fe complied with applicable requirements to secure its Schedule II substances. However, Santa Fe did not institute all recommended security precautions or have adequate internal controls over these substances at its outpatient and inpatient pharmacies. In addition, Santa Fe did not always comply with applicable requirements to account for Schedule II substances at its outpatient pharmacy and automated dispensing units in the outpatient department and inpatient ward. As a result, Schedule II substances at Santa Fe were vulnerable to theft and mismanagement.

We recommend that IHS direct Santa Fe to enforce the security, internal, and accountability controls detailed in our report.

In its written comments on our draft report, IHS concurred with our findings and recommendations and stated that Santa Fe 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-06-06-00032.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

SAFEGUARDS OVER CONTROLLED SUBSTANCES AT SANTA FE INDIAN HOSPITAL

Daniel R. Levinson
Inspector General

April 2007
A-06-06-00032

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 Santa Fe Indian Hospital (Santa Fe) in Santa Fe, New Mexico. Santa Fe is one of 83 IHS-operated hospitals and health centers.

OBJECTIVE

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

SUMMARY OF FINDINGS

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

- At the outpatient and inpatient pharmacies, an alarm system was not in place to monitor Schedule II substances after pharmacy hours as Federal regulations recommend.

- At the outpatient pharmacy, key duties and responsibilities for Schedule II substances were not separated among pharmacists as the Office of Management and Budget generally requires.

Santa Fe did not always comply with applicable requirements to account for its Schedule II substances. Specifically:

- At the outpatient pharmacy, contrary to IHS policy, pharmacists did not account for all onhand Schedule II substances on the monthly inventory reports.

- At the automated dispensing units in the outpatient department and inpatient ward, contrary to Santa Fe policy, medical staff did not consistently document the disposal of wasted Schedule II substances.

These deficiencies occurred because Santa Fe officials did not enforce applicable policies and procedures. As a result, Schedule II substances at Santa Fe were vulnerable to theft and mismanagement.

RECOMMENDATIONS

We recommend that IHS direct Santa Fe to enforce the following security and internal controls:

- At the outpatient and inpatient pharmacies, consider monitoring Schedule II substances with an alarm system after pharmacy hours.

- At the outpatient pharmacy, separate key duties and responsibilities related to Schedule II substances among pharmacists.

We further recommend that IHS direct Santa Fe to enforce the following accountability controls:

- At the outpatient pharmacy, ensure that pharmacists account for all onhand Schedule II substances on the monthly inventory reports.

- At the automated dispensing units in the outpatient department and inpatient ward, ensure that the disposal of wasted Schedule II substances is appropriately documented.

INDIAN HEALTH SERVICE'S COMMENTS

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

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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.

Santa Fe Indian Hospital

This report addresses safeguards over Schedule II substances at Santa Fe Indian Hospital (Santa Fe) in Santa Fe, New Mexico. Santa Fe 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. Santa Fe's pharmacies have a staff of eight pharmacists and three pharmacy technicians. The chief pharmacist is responsible for procuring, securing, storing, dispensing, and accounting for Schedule II substances in the pharmacies. Santa Fe's service unit director (chief executive officer) is responsible for the overall safeguarding and handling of these substances.

Santa Fe stores its Schedule II substances in the following areas:

- a metal cabinet in the outpatient pharmacy;
- a metal cabinet in the inpatient pharmacy; and
- three automated dispensing units, one each in the outpatient department, inpatient ward, and recovery room/area.

Santa Fe stores most of its Schedule II substances in the outpatient pharmacy.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Santa Fe 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 20 of the 40 Schedule II substances that the pharmacies stored and dispensed from November 2004 through August 2005. We based our selection on several factors, including whether a substance had a history of theft at another IHS hospital or was unaccounted for or incorrectly recorded on Santa Fe inventory reports. We limited our review of Santa Fe's internal controls to those related to securing and accounting for Schedule II substances.

We performed our fieldwork at Santa Fe in August and September 2005.

Methodology

To perform our audit, we:

- reviewed applicable Federal requirements and Santa Fe policies;
- evaluated Santa Fe's controls over the safeguarding and recordkeeping of its Schedule II substances at the outpatient pharmacy, inpatient pharmacy, and automated dispensing units;
- interviewed Santa Fe management and pharmacy and medical staff;
- compared Schedule II substance inventory reports, perpetual inventory records, and vendor invoices to determine whether the 20 selected Schedule II substances were correctly reported on the monthly inventory reports and matched quantity-on-hand amounts at the outpatient and inpatient pharmacies as of August 31, 2005;
- analyzed perpetual inventory records, prescription forms, and medical charts for the 20 selected Schedule II substances to determine whether these substances were transferred from the outpatient pharmacy to other storage locations, dispensed to patients from the outpatient pharmacy, or administered to patients from the inpatient pharmacy or automated dispensing units;

- reviewed controlled-drug usage records and medical charts for 8 of the 20 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 dispensed; and

- discussed our findings and recommendations with Santa Fe and area office officials.

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

FINDINGS AND RECOMMENDATIONS

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

- At the outpatient and inpatient pharmacies, an alarm system was not in place to monitor Schedule II substances after pharmacy hours as Federal regulations recommend.

- At the outpatient pharmacy, key duties and responsibilities for Schedule II substances were not separated among pharmacists as the Office of Management and Budget generally requires.

Santa Fe did not always comply with applicable requirements to account for its Schedule II substances. Specifically:

- At the outpatient pharmacy, contrary to IHS policy, pharmacists did not account for all onhand Schedule II substances on the monthly inventory reports.

- At the automated dispensing units in the outpatient department and inpatient ward, contrary to Santa Fe policy, medical staff did not consistently document the disposal of wasted Schedule II substances.

These deficiencies occurred because Santa Fe officials did not enforce applicable policies and procedures. As a result, Schedule II substances at Santa Fe were vulnerable to theft and mismanagement.

SECURITY AND INTERNAL CONTROL WEAKNESSES

Santa Fe did not monitor its Schedule II substances with a recommended alarm system at the outpatient and inpatient pharmacies or have adequate internal controls over these substances at the outpatient pharmacy.

Pharmacies Were 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 a hospital's 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.

Santa Fe's clinical director told us that the outpatient and inpatient pharmacies did not have an alarm system to monitor Schedule II substances after pharmacy hours because he felt comfortable with the current level of physical security. He added that there had been no indication of a potential theft of controlled substances since he began working at the hospital 3 years earlier.

Although the clinical director could not recall an attempted intrusion into the pharmacies, Schedule II substances were vulnerable to theft after pharmacy hours, and an intrusion could go undetected until the following workday. The clinical director told us that, upon our recommendation, he would ensure that an alarm system was installed at both pharmacies.

Key Duties and Responsibilities Were Not Separated Among Pharmacists

Santa Fe granted one pharmacist, the outpatient pharmacy supervisor, a power of attorney to place all of Santa Fe's orders for Schedule II substances. However, this pharmacist, as well as the seven others at Santa Fe, could also accept delivery of Schedule II substances and record the receipt of those substances in the perpetual inventory records. These duties should be separated to mitigate the risk of fraud and mismanagement; specifically, the risk that a pharmacist who performs two or more key duties related to Schedule II substances (ordering, accepting delivery, and recording their receipt in inventory records) could pilfer a Schedule II substance.

Although no IHS, Santa Fe, 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."

ACCOUNTABILITY WEAKNESSES

Santa Fe did not appropriately account for its Schedule II substances at the outpatient pharmacy or at automated dispensing units in the outpatient department and inpatient ward.

Pharmacists Did Not Account for All Schedule II Substances on Monthly Inventory Reports

Santa Fe's "Pharmaceutical Services Policy and Procedure Manual," sections MM.2.20–2.40, requires a monthly physical inventory of all controlled substances on hand. According to the

"Indian Health Manual," section 3-7.3D(8b)(ii)(c), the Monthly Report for Narcotics and Other Controlled Substances ". . . must be completed monthly for all Schedule II-drugs . . . with a copy sent to the APO [area pharmacy officer] monthly."

Santa Fe's pharmacists did not account for all onhand Schedule II substances on the monthly inventory reports. According to the perpetual inventory records, the outpatient pharmacy received 200 (50 mg/ml) syringes of Demerol® and 1,300 (325/5 mg) tablets of Percodan® in February and June 2005, respectively, from the hospital's drug vendor. However, the pharmacists had not reported these Schedule II substances on the monthly inventory reports as of August 5, 2005.

A pharmacist told us that this was an oversight on the part of the pharmacists. The pharmacist added that the hospital had mistakenly ordered more Demerol® and Percodan® than was needed, resulting in an overstock of these substances. The overstock was stored separately from the rest of the Schedule II substances in a locked metal cabinet because of a storage space limitation and was inadvertently overlooked when the monthly inventory reports were prepared. We performed a physical inventory of the overstock and found that the amounts received in February and June were still on hand and matched the perpetual inventory records.

Although there was no indication that these substances were subject to loss or theft, lapses in accounting for all onhand Schedule II substances on the monthly inventory reports increase the risk of fraud and mismanagement. According to an IHS area pharmacy officer, these reports are used to monitor the amount of Schedule II substances procured and dispensed to help detect a diversion of narcotics.

Disposal of Wasted Schedule II Substances at Automated Dispensing Units Was Not Documented

Santa Fe's "Pharmaceutical Services Policy and Procedure Manual," section MM.5.10, states: "Whenever controlled substances are to be wasted . . . [the disposal] . . . must be [electronically] signed off by the nurse disposing the drug, and co-signed by a nurse, Pharmacist or Pharmacy technician [who witnessed the disposal]." The manual describes common causes of wastage, such as administering a partial dose of a controlled substance. For example, administering 2 milligrams of morphine to a patient from a 10-milligram syringe would require wasting and disposing of 8 milligrams.

Santa Fe medical staff did not consistently document the disposal of wasted Schedule II substances at two automated dispensing units, one in the outpatient department and one in the inpatient ward. Of the 16 controlled-drug usage records we reviewed for wastage (which pertained to 8 Schedule II substances), 8 records documented that the entire dosage amount had been administered to patients. The remaining eight records indicated that the disposal of a wasted portion was required. Of these eight records, three (38 percent) did not document the disposal of the wasted portion.

A nurse from the outpatient department and a nurse from the inpatient ward told us that they had not recorded the wastage because they were too busy or because staff was unavailable to witness

the disposals. Without this documented evidence, however, pharmacists could not provide assurance that medical staff had not pilfered Schedule II substances intended for disposal.

RECOMMENDATIONS

We recommend that IHS direct Santa Fe to enforce the following security and internal controls:

- At the outpatient and inpatient pharmacies, consider monitoring Schedule II substances with an alarm system after pharmacy hours.

- At the outpatient pharmacy, separate key duties and responsibilities related to Schedule II substances among pharmacists.

We further recommend that IHS direct Santa Fe to enforce the following accountability controls:

- At the outpatient pharmacy, ensure that pharmacists account for all onhand Schedule II substances on the monthly inventory reports.

- At the automated dispensing units in the outpatient department and inpatient ward, ensure that the disposal of wasted Schedule II substances is appropriately documented.

INDIAN HEALTH SERVICE'S COMMENTS

In its written comments on our draft report, IHS concurred with our findings and recommendations and stated that Santa Fe 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 Santa Fe Indian Hospital (A-06-06-00032)," issued January 25, 2007

The Indian Health Service (IHS) has reviewed the Office of Inspector General (OIG) draft audit report, "Safeguards Over Controlled Substances at Santa Fe Indian Hospital," and concurs with all OIG findings and recommendations to enforce all applicable security, internal, and accountability controls for Schedule II substances. The Santa Fe Indian Hospital (SFIH) 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: "At the outpatient and inpatient pharmacies, consider monitoring Schedule II substances with an alarm system after pharmacy hours."

IHS Response: Concur. The SFIH pharmacy ordered and received an electronic alarm system for the inpatient and outpatient pharmacy which is in the process of being installed. The pharmacy department has ordered a Cardinal Health Pyxis C-II Narcotic Safe (Pyxis C-II safe). Estimated delivery of the Pyxis C-II safe is within 60 days of this report. All Schedule II substances will be stored in this computerized Pyxis C-II safe. The Pyxis C-II safe will be physically located within the outpatient pharmacy. Once the Pyxis C-II safe is installed, controlled substances will no longer be stored in the inpatient pharmacy.

OIG Recommendation: "At the outpatient pharmacy, separate key duties and responsibilities related to Schedule II substances among pharmacists."

IHS Response: Concur. This process has been changed and pharmacy management is reorganized. There is now a primary narcotic officer assigned to overview the ordering of controlled substances. All full-time SFIH pharmacists have been granted Power of Attorney authority to order controlled substances, thereby ensuring the separation of responsibilities between Schedule II substance procurement and control. The pharmacist who places an order for controlled substance will not sign and accept the order or put the order into the locked pharmacy inventory. All items received will be recorded in a perpetual inventory log maintained by the pharmacy. With the addition of the Pyxis C-II safe, a computerized perpetual inventory of all controlled substances will be instantly and electronically available.

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OIG Recommendation: "At the outpatient pharmacy, ensure that pharmacists account for all on-hand Schedule II substances on the monthly inventory reports."

IHS Response: Concur. The SFIH pharmacy has ordered a Pyxis C-II safe to maintain a computerized inventory of all controlled substance transactions which involve the following: procurement of controlled substances, issue of controlled substances to Pyxis Med-stations located in General Medical Services, the Urgent Care Clinic, and the Recovery Room, prescriptions to individual patients, manufacturer drug recalls, return of expired drugs for destruction, and monthly narcotic audits. The SFIH pharmacy will complete a monthly audit report and supply a copy of this report to the Area Pharmacy Officer.

OIG Recommendation: "At the automated dispensing units in the outpatient department and inpatient ward, ensure that the disposal of wasted Schedule II substances is appropriately documented."

IHS Response: Concur. The SFIH pharmacy will provide training for providers and nursing staff that emphasizes the importance of proper documentation of wasted controlled substances. The SFIH pharmacy will then conduct monthly random waste audits, utilizing the electronic Pyxis Med-Station wasted substances report, to ensure compliance with the proper documentation of wasted controlled substances. The SFIH pharmacy, to the extent possible, will obtain Schedule II substances of multiple dosages to decrease the likelihood of wasted product. An example was cited in this audit report where two milligrams of morphine was administered from a ten milligram syringe without proper documentation of the eight milligrams of wasted morphine. The pharmacy now stocks two milligram morphine syringes, in addition to the ten milligram syringes, to decrease waste and potential diversion.

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.

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