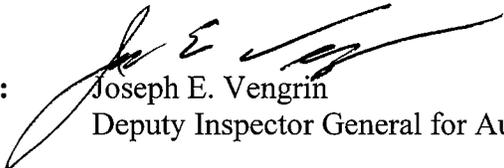




MAY 10 2007

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 W.W. Hastings Indian Hospital
(A-06-07-00048)

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

Hastings complied with applicable requirements to secure and account for its Schedule II substances. However, Hastings did not have adequate internal controls over its Schedule II substances because key duties and responsibilities for these substances were not separated among pharmacists at the inpatient pharmacy as the Office of Management and Budget generally requires. This deficiency occurred because Hastings officials did not have applicable policies and procedures. As a result, Schedule II substances at Hastings were vulnerable to theft and mismanagement.

We recommend that IHS direct Hastings to establish and enforce written policies and procedures that separate key duties and responsibilities related to Schedule II substances among pharmacists.

In its written comments on our draft report, IHS concurred with our findings and recommendation and stated that Hastings had implemented, or was currently implementing, the recommended corrective action.

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-06-07-00048.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SAFEGUARDS OVER
CONTROLLED SUBSTANCES AT
W.W. HASTINGS
INDIAN HOSPITAL**



Daniel R. Levinson
Inspector General

May 2007
A-06-07-00048

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 W.W. Hastings Indian Hospital (Hastings) in Tahlequah, Oklahoma. Hastings is one of 83 IHS-operated hospitals and health centers.

OBJECTIVE

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

SUMMARY OF FINDINGS

Hastings complied with applicable requirements to secure and account for its Schedule II substances. However, Hastings did not have adequate internal controls over its Schedule II substances because key duties and responsibilities for these substances were not separated among pharmacists at the inpatient pharmacy as the Office of Management and Budget generally requires. This deficiency occurred because Hastings officials did not have applicable policies and procedures. As a result, Schedule II substances at Hastings were vulnerable to theft and mismanagement.

RECOMMENDATION

We recommend that IHS direct Hastings to establish and enforce written policies and procedures that separate key duties and responsibilities related to Schedule II substances among pharmacists.

INDIAN HEALTH SERVICE'S COMMENTS

In its written comments on our draft report, IHS concurred with our findings and recommendation and stated that Hastings had implemented, or was currently implementing, the recommended corrective action. 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.

W.W. Hastings Indian Hospital

This report addresses safeguards over Schedule II substances at W.W. Hastings Indian Hospital (Hastings) in Tahlequah, Oklahoma. Hastings is one of 83 IHS-operated hospitals and health centers. It is part of the Tahlequah service unit, which is under the jurisdiction of the Oklahoma City area office of IHS. Hastings's pharmacies have a staff of 16 pharmacists, 11 pharmacy technicians, 3 pharmacy aides, and 2 administrative personnel. The chief pharmacist is responsible for procuring, securing, storing, dispensing, and accounting for Schedule II substances in the pharmacies. Hastings's service unit director is responsible for the overall safeguarding and handling of these substances.

Hastings stores its Schedule II substances in the following areas:

- a storage closet and a locked cabinet in the inpatient pharmacy;
- a storage closet and a locked cabinet in the outpatient pharmacy;
- a locked cabinet in the satellite pharmacy, which is a smaller outpatient pharmacy at Hastings;

- 11 automated dispensing units, 1 each in the four operating rooms, intensive care unit, emergency room, and recovery ward and 2 each in the medical/surgical unit and the maternity ward;
- a wall lockbox in the dental clinic; and
- a wall lockbox in the outpatient surgery clinic.

Hastings stores most of its Schedule II substances in the inpatient and outpatient pharmacies.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Hastings 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 12 of the 24 Schedule II substances that the pharmacies stored and dispensed from January 2004 through April 2005. According to monthly inventory reports and automated dispensing unit transaction reports, the 12 substances were the most frequently stored or dispensed Schedule II substances. In addition to being 1 of the 12 most frequently stored or 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 Hastings's internal controls to those related to securing and accounting for Schedule II substances.

We performed our fieldwork of Hastings from February through May 2005.

Methodology

To perform our audit, we:

- reviewed applicable Federal, IHS, and Hastings requirements;
- evaluated Hastings's controls over the safeguarding and recordkeeping of its Schedule II substances at the inpatient pharmacy, outpatient pharmacy, satellite pharmacy, automated dispensing units, dental clinic, and outpatient surgery clinic;
- interviewed Hastings pharmacy and medical staff;

- performed a physical count of the 12 selected Schedule II substances and compared this count with the most recent monthly Schedule II inventory reports and perpetual inventory records to verify onhand amounts;
- analyzed order forms, vendor invoices, and perpetual inventory records to verify that Schedule II substances were received in the quantity ordered and recorded as inventory;
- compared perpetual inventory records from the inpatient and outpatient pharmacies with perpetual inventory records at other storage locations to determine whether 8 of the 12 selected Schedule II substances were accurately transferred from the inpatient and outpatient pharmacies to other storage locations;
- reviewed prescription forms, perpetual inventory records, and medical charts for the 12 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 pharmacies' inventories;
- reviewed controlled-drug usage records and automated dispensing unit transaction reports for 5 of the 12 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 Hastings and area office officials.

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

FINDINGS AND RECOMMENDATION

Hastings complied with applicable requirements to secure and account for its Schedule II substances. However, Hastings did not have adequate internal controls over its Schedule II substances because key duties and responsibilities for these substances were not separated among pharmacists at the inpatient pharmacy as the Office of Management and Budget generally requires. This deficiency occurred because Hastings officials did not have applicable policies and procedures. As a result, Schedule II substances at Hastings were vulnerable to theft and mismanagement.

EFFECTIVE SECURITY AND ACCOUNTABILITY CONTROLS

Hastings routinely secured and accounted for the Schedule II substances in our review in accordance with Federal regulations and the "Indian Health Manual." Hastings had adequate storage facilities and monitoring controls in place to secure the Schedule II substances in our review. Our review of the alarm systems, key and combination lock mechanisms, and other physical security controls found that Hastings appropriately monitored and secured its Schedule II substances.

Hastings also appropriately accounted for the Schedule II substances in our review. Inventory records, invoices, and other documentation for our review period showed that Hastings appropriately ordered, inventoried, administered, and dispensed its Schedule II substances.

INTERNAL CONTROL WEAKNESS

Hastings did not have adequate internal controls over its Schedule II substances at the inpatient pharmacy. The assistant chief pharmacist for the inpatient pharmacy was the only person authorized to order Schedule II substances for Hastings. However, Hastings did not separate the duties of accepting delivery of these substances and recording their receipt in the perpetual inventory records. Pharmacy records showed that on two of the five occasions that we reviewed, the assistant chief pharmacist accepted delivery of Schedule II substances and recorded their receipt in the 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, Hastings, or other Federal policy specifically mandates separating 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.”

RECOMMENDATION

We recommend that IHS direct Hastings to establish and enforce written policies and procedures that separate key duties and responsibilities related to Schedule II substances among pharmacists.

INDIAN HEALTH SERVICE’S COMMENTS

In its written comments on our draft report, IHS concurred with our findings and recommendation and stated that Hastings had implemented, or was currently implementing, the recommended corrective action. 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 W.W. Hastings Indian Hospital (A-06-07-00048)," 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 W.W. Hastings Indian Hospital," and concurs with the OIG finding and recommendation to implement and enforce applicable internal controls for Schedule II controlled substances. The Oklahoma City Area IHS will issue a directive to enforce adherence to internal controls only if deemed necessary, because the W.W. Hastings Indian Hospital has implemented, or is currently implementing, the OIG recommended corrective action. The following response to the OIG recommendation includes the corrective action implemented:

OIG Recommendation: "We recommend that IHS direct Hastings to establish and enforce written policies and procedures that separate key duties and responsibilities related to Schedule II substances among pharmacists."

IHS Response: Concur. The W.W. Hastings Indian Hospital pharmacy has implemented a new policy that ensures separation of responsibilities for Schedule II controlled substance procurement and control. Currently, authorized personnel are not allowed to order and receive the same shipment of Schedule II controlled substances. The Area Pharmacy Consultant has added this policy for review to their annual inspection requirements. Also, the Chief Pharmacist, or his or her designee, performs a monthly audit of all Schedule II controlled substances and the Area Pharmacy Consultant conducts an annual audit of all Schedule II controlled substances. The Area Pharmacy Consultant provided training and instruction to the Chief Pharmacist concerning the separation of key duties and responsibilities related to Schedule II 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, D.D.S., M.H.S.A.
Assistant Surgeon General