DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

DEC - 5 2006

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

FROM: Daniel R. Levinson
Inspector General

SUBJECT: Safeguards Over Controlled Substances at Lawton Indian Hospital (A-06-06-00035)

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

Lawton did not always comply with applicable requirements to secure and account for its Schedule II substances. Specifically, Lawton did not appropriately secure or have adequate internal controls over its Schedule II substances at the main pharmacy or at an automated dispensing unit in the emergency room. Lawton also did not appropriately account for its Schedule II substances at the dental clinic, main pharmacy, or automated dispensing units in the emergency room and surgical ward. As a result, Schedule II substances at Lawton were vulnerable to theft and mismanagement, as evidenced by a dentist's admission that she had pilfered a Schedule II substance from the dental clinic.

We recommend that IHS direct Lawton 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 Lawton 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) 619-1166 or through e-mail at Joe.Green@oig.hhs.gov. Please refer to report number A-06-06-00035.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

SAFEGUARDS OVER CONTROLLED SUBSTANCES AT LAWTON INDIAN HOSPITAL

Daniel R. Levinson
Inspector General

December 2006
A-06-06-00035

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

OBJECTIVE

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

SUMMARY OF FINDINGS

Lawton did not always comply with applicable requirements to secure and account for its Schedule II substances. Lawton did not appropriately secure or have adequate internal controls over its Schedule II substances at all locations. Specifically:

- At the main pharmacy, (1) the safe used to store Schedule II substances was not always locked during pharmacy hours as Federal regulations and IHS policy require, (2) an alarm system was not used to monitor Schedule II substances after pharmacy hours as Federal regulations recommend, and (3) key duties and responsibilities for Schedule II substances were not separated among pharmacists as the Office of Management and Budget generally requires.

- At an automated dispensing unit in the emergency room, contrary to Lawton policy, physicians shared their identification codes and passwords with nurses who could have used this information to access Schedule II substances.

Lawton also did not appropriately account for its Schedule II substances at all locations. Specifically:

- At the dental clinic, contrary to Lawton policy, monthly pharmacy audits did not include random checks against medical records to ensure that Schedule II substances had been administered to patients.

- At the main pharmacy, contrary to IHS policy, the chief pharmacist did not submit to the area pharmacy officer monthly inventory reports on Schedule II substances for reporting periods from February through December 2004. The area pharmacy officer told us that Lawton had submitted these required reports since the reporting period beginning January 2005.

- At the automated dispensing units in the emergency room and surgical ward, contrary to Lawton policy, medical staff did not consistently document the disposal of wasted Schedule II substances.

These deficiencies occurred because Lawton officials did not enforce applicable policies and procedures. As a result, Schedule II substances at Lawton were vulnerable to theft and mismanagement, as evidenced by a dentist's admission that she had pilfered a Schedule II substance from the dental clinic.

RECOMMENDATIONS

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

- At the main pharmacy, (1) store Schedule II substances in a locked safe during pharmacy hours, (2) consider monitoring Schedule II substances with an alarm system after pharmacy hours, and (3) separate key duties and responsibilities related to Schedule II substances among pharmacists.

- At the emergency room's automated dispensing unit, ensure that medical staff do not share identification codes and passwords.

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

- At the dental clinic, perform random checks of controlled-drug inventories against medical records each month to ensure that Schedule II substances are administered to patients.

- At the main pharmacy, continue to submit monthly Schedule II inventory reports to the area pharmacy officer.

- At the automated dispensing units in the emergency room and surgical 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 Lawton had implemented, or was currently implementing, all recommended corrective actions. The complete text of IHS's comments is 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.

Lawton Indian Hospital

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

Lawton stores its Schedule II substances in the following areas:

1. a safe in the main pharmacy;

2. a safe in the satellite pharmacy, which is a smaller pharmacy at Lawton;

3. three automated dispensing units, one each in the emergency room, surgical ward, and maternity ward;

4. two safes in the dental clinic;

5. two tray carts in the operating rooms; and

6. a wall lockbox in the recovery room.

Lawton stores most of its Schedule II substances in the main pharmacy.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Lawton 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 8 of the 24 Schedule II substances that the main pharmacy stored and dispensed from January 2004 through February 2005. According to monthly inventory reports, the eight substances were the most frequently stored or dispensed Schedule II substances. We limited our review of Lawton's internal controls to those related to securing and accounting for Schedule II substances.

We performed our fieldwork of Lawton from December 2004 through February 2005.

Methodology

To perform our audit, we:

- reviewed applicable Federal requirements and Lawton policies;

- evaluated Lawton's controls over the safeguarding and recordkeeping of its Schedule II substances at the following locations: main pharmacy, satellite pharmacy, automated dispensing units, dental clinic, operating room, and recovery room;

- interviewed Lawton management and pharmacy and medical staff;

- analyzed order forms, vendor invoices, perpetual inventory logs, and monthly inventory reports to determine whether three of the eight selected Schedule II substances were recorded in the perpetual inventory logs or matched quantity-on-hand amounts at the main pharmacy (the only location that received shipments of controlled substances from Lawton's drug vendor);

- compared the main pharmacy's perpetual inventory logs with inventory logs at other storage locations to determine whether the logs accurately reflected the transfers of three

of the eight selected Schedule II substances from the main pharmacy to other storage locations;

- reviewed prescription forms, perpetual inventory logs, patient signature logs, and medical charts for all eight 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 four of the eight 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 administered or dispensed; and

- discussed our findings and recommendations with Lawton and area office officials.

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

FINDINGS AND RECOMMENDATIONS

Lawton did not always comply with applicable requirements to secure and account for its Schedule II substances. Lawton did not appropriately secure or have adequate internal controls over its Schedule II substances at all locations. Specifically:

- At the main pharmacy, (1) the safe used to store Schedule II substances was not always locked during pharmacy hours as Federal regulations and IHS policy require, (2) an alarm system was not used to monitor Schedule II substances after pharmacy hours as Federal regulations recommend, and (3) key duties and responsibilities for Schedule II substances were not separated among pharmacists as the Office of Management and Budget generally requires.

- At an automated dispensing unit in the emergency room, contrary to Lawton policy, physicians shared their identification codes and passwords with nurses who could have used this information to access Schedule II substances.

Lawton also did not appropriately account for its Schedule II substances at all locations. Specifically:

- At the dental clinic, contrary to Lawton policy, monthly pharmacy audits did not include random checks against medical records to ensure that Schedule II substances had been administered to patients.

- At the main pharmacy, contrary to IHS policy, the chief pharmacist did not submit to the area pharmacy officer monthly inventory reports on Schedule II substances for reporting periods from February through December 2004. The area pharmacy officer told us that

Lawton had submitted these required reports since the reporting period beginning January 2005.

- At the automated dispensing units in the emergency room and surgical ward, contrary to Lawton policy, medical staff did not consistently document the disposal of wasted Schedule II substances.

These deficiencies occurred because Lawton officials did not enforce applicable policies and procedures. As a result, Schedule II substances at Lawton were vulnerable to theft and mismanagement, as evidenced by a dentist's admission that she had pilfered a Schedule II substance from the dental clinic.

SECURITY AND INTERNAL CONTROL WEAKNESSES

Lawton did not appropriately secure its Schedule II substances at the main pharmacy or at an automated dispensing unit in the emergency room or have adequate internal controls over the substances at the main pharmacy.

Main Pharmacy Did Not Secure or Have Adequate Internal Controls Over Its Schedule II Substances

At the main pharmacy, (1) the safe used to store Schedule II substances was not always locked during pharmacy hours, (2) an alarm system was not used to monitor Schedule II substances after pharmacy hours as Federal regulations recommend, and (3) key duties and responsibilities for Schedule II substances were not separated among pharmacists.

Safe Was Not Always Locked During Pharmacy Hours

Federal regulations (21 CFR § 1301.75) require that controlled substances listed in Schedule II be ". . . stored in a securely locked, substantially constructed cabinet." Consistent with this rule, 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."

Lawton's chief pharmacist told us that the safe used to store Schedule II substances was not always locked during pharmacy hours because pharmacists required frequent access to its contents. According to the chief pharmacist, the contents of the safe were secure because it was always within sight of a pharmacist and because the doors leading into the main pharmacy were locked.

However, on four occasions when we interviewed pharmacists at the main pharmacy, we opened a door to the pharmacy that was supposed to be locked. This door led to a small office that held the safe containing Schedule II substances. On two of these four occasions, we opened the door to the safe, which was supposed to be locked, and could have accessed its contents without detection because pharmacy employees were not in the office. The substances in the safe were

also vulnerable to theft by technicians who worked in the main pharmacy but were not authorized to access the safe.

Main 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 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.

Lawton's chief pharmacist told us that an alarm system did not monitor the main pharmacy after pharmacy hours. He added, and the area pharmacy officer confirmed, that the main pharmacy was wired for an alarm but that the alarm had not been activated for years because it needed repair. As a result, Schedule II substances were vulnerable to theft after pharmacy hours, and intrusion into the main pharmacy could go undetected until the following workday. Because most of Lawton's Schedule II substances are stored in the main pharmacy, an alarm system would significantly strengthen security over these substances.

Key Duties and Responsibilities Were Not Separated Among Pharmacists

Lawton senior pharmacists told us that three senior pharmacists at the main pharmacy 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.

One senior pharmacist told us that it was convenient for the pharmacist who placed the order to account for the Schedule II substances upon delivery because the ordering pharmacist knew which controlled substances were expected. However, these duties should be separated to mitigate the risk of fraud and mismanagement; specifically, the risk that a pharmacist with authority to order a substance, accept delivery, and record its receipt in inventory records could pilfer a Schedule II substance. Although no IHS, Lawton, 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."

Automated Dispensing Unit Identification Codes and Passwords Were Shared

A Lawton document entitled "Hospital Wide Policy," section 1A, requires medical staff to ". . . protect their ID [identification] code and password and to not share them with any other individual." The chief pharmacist drafted this policy in 2004. Although the policy remained in draft form during the review period, the chief pharmacist told us that he had implemented the policy under his authority as chief of Lawton's pharmacies pending the policy's final approval by Lawton management.

A Lawton nurse told us that doctors had shared their identification codes and passwords with nurses because doctors could not retrieve substances from the automated dispensing unit in the emergency room as quickly as nurses. The chief pharmacist told us that he had suspected that users were sharing identification codes and passwords prior to our review and that he had emphasized to all medical personnel that they were not to do so. Because doctors shared their identification codes and passwords, the nurses could have used this information to access the Schedule II substances stored in the automated dispensing unit. These substances were thus vulnerable to theft.

ACCOUNTABILITY WEAKNESSES

Lawton did not appropriately account for its Schedule II substances at the dental clinic, main pharmacy, or automated dispensing units in the emergency room and surgical ward.

Dental Clinic Audits of Controlled-Drug Inventories Did Not Include Random Checks Against Medical Records

Lawton pharmacy policy number 35 states: "Controlled drug inventories are audited each month . . . ." As part of this audit process, "A random check of administration records (patient charts) will be done to insure that all drugs signed out on the CDUR [controlled-drug usage record] were ordered and administered, and that all records agree." Although pharmacists audited controlled-drug inventories each month, the chief pharmacist told us that the dental clinic audits did not include random checks against medical records as required. He conceded that this was an oversight on the part of the pharmacy.

This oversight likely contributed to a security environment that permitted pilfering by one of Lawton's staff members. In this regard, we identified a dentist who had pilfered Schedule II substances from the dental clinic. According to a controlled-drug usage record, the dentist administered Demerol®, a Schedule II substance, to a patient on October 1, 2004. Our examination of medical records, however, showed that the patient had canceled the dental appointment for that date and had not received the drug. We asked to meet with the dentist about this discrepancy, but she was unavailable. The chief pharmacist told us later that the dentist had met with Lawton management and admitted that she had pilfered Demerol® from the dental clinic for her personal use. We then referred the matter to our Office of Investigations (OI).

OI interviewed several Lawton medical personnel about the theft and requested the total amount of Demerol® pilfered. OI also met with the U.S. Attorney's Office to discuss the matter. According to the U.S. Attorney's Office, the dentist pled guilty to unlawful possession of 9,100 milligrams of Demerol® taken from the dental clinic from about August 2002 through January 2005. She admitted to covering up the theft by falsifying records to show that Demerol® had been administered to patients. The dentist no longer works at Lawton.

Main Pharmacy's Schedule II Inventory Reports Were Not Submitted to the Area Pharmacy Officer

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." The area pharmacy officer stated that he did not have the Lawton main pharmacy's reports on file for reporting periods from February through December 2004.

The chief pharmacist told us that the former area pharmacy officer, in charge until late 2004, had told him to stop submitting these reports because they were "just filed away." However, the current area pharmacy officer told us that these reports were needed to monitor the amount of Schedule II substances procured and dispensed to help detect a diversion of narcotics. He added that Lawton had submitted these required reports since the reporting period beginning January 2005.

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

Lawton pharmacy policy number 35 states: "When a controlled drug is wasted . . . the nurse or individual who wastes . . . the controlled drug must enter this information on the CDUR, sign his/her name, list the amount wasted, and have a witness (nurse, physician, or pharmacist) countersign the entry." Wastage is necessary when medical staff administer partial doses of Schedule II substances to patients. For example, administering 2 milligrams of morphine to a patient from a 10-milligram syringe would require wasting and disposing of 8 milligrams.

Lawton medical staff did not consistently document the disposal of wasted Schedule II substances at two automated dispensing units. Of the 75 controlled-drug usage records we reviewed, 30 records documented that the entire dosage amount had been administered to patients. The remaining 45 records, which were from the automated dispensing units in the emergency room and surgical ward, indicated that the disposal of a wasted portion was required. Of these 45 records, 9 (20 percent) did not contain documentation of the disposal of the wasted portion.

A nurse from the emergency room and a nurse from the surgical ward told us that they had not recorded the wastage because they were "too busy" when the disposals occurred. 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 Lawton to enforce the following security and internal controls:

- At the main pharmacy, (1) store Schedule II substances in a locked safe during pharmacy hours, (2) consider monitoring Schedule II substances with an alarm system after pharmacy hours, and (3) separate key duties and responsibilities related to Schedule II substances among pharmacists.

- At the emergency room's automated dispensing unit, ensure that medical staff do not share identification codes and passwords.

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

- At the dental clinic, perform random checks of controlled-drug inventories against medical records each month to ensure that Schedule II substances are administered to patients.

- At the main pharmacy, continue to submit monthly Schedule II inventory reports to the area pharmacy officer.

- At the automated dispensing units in the emergency room and surgical 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 Lawton had implemented, or was currently implementing, all recommended corrective actions. IHS provided detailed explanations of these corrective actions. The complete text of IHS's comments is included as the Appendix.

APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Indian Health Service
Rockville MD 20852

OCT 12 2006

TO: Inspector General

FROM: Director

SUBJECT: Response to Draft Office of Inspector General Report, "Safeguards Over Controlled Substances at Lawton Indian Hospital (A-06-06-00035)," issued August 22, 2006

The Indian Health Service (IHS) has reviewed the Office of Inspector General (OIG) draft audit report, "Safeguards Over Controlled Substances at Lawton Indian Hospital," and concurs with all OIG findings and recommendations to enforce all applicable security, internal, and accountability controls for Schedule II substances. An appropriate directive from our Oklahoma City Area IHS will be issued to enforce adherence to identified security and internal controls only if deemed necessary, because the Lawton Indian Hospital (Lawton) 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 main pharmacy: (1) store Schedule II substances in a locked safe during pharmacy hours, (2) consider monitoring Schedule II substances with an alarm system after pharmacy hours, and (3) separate key duties and responsibilities related to Schedule II substances among pharmacists."

IHS Response: Concur. (1) The Lawton pharmacy has replaced their safe with a dedicated, walk-in narcotic vault which has an automatic closing door and a punch-lock system. This type of controlled drug vault has been recommended by the Oklahoma City Area Pharmacy Consultant (OCAPC) for all new and renovated facilities. The Lawton policy and procedures for the pharmacy department have been revised to reflect this requirement that is now strictly enforced for all Schedule II controlled substances.

(2) The OCAPC reviews all Area pharmacies on an annual basis to determine if an alarm system is essential to properly monitor Schedule II substances after pharmacy hours. An alarm system is scheduled for installation in FY 2007 at the new Lawton pharmacy, which is currently under construction. The alarm system will include door, window, and motion sensors in all pharmaceutical drug storage areas.

(3) The Lawton pharmacy was provided in-service training on the separation of duties during the OCAPC's annual controlled substances review, and was instructed to separate the key duties of ordering and receiving narcotics. The Lawton pharmacy has since implemented a system in which two pharmacists are responsible for placing orders of Schedule II substances, and the receipt or check-in of those orders. The Policy and Procedures Manual for the Lawton pharmacy

has been revised to reflect this change, and includes the requirement for a monthly inventory audit by the Chief Pharmacist as an additional internal control.

OIG Recommendation: "At the emergency room's automated dispensing unit, ensure that medical staff do not share identification codes and passwords."

IHS Response: Concur. All Lawton medical and nursing personnel have recently had in-service training on the necessity of maintaining security of identification (ID) codes. The responsibility for issuing ID codes has been assigned to a single pharmacist who is also responsible for periodically changing access and security codes. In addition, overall responsibility for this function has been added to the performance standards of the OCAPC. The OCAPC will monitor this activity and ensure that disciplinary action is taken when employees share automated dispensing cabinet security codes or otherwise compromise their ID codes.

OIG Recommendation: "At the dental clinic, perform random checks of controlled-drug inventories against medical records each month to ensure that Schedule II substances are administered to patients."

IHS Response: Concur. The Lawton pharmacy program has added end-user audits to both inpatient and outpatient areas that include a review of pharmacy records, patient charts, and patient interviews. The audit includes the dental clinic where controlled substances are audited on a monthly basis using random sampling of patients that have received a controlled substance. The Lawton pharmacy department has revised their Policy and Procedures Manual to reflect these changes for monitoring controlled substances. The OCAPC will review and ensure compliance with the revised policy and procedures in the 2007 annual controlled substances audit.

OIG Recommendation: "At the main pharmacy, continue to submit monthly Schedule II inventory reports to the area pharmacy officer."

IHS Response: Concur. The OCAPC has provided in-service training to all Oklahoma City Area Chief Pharmacists of the requirement to perform a complete annual controlled substances inventory and the requirement to submit monthly Schedule II inventory reports. All Oklahoma City Area IHS facilities have submitted monthly reports since January 2005, including Lawton which has complied with this requirement since its establishment. This activity is monitored by the OCAPC who performs a monthly file review to ensure submission of all monthly inventories of schedule II controlled substances by each facility Chief Pharmacist.

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

IHS Response: Concur. This activity is now covered in the monthly pharmacy inspection and audit performed at Lawton. The Omnicell automated dispensing unit's record for issuances of

Schedule II controlled substances is used to select a random sampling of patient records that represent a complete cross section of all staff providing patient care. The information contained in the Omnicell Administration Record is compared to the Medication Administration Record (including progress notes, flow sheets, op-notes, anesthesia records, and ER records) of the patient to determine if he or she was actually administered the prescribed medication procured from the Omnicell automated dispensing unit. The Lawton pharmacy department has revised their Policy and Procedures Manual to reflect these changes for documenting and monitoring wastages of controlled substances. The OCAPC will review and ensure compliance with the revised policy and procedures in the 2007 annual controlled substances audit and maintain the appropriate records at the Oklahoma City Area IHS.

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

Charles W. Grim, DDS

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