SEP 25 2008

TO: Elias A. Zerhouni, M.D.
Director
National Institutes of Health

FROM: Daniel R. Levinson Daniel R. Levinson
Inspector General

SUBJECT: Safeguards Over Controlled Substances at the National Institutes of Health Clinical Center Pharmacy for the Period May 2006 to June 2007 (A-03-07-00353)

The attached final report provides the results of our review of safeguards over controlled substances at the National Institutes of Health (NIH) Clinical Center Pharmacy for the period May 2006 to June 2007.

The NIH Clinical Center in Bethesda, Maryland, provides clinical care to inpatients and outpatients participating in intramural research protocols. The Clinical Center Pharmacy (the Pharmacy) provides pharmaceutical care to these patients. The Pharmacy procures and dispenses certain addictive drugs, the possession and use of which are regulated under the Controlled Substances Act (the Act) of 1970, as amended, and implementing regulations. The Act classifies these drugs as controlled substances and divides them among five schedules based on their medical use and potential for abuse. Consistent with the requirements of the Act, the Pharmacy must securely store controlled substances and maintain complete and accurate inventory records of all transactions involving controlled substances. 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 the Pharmacy complied with applicable requirements to secure and account for its Schedule II substances.

The Pharmacy generally complied with applicable requirements to account for its Schedule II substances. However, the Pharmacy did not always appropriately secure or have adequate internal controls over the substances.

- The Pharmacy stored Schedule II substances in an unlocked storage cabinet and in an unlocked lockbox located in a refrigerator with no lock.

- The Pharmacy did not always segregate duties and responsibilities for ordering and receiving shipments of Schedule II substances among pharmacists.

These deficiencies occurred because Pharmacy officials did not comply with Federal requirements or Clinical Center procedures for securing Schedule II substances and were unaware of the requirement to segregate duties. As a result, Schedule II substances were vulnerable to loss, diversion, and mismanagement. We discussed our findings with the chief of the pharmaceutical procurement and control section, who concurred and immediately implemented corrective actions.

We recommend that NIH ensure that the Pharmacy continues to enforce its policies and procedures to secure and control Schedule II substances.

In its comments on our draft report, NIH concurred with our recommendation.

Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, this report will be posted on the Internet at http://oig.hhs.gov.

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 Lori S. Pilcher, Assistant Inspector General for Grants, Internal Activities, and Information Technology Audits, at (202) 619-1175 or through e-mail at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-03-07-00353 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

SAFEGUARDS OVER CONTROLLED SUBSTANCES AT THE NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER PHARMACY FOR THE PERIOD MAY 2006 TO JUNE 2007

Daniel R. Levinson
Inspector General

September 2008
A-03-07-00353

Office of Inspector General

http://oig.hhs.gov

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Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5).

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

The National Institutes of Health (NIH), an agency within the U.S. Department of Health and Human Services, conducts and supports medical research. As part of its research function, NIH provides clinical care to inpatients and outpatients participating in intramural research protocols at its Clinical Center in Bethesda, Maryland. The Clinical Center Pharmacy (the Pharmacy) provides pharmaceutical care to these patients. The Pharmacy procures and dispenses certain addictive drugs, the possession and use of which are regulated under the Controlled Substances Act (the Act) of 1970, as amended (21 U.S.C §§ 801 et seq.), and implementing regulations (21 CFR pts. 1300–1316). The Act classifies these drugs as controlled substances and divides them among five schedules based on their medical use and potential for abuse.

The Drug Enforcement Administration (DEA) is the primary Federal agency responsible for enforcing the Act. Consistent with the requirements of the Act, the Pharmacy is required to register with DEA. All DEA registrants must securely store controlled substances and maintain complete and accurate inventory records of all transactions involving controlled substances in accordance with the Act.

This report addresses the Pharmacy's safeguards over Schedule II controlled substances (Schedule II substances) for the period May 2006 to June 2007. We focused on Schedule II substances because they have the highest potential for abuse among controlled substances with an accepted medical use.

OBJECTIVE

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

SUMMARY OF FINDINGS

The Pharmacy generally complied with applicable requirements to account for its Schedule II substances. Invoices, inventory records, and other documents showed that the Pharmacy appropriately ordered and inventoried the substances and maintained appropriate documentation of their administration and dispensing. However, the Pharmacy did not always appropriately secure or have adequate internal controls over its Schedule II substances.

- The Pharmacy stored Schedule II substances in an unlocked storage cabinet and in an unlocked lockbox located in a refrigerator with no lock, both located in the Pharmacy dispensing unit.

- The Pharmacy did not always segregate duties and responsibilities for ordering and receiving shipments of Schedule II substances among pharmaceutical procurement and control section pharmacists.

These deficiencies occurred because Pharmacy officials did not comply with Federal requirements or Clinical Center procedures for securing Schedule II substances and were unaware of the requirement to segregate duties. As a result, Schedule II substances were vulnerable to loss, diversion, and mismanagement.

We discussed our findings with the chief of the pharmaceutical procurement and control section, who concurred and immediately implemented corrective actions.

RECOMMENDATION

We recommend that NIH ensure that the Pharmacy continues to enforce its policies and procedures to secure and control Schedule II substances.

NATIONAL INSTITUTES OF HEALTH COMMENTS

In its comments on our draft report, NIH concurred with our recommendation. NIH's comments, except for technical comments, are included as the Appendix.

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INTRODUCTION

BACKGROUND

National Institutes of Health

The National Institutes of Health (NIH), an agency within the U.S. Department of Health and Human Services, conducts and supports medical research. As part of its research function, NIH provides clinical care to inpatients and outpatients participating in intramural research protocols at its Clinical Center in Bethesda, Maryland. The Clinical Center Pharmacy (the Pharmacy) provides pharmaceutical care to these patients. The Pharmacy procures and dispenses certain addictive drugs, the possession and use of which are regulated under the Controlled Substances Act (the Act) of 1970, as amended (21 U.S.C §§ 801 et seq.), and implementing regulations (21 CFR pts. 1300–1316).

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 (21 U.S.C. § 812). 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 OxyContin®, Duragesic®, Roxicodone®, and Dilaudid®.

The Drug Enforcement Administration (DEA) is the primary Federal agency responsible for enforcing the Act (21 CFR § 1300.01(b)(3)). Consistent with the requirements of the Act, the Pharmacy is required to register with DEA (21 U.S.C § 823(b) and 21 CFR § 1301.11). All DEA registrants must securely store controlled substances and maintain complete and accurate inventory records of all transactions involving controlled substances in accordance with the Act (21 CFR §§ 1301.71 and 1304.11).

Clinical Center Pharmacy

This report addresses safeguards over Schedule II substances at the Pharmacy, where a total of 45 pharmacists are authorized to access Schedule II substances and fill patient prescriptions. The chief of the pharmaceutical procurement and control section (the control section) has primary responsibility for securing and accounting for the Pharmacy's Schedule II substances.

Upon their arrival, Schedule II substances are transported from NIH's delivery dock to the control section. This section counts and inventories the substances and stores them in a vault until transfer to the Pharmacy dispensing unit. After transfer, the dispensing unit stores its Schedule II substances in a medications vault and in Pyxis Medstations (Medstations), which are automated, secured, medication-dispensing machines located throughout the inpatient and outpatient clinical care units. The dispensing unit also stores outpatient clinic Schedule II

prescriptions awaiting patient pickup in a storage cabinet and intravenous solution bags prepared with Schedule II substances in a refrigerator.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the Pharmacy 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 4 of the 103 Schedule II substances that the Pharmacy purchased, stored, or dispensed from May 1, 2006, through June 4, 2007. According to the Pharmacy's procurement summary record for our audit period, the four Schedule II substances represented 198,420 unit doses, or 39 percent of the 508,161 total unit doses purchased during the period.

We limited our review of the Pharmacy's internal controls to those related to securing and accounting for Schedule II substances.

We performed our fieldwork at the Pharmacy and the inpatient and outpatient clinical care units at the Clinical Center in Bethesda, Maryland.

Methodology

To meet our objective, we:

- reviewed applicable Federal regulations and Clinical Center policies and procedures for securing and accounting for Schedule II substances;[1]

- toured the Pharmacy and inpatient and outpatient clinical care units and observed Medstations and other storage containers to determine whether Schedule II substances were properly secured;

- interviewed employees responsible for picking up and disposing of medical pathological waste containers to determine how the Pharmacy handled waste from Schedule II substances;

- analyzed discrepancy reports, diversion reports, and waste reports for Medstations in the Pharmacy and clinical care units;

[1]The Federal Government has exclusive jurisdiction over the NIH campus; therefore, Maryland law regarding the registration and handling of controlled substances does not apply.

- obtained the Pharmacy's procurement summary record for all Schedule II substances procured from May 1, 2006, through June 4, 2007;

- judgmentally selected 4 of the 103 Schedule II substances that the Pharmacy purchased, stored, or dispensed during our audit period and observed and documented for 1 day:

    - the transfer of the substances from the NIH loading dock to the control section;

    - the check-in of the substances at the control section, which counted and inventoried the items and stored them in the vault; and

    - the transfer of the substances to the Pharmacy dispensing unit and to the Medstations in the inpatient and outpatient clinical care units;

- observed and documented how the Pharmacy returned outdated/expired Schedule II substances to the original distributor; and

- interviewed the chief of the control section and discussed our findings and recommendation with Pharmacy officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATION

The Pharmacy generally complied with applicable requirements to account for its Schedule II substances. Invoices, inventory records, and other documents showed that the Pharmacy appropriately ordered and inventoried the substances and maintained appropriate documentation of their administration and dispensing. However, the Pharmacy did not always appropriately secure or have adequate internal controls over its Schedule II substances.

- The Pharmacy stored Schedule II substances in an unlocked storage cabinet and in an unlocked lockbox located in a refrigerator with no lock, both located in the Pharmacy dispensing unit.

- The Pharmacy did not always segregate duties and responsibilities for ordering and receiving shipments of Schedule II substances among control section pharmacists.

These deficiencies occurred because Pharmacy officials did not always comply with Federal requirements or Clinical Center procedures for securing Schedule II substances and were unaware of the requirement to segregate duties. As a result, Schedule II substances were vulnerable to loss, diversion, and mismanagement.

SECURITY AND INTERNAL CONTROL WEAKNESSES

Weaknesses in Securing Stored Schedule II Substances

Federal regulations (21 CFR § 1301.75(b)) state that Schedule II substances "shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances." The Clinical Center's procedures state that "[a]ll controlled substances are stored in a secured and locked storage device or Pyxis Medstation."[2]

The Pharmacy generally stored Schedule II substances as required by Federal regulations and Clinical Center procedures; however, we found the weaknesses described below.

- An unlocked storage cabinet, located in the Pharmacy dispensing unit, contained filled outpatient clinic Schedule II prescriptions awaiting pickup. These prescriptions were segregated on a separate shelf, not dispersed throughout the stock of noncontrolled substances. A number of pharmacists told us that the lock had been broken for about a week. They stated, and we observed, that because of the need for frequent access to the cabinet, pharmacists generally left the cabinet unlocked as a matter of convenience.

- An unlocked stainless steel lockbox, stored in a Pharmacy dispensing unit refrigerator with no lock, contained several intravenous solution bags prepared with Schedule II substances. The chief of the control section told us that because pharmacists needed to access the lockbox frequently, they generally left the box unlocked.

Because the Pharmacy did not always comply with Federal requirements or Clinical Center procedures for securing Schedule II substances, the substances were vulnerable to loss and diversion.

Lack of Segregation of Duties

Office of Management and Budget Circular A-123, § II.C, "Management's Responsibility for Internal Control," states: "Control activities include policies, procedures and mechanisms in place to help ensure that agency objectives are met. . . . [E]xamples include: proper segregation of duties (separate personnel with authority to authorize a transaction, process the transaction, and review the transaction). . . ." No one individual should control all key aspects of a transaction or event.

The chief of the control section was responsible for ordering Schedule II substances, accepting delivery, recording receipt in the inventory records, and storing the substances in the vault. Other pharmacists in the section sometimes—but not always—assisted in these duties. Because

[2]Appendix 1(I)(A), "NIH Warren Grant Magnuson Clinical Center Nursing and Patient Care Services Procedure: Controlled Substances" (July 1983, revised November 2003).

the Pharmacy did not always segregate duties among pharmacists, there was undue risk of diversion and mismanagement of Schedule II substances.

PHARMACY'S CORRECTIVE ACTIONS

We discussed our findings with the chief of the control section, who concurred and immediately implemented the following corrective actions.

- The Pharmacy repaired the broken lock on the prescription storage cabinet in the Pharmacy dispensing unit and assigned responsibility for the key to one pharmacist in each shift. In addition, pharmacists were instructed to lock the lockbox stored in the refrigerator at all times.

- The Pharmacy developed a new policy that segregated duties for ordering and receiving Schedule II substances among two or more control section pharmacists.

We verified that the Pharmacy had implemented these security controls.

RECOMMENDATION

We recommend that NIH ensure that the Pharmacy continues to enforce its policies and procedures to secure and control Schedule II substances.

NATIONAL INSTITUTES OF HEALTH COMMENTS

In its comments on our draft report, NIH concurred with our recommendation and offered some technical comments, which we addressed as appropriate. NIH's comments, except for technical comments, are included as the Appendix.

APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

AUG 25 2008

TO: Daniel R. Levinson
Inspector General, HHS

FROM: Director, NIH

SUBJECT: Comments on the Draft Office of Inspector General Report, *Safeguards over Controlled Substances at the National Institutes of Health Clinical Center Pharmacy for the Period May 2006 to June 2007* (A-03-07-00353)

The National Institutes of Health (NIH) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report, entitled *Safeguards over Controlled Substances at the National Institutes of Health Clinical Center Pharmacy for the Period May 2006 to June 2007.*

The report recommends that we ensure that the Clinical Center Pharmacy "continues to enforce its policies and procedures to secure and control Schedule II substances."

We concur with the above recommendation, albeit with reservations about the need for issuing such a recommendation. We have already implemented corrective actions over the security and control of Schedule II substances, and the OIG has already verified the implementation of these actions. Specific comments on the report are attached.

For any questions concerning the comments, please contact Ms. Maureen Gormley, Chief Operating Officer, NIH Clinical Center, at 301-496-2897 or mgormley@mail.cc.nih.gov.

Again, thank you for the opportunity to review and comment.

Elias A. Zerhouni, M.D.

Attachment

Comments from the National Institutes of Health on the Office of Inspector General Draft Report, *Safeguards over Controlled Substances at the National Institutes of Health Clinical Center Pharmacy for the Period May 2006 to June 2007*
(A-03-07-00353)

The National Institutes of Health (NIH) concurs with the Office of Inspector General's (OIG) recommendation that NIH "ensure that the Pharmacy continues to enforce its policies and procedures to secure and control Schedule II substances" but questions whether any recommendation at all is necessary, especially considering that NIH has already taken actions to correct the identified weaknesses, and the OIG has already verified that these corrective actions have been implemented. Furthermore, "continuing" to enforce policies and procedures implies full ongoing compliance with those policies and procedures.