

OFFICE OF AUDITS & ADVISORY SERVICES



CONTROLLED SUBSTANCES – SHERIFF’S DEPARTMENT MEDICAL SERVICES DIVISION

FINAL AUDIT REPORT

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TREASURER-TAX COLLECTOR

June 4, 2013

TO: William D. Gore, Sheriff
Sheriff's Department

FROM: Juan R. Perez
Chief of Audits

**FINAL REPORT: CONTROLLED SUBSTANCES AUDIT – SHERIFF'S DEPARTMENT
MEDICAL SERVICES DIVISION**

Enclosed is our report on the Controlled Substances – Sheriff's Department Medical Services Division. We have reviewed your responses to our recommendations and have attached them to the audit report.

The actions taken and/or planned, in general, are responsive to the recommendations in the report. As required under Board Policy B-44, we respectfully request that you provide quarterly status reports on the implementation progress of the recommendations. The Office of Audits & Advisory Services will contact you or your designee near the end of each quarter to request your response.

Also attached is an example of the quarterly report that is required until all actions have been implemented. To obtain an electronic copy of this template, please contact Tatiana Foster at (858) 495-5667.

If you have any questions, please contact me at (858) 495-5661.

JUAN R. PEREZ
Chief of Audits

AUD:TF:aps

Enclosure

c: Ronald J. Lane, Deputy Chief Administrative Officer, Public Safety Group
Tracy M. Sandoval, Deputy Chief Administrative Officer/Auditor and Controller
Dorothy Y. Thrush, Group Finance Director, Public Safety Group

INTRODUCTION

Audit Objective The Office of Audits & Advisory Services (OAAS) completed an audit of the Controlled Substances – Sheriff’s Department’s Medical Services Division (MSD). The objective of the audit was to verify that adequate controls exist over the purchase, storage, and use of controlled substances.

Background The mission of MSD is to deliver comprehensive health care services to individuals who are detained in the custody of the Sheriff’s Department. As part of these services, MSD operates a pharmacy which is responsible for dispensing medications, including controlled substances, to seven detention facilities¹ throughout San Diego County. In addition, the pharmacy is responsible for purchasing, storing, and disposing of unusable medications.²

The use and possession of controlled substances is regulated by the Controlled Substance Act (CSA) of 1970, which is primarily enforced by the Drug Enforcement Administration (DEA). Title 21 of the Code of Federal Regulations (CFR) outlines controlled substance regulations used by the DEA to enforce the CSA.

Drugs and other substances that are considered controlled substances under the CSA are divided into five schedules based on their potential for abuse, medical use, and safety or dependence liability.³ The DEA has strict requirements for recordkeeping, inventory, security, and handling of controlled substances.

MSD has established policies related to controlled substances that outline protocols and practices for activities such as receipt, storage, inventory, and disposal of drugs.

Audit Scope & Limitations The scope of the audit focused on Schedule II Controlled Substances (controlled substances) administered at MSD’s pharmacy and detention facilities. OAAS evaluated data from FY 2010-11 to present.

This audit was conducted in conformance with the International Standards for the Professional Practice of Internal Auditing prescribed by the Institute of Internal Auditors as required by California Government Code, Section 1236.

¹ Detention facilities include East Mesa, Facility 8, George Bailey, Las Colinas, South Bay, Vista, and San Diego Central Jail.

² Unusable medications include drugs that have been expired, recalled, and wasted (e.g., patient refuses to take or spit out, spillage, breakage, etc.).

³ Schedule I Controlled Substances have no currently accepted medical use in the United States; Schedule II Controlled Substances have a high potential for abuse which may lead to severe dependence; Schedule III-V Controlled Substances have a less potential for abuse than Schedule II.

Methodology

OAAS performed the audit using the following methods:

- Reviewed applicable Federal and State laws and regulations.
- Examined MSD policies and procedures related to controlled substances.
- Evaluated MSD's controls over the safeguarding and recordkeeping of their controlled substances.
- Assessed compliance with key requirements and internal policies.
- Interviewed key personnel on policies and processes regarding controlled substances.
- On a sample basis, conducted specific audit procedures, such as direct observation, inspections, reconciliations, recalculations, and data analysis of processes relevant to the administration of controlled substances.

AUDIT RESULTS

Summary

Within the scope of the audit, there is reasonable assurance that adequate controls exist over the purchase, storage, and use of controlled substances. However, we noted the following exceptions:

Finding I:**Controls Over the Disposal Process of Controlled Substances Need Improvement**

The detention facilities transfer unusable medications to MSD for disposal. Subsequently, a waste disposal company picks up the drugs from MSD for destruction.

Audit work identified the following issues and control weaknesses related to the disposal of controlled substances:

- **Discarded Controlled Substances Were Not Disposed of Through a California DEA Registered Reverse Distributor**

Federal law is designed to ensure proper accountability of controlled substances by regulating their entire cycle, from production to dispensing or destruction. Accordingly, the DEA has specific regulations that require unusable controlled substances to be transferred to a DEA registered reverse distributor that handles the disposal of controlled substances. When a pharmacy transfers controlled substances for destruction, the reverse distributor must issue an official order form (DEA Form 222) to the pharmacy. The DEA registered reverse distributor is responsible for submitting a DEA Form 41 to the DEA when the controlled substances have been destroyed.⁴

⁴ Title 21 CFR 1307.21 outlines procedures for disposing controlled substances. Rules – 2005 amends section 1307, clarifies the term “reverse distributor”, and outlines the reverse distributor’s responsibilities.

OAAS found that MSD discarded controlled substances as medical waste commingled with other drugs. The drugs were not disposed of through a California DEA registered reverse distributor; therefore, proper notification of destruction of controlled substances is not being submitted to the DEA.

- **Wasted Controlled Substances Were not Disposed of Properly**
OAAS reviewed a sample of 20 doses of controlled substances recorded as waste at one detention facility and found that 2 out of the 20 sample items tested were disposed of down the drain.

In addition to established DEA requirements about disposal of controlled substances, the Environmental Protection Agency (EPA) does not recommend sewer disposal of medications.

- **Controlled Substances Awaiting Disposal Were not Secured Properly**

Upon receipt of unusable medications from the detention facilities, MSD placed these drugs into an open bin for accumulation before they were picked up for disposal. This practice is not consistent with federal regulations (Title 21 CFR 1301.75) and MSD Policies and Procedures Manual MSD.P.1, which require that controlled substances be stored in a securely locked cabinet or drawer. Not properly securing controlled substances awaiting disposal increases the risk of drugs being misappropriated, lost, or diverted.

As a result of the audit, MSD corrected this issue during the course of audit fieldwork.

- **Inadequate Audit Trail for Unusable Controlled Substances**
MSD does not have a process in place to document and account for controlled substances received from the detention facilities to be disposed of. Specifically, OAAS tested 13 doses of controlled substances recorded as waste at one of the detention facilities to verify receipt and disposal by MSD. MSD was unable to account for 3 of the 13 selected doses of controlled substances. MSD stated that it was likely that the 3 missing doses were crushed pills disposed down the drain at the detention facility. However, no evidence was provided to verify this statement.

An adequate set of records that provide documentary evidence of a procedure is a key element of a strong system of internal controls. Absence of an adequate audit trail increases the risk of drugs being lost, unaccounted for, or diverted.

- **Expired Controlled Substances Records Commingled with Others**
MSD maintains records of expired Schedule II controlled substances commingled with records of other drug schedules. In conformance with recordkeeping requirements of federal law, Title 21 CFR 1304.04, records of controlled substances listed in

Schedule I and II shall be maintained separately from all other drug records.

While MSD has a detailed controlled substances policy, it does not outline specific procedures and requirements for the disposal of unusable controlled substances, including recordkeeping.

Recommendation: To strengthen controls over the disposal process of controlled substances and to ensure compliance with federal regulations, MSD should:

1. Ensure that unusable controlled substances are disposed through a California DEA registered reverse distributor, as required by Title 21 CFR 1307.21.
2. Develop and implement policies and procedures specific to the disposal of controlled substances process in compliance with DEA regulations, including the following:
 - Ensure that wasted controlled substances at the detention facilities, including breakage or spillage, are not disposed down the drain but delivered to MSD for proper disposal.
 - Develop adequate records to document the delivery and receipt of wasted controlled substances. At a minimum, these records should document date, drug name, quantity, and include the signature or initials of the staff recording the waste.
 - Ensure that MSD records of expired Schedule II Controlled Substances are maintained separately from all other drug schedules.
3. Develop a training plan to properly communicate new policy and related procedures changes to staff.

Finding II: **Inventory Records of Schedule II Controlled Substances Were Commingled with Other Drug Schedules**

Title 21 CFR 1304.04, requires records and inventories of Schedule II Controlled Substances to be maintained separately from all other records. However, OAAS found that annual inventory count records of Schedule II Controlled Substances at three detention facilities were commingled with other drug schedules. According to MSD, maintaining all controlled substances records together facilitated the recordkeeping process.

Recommendation: MSD should ensure that inventory records of Schedule II Controlled Substances at the detention facilities are maintained separately from all other records.

Finding III: Inventory Counts of Controlled Substances Not Conducted as Required

MSD Policy and Procedure Manual MSD.P.3, requires detention facilities to conduct weekly physical counts of reserve controlled substances.

OAAS reviewed a sample of physical inventory records at one detention facility for a period of 41 weeks. OAAS found that a physical count of reserve controlled substances was not conducted for five weeks.

MSD staff indicated that while the policy requires a weekly inventory count, there is no monitoring or review of these procedures to ensure compliance by the detention facilities.

Untimely inventory counts increase the risk of errors or missing drugs going undetected.

Recommendation: MSD should provide adequate oversight of the detention facilities to ensure that weekly physical counts of reserve controlled substances are conducted in compliance with policy.

Finding IV: Delayed System Interface Could Increase Wasted Medication

The Sheriff's Department uses Jail Information Management System (JIMS) to manage and maintain inmate's records. WORx is an independent system used at MSD for inmate's drug management.

When an inmate is transferred or released from detention, JIMS' records are immediately updated. JIMS interfaces with WORx to update an inmate's status. However, audit work found that a continuous interface between JIMS and WORx is not occurring. More specifically, OAAS identified one instance of a three day delay to update an inmate status in WORx after the inmate had been released from detention. As a result, doses of controlled substances were wasted for three consecutive days.

According to MSD staff, this is a known issue between JIMS and WORx and they are currently working with Information Technology (IT) staff to resolve it.

Recommendation: To minimize wasted medication, MSD should continue working with IT staff to ensure a timely interface between JIMS and WORx. If this continues to be an issue, MSD should consider exploring other solutions including the acquisition of a new integrated system to increase efficiency and accuracy of data.

Office of Audits & Advisory Services

Compliance Reliability Effectiveness Accountability Transparency Efficiency

VALUE

DEPARTMENT'S RESPONSE



San Diego County Sheriff's Department

Post Office Box 939062 • San Diego, California 92193-9062



William D. Gore, Sheriff

May 24, 2013

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MAY 30 2013

TO: Juan R. Perez
Chief of Audits

OFFICE OF AUDITS &
ADVISORY SERVICES

FROM: Earl H. Goldstein, MD
Sheriff's Medical Director

DEPARTMENT RESPONSE TO AUDIT RECOMMENDATIONS: CONTROLLED
SUBSTANCES AUDIT – SHERIFF'S DEPARTMENT MEDICAL SERVICES DIVISION

Finding I: Controls Over the Disposal Process of Controlled Substances Need Improvement

OAAS Recommendation: To strengthen controls over the disposal process of controlled substances and to ensure compliance with federal regulations, MSD should:

1. Ensure that unusable controlled substances are disposed through a California DEA registered reverse distributor, as required by Title 21 CFR 1307.21.
2. Develop and implement policies and procedures specific to the disposal of controlled substances process in compliance with DEA regulations, including the following:
 - Ensure that wasted controlled substances at the detention facilities, including breakage or spillage, are not disposed down the drain but delivered to MSD for proper disposal.
 - Develop adequate records to document the delivery and receipt of wasted controlled substances. At a minimum, these records should document date, drug name, quantity, and include the signature or initials of the staff recording the waste.
 - Ensure that MSD records of expired Schedule II Controlled Substances are maintained separately from all other drug schedules.

Develop a training plan to properly communicate new policy and related procedures changes to staff.

Keeping the Peace Since 1850

Action Plan:

- 1) We have contracted EXP Pharmacy Services Corp. to dispose of our narcotic wastage and they are currently doing so.
- 2) New policy has been developed for wasting narcotic medications.
 - a. Locked narcotic wastage bins have been given to each facility along with a narcotic wastage log sheet
 - b. When a medication is wasted, the nurse will place the wasted medication into the narcotic bin and record the date, drug name, number of tablets, and the Automated Regional Justice Information System number of the nurse recording the waste on the narcotic wastage log sheet
 - i. All Narcotic wastage, including broken or crushed medication will be returned to the pharmacy
 - c. The medication in the locked bin will be picked up by the pharmacy staff weekly
 - d. Only the pharmacists have keys to the bins
 - e. The medications in the wastage bin will be verified against the narcotic wastage log sheet by a pharmacist
 - f. Expired Schedule II cassettes will be logged on a separate form from the other controlled medications
- 3) Nursing staff will be trained to use the narcotic wastage bins.

Planned Completion Date: May 1, 2013

Contact Information for Implementation: Jeffery Crutchfield, Pharmacist

Finding II: Inventory Records of Schedule II Controlled Substances Were Commingled with Other Drug Schedules

OAAS Recommendation: MSD should ensure that inventory records of Schedule II Controlled Substances at the detention facilities are maintained separately from all other records.

Action Plan: The annual inventory of all controlled medication will be divided in to CII and CIII to CV. The inventory sheets will be kept separately.

Planned Completion Date: May 31, 2013 (next inventory date)

Contact Information for Implementation: Jeffery Crutchfield, Pharmacist

Finding III: Inventory Counts of Controlled Substances Not Conducted as Required

OAAS Recommendation: MSD should provide adequate oversight of the detention

facilities to ensure that weekly physical counts of reserve controlled substances are conducted in compliance with policy.

Action Plan:

- 1) A Pharmacist will make certain the reserve inventory count log sheet is completed weekly by the nursing staff and faxed weekly to the pharmacist.
 - a. If the log sheet is not filled out the pharmacist will notify the supervisory nurse or their designee to make certain the weekly narcotic count is completed and faxed

Planned Completion Date: May 28, 2013

Contact Information for Implementation: Jeffery Crutchfield, Pharmacist

Finding IV: Delayed System Interface Could Increase Wasted Medication

OAAS Recommendation: To minimize wasted medication, MSD should continue working with IT staff to ensure a timely interface between JIMS and WORx. If this continues to be an issue, MSD should consider exploring other solutions including the acquisition of a new integrated system to increase efficiency and accuracy of data.

Action Plan: The Sheriff's Medical Services Division in conjunction with the Sheriff's Data Services Division have held numerous meetings and corresponded with two contractors, Tiburon Corporation, the Jail Medical Information System (JIMS) contractor and the Pharmacy software company MediWare WORx system.

Due to Users' data entry errors, timing of the transmission of an entry can cause errors between the two systems which have occurred; the two corporations are unable to find a solution that will prevent each of the uniquely occurring errors due to minor nuances in each of the ordering data entries. However, each error is reported to Data Services and individually corrected by the two Corporations. The time lag between the detection of an error fix and a fix can cause medications to remain on the Patient's medication administration sheet when they should have been deleted, thus wasting the medication(s).

CORRECTIVE ACTION: The Sheriff Department performed its due diligence through a release of a Request for Information (RFI) for a replacement electronic medical record. Those companies that responded were not able to demonstrate that the software they represented could fulfill the RFI requirements or facilitate the size of the Sheriff's jail population with the current inmate population, or projected growth in inmates and users.

Planned Completion Date: The search continues to replace the current JIMS system with a new system, within the next two fiscal years.

Contact Information for Implementation: William D. Didier, RHIA, Chief Medical Records. Phone 858 974 5994.

If you have any questions, please contact me at (858) 974-5963.