

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AUDIT SERVICES**

**UCSF Medical Center
Pharmaceutical Services
Controlled Substances
Project #13-048**

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**UCSF Medical Center
Pharmaceutical Services – Controlled Substances
Project #13-048**

MANAGEMENT SUMMARY

As a planned audit for fiscal year 2012-2013, Audit Services conducted a limited scope review of controlled substances within the Department of Pharmaceutical Services (Pharmacy). The objectives of this review were to:

- Analyze and assess Pharmacy's processes and controls for the purchase, receiving, inventory and dispensing of controlled substances;
- Evaluate the controls for the wasting and disposal of controlled substances;
- Evaluate the effectiveness of controls for monitoring and detecting diversion of controlled substances; and
- Determine compliance with department and University policies and external laws and regulations for use and handling of controlled substances.

The scope of the review was limited to the management and oversight of controlled substances within Pharmacy at three main locations: Parnassus, Mission Bay and Mt. Zion.

In completing this review, Audit Services interviewed Pharmacy personnel involved in management and oversight of controlled substance, reviewed relevant requirements as published by DEA and University Policies, examined records, evaluated existing controls, procedures, and practices and assessed the effectiveness of current controls for managing controlled substances.

Based on work performed, controls for managing and administering controlled substances within Pharmacy were operating effectively. Also, built-in controls within the CII safe system have greatly improved the control environment by retaining electronic records for transactions and enabling monitoring reports to be used to assure accountability of controlled substances. However, the Medical Center needs to enhance its existing diversion detection and prevention program by implementing an on-going education and training program for all health professionals and strengthening the diversion detection and monitoring processes. Furthermore, development of standard operating procedures for Pharmacy personnel is required for consistency and standardization in the performance of tasks.

Detailed information on the observations and management corrective actions can be found in the body of the report.

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I. BACKGROUND

As a planned audit for fiscal year 2013, Audit Services completed a review of the management and oversight of controlled substances within Pharmaceutical Services. Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules (I through V) and placed in their respective schedules based on whether they have a currently accepted medical use in treatment, their relative abuse potential and likelihood of causing dependency when abused.¹ The CSA and its enforcement agency, the Drug Enforcement Administration (DEA), have set out various requirements for retail pharmacies, hospitals, manufacturers and vendors for the handling of controlled substances including registration of all those authorized by the DEA to handle controlled substances, maintenance of complete and accurate inventories and records of all transactions involving controlled substances, security for the storage of controlled substances and reporting of controlled substances loss/theft. Ineffective management and oversight of controlled substances can lead to regulatory penalties and fines by the DEA. Furthermore, inadequate controls for preventing and detecting diversion of controlled substances could adversely affect patient care and safety.

The Department of Pharmaceutical Services (Pharmacy) is responsible for assuring that all controlled substances for UCSF Medical Center are purchased, received, dispensed and accounted for in accordance with University and Pharmacy policies and procedures (P&P) and other regulatory requirements. Supplies of controlled substances are stored in three locations: Parnassus Moffitt/Long Hospital, Mission Bay and Mt. Zion Hospital. These locations restock controlled substances in clinical areas including Nursing Units. Additionally, Nursing Units are held accountable for following guidelines established by the Pharmacy and Nursing Departments for proper handling of controlled substances.

Pyxis CII Safe systems have been installed in the three locations that store the major supply of controlled substances. These systems are used to track and monitor the receipt and replenishment of substances. The Medical Center uses Pyxis medstations to manage controlled substances stored in clinical areas. Pharmacy recently added Pyxis Anesthesia System (PAS) stations for dispensing of anesthesia drugs as a pilot program at the Orthopedic Institute at Mission Bay.

II. AUDIT PURPOSE AND SCOPE

The objectives for this review were to: 1) analyze and assess Pharmacy's processes and controls for the purchase, receiving, inventory and dispensing of controlled substances; 2) evaluate the controls for the wasting and disposal of controlled substances; 3) evaluate the effectiveness of controls for monitoring and detecting diversion of controlled substances; and 4) determine compliance with department and University policies and external laws and regulations for use and handling of controlled substances.

¹ US Department of Justice, DEA Definition of Controlled Substance Schedules

The scope of the review was limited to the management and oversight of controlled substances within Pharmacy. To conduct the review, Audit Services performed the following procedures at the three main Pharmacy locations (Parnassus Moffitt/Long Hospital, Mission Bay and Mt. Zion Hospital):

- Reviewed Pharmacy and Nursing policies and procedures related to handling of controlled substances;
- Interviewed Pharmacy personnel responsible for management and oversight of controlled substances to gain an understanding of the controls and processes in place;
- Reviewed the current list of users who are granted access to CII Safe to determine whether there is an effective access management process;
- Observed physical security measures in use for areas containing controlled substances including a sample of satellite locations and refrigerators to validate controlled substances are securely stored;
- Compared electronic invoices from vendors to Pharmacy's receiving records to validate the accuracy of entries in the CII Safe system and accountability of controlled substances ordered;
- Reviewed and validated evidence of audits performed for returned controlled substances collected by the reverse distributor;
- Validated that full physical inventory count is performed biennially to meet minimum regulatory requirements;
- Reviewed biennial physical inventory count records to ensure that there is proper review and disposition of discrepancies identified during the count;
- Performed physical inventory count for a sample of controlled substances to validate the accuracy of inventory records maintained;
- Assessed the effectiveness of the current diversion monitoring program and identified best practices implemented at other UC Medical Centers and other healthcare entities; and
- Identified some of the key controls required by DEA and UCSF Pharmacy policies and procedures and assessed if current processes for handling controlled substances meet these requirements.

Since work performed was limited to the specific procedures identified the above, this report is not intended to, nor can it be relied upon to provide an assessment of the effectiveness of controls beyond those areas and systems specifically reviewed. Furthermore, this assessment represents the status of controlled substance handling processes effective as of the last date of fieldwork. Fieldwork was conducted March through April 2013.

III. CONCLUSION

Based on the work performed, overall internal controls for managing and administering controlled substances within the Pharmacy appear to be in place including segregation of duties for purchasing and receiving, good inventory controls and procedures for ensuring accountability of controlled substances.

Also, implementation of CII Safe systems has greatly improved controls for handling controlled substances and retention of electronic records for transactions.

The review identified opportunities for improving controls in the following areas:

- Development of a comprehensive and effective diversion prevention and detection program which includes implementing on-going education and training for all health professionals and developing standardized procedures for regular auditing, monitoring and oversight;
- Compliance with regulatory requirements for Power of Attorney (POA) authorization;
- Maintenance of data integrity in the CII Safe by ensuring data entered into the CII Safe is accurate;
- Increased frequency of the full inventory count and enhancements to the physical security of Parnassus Pharmacy control substances storage area; and
- Development of standard operating procedures that clearly define requirements for handling of controlled substances by Pharmacy personnel including validation and review of control substances discrepancy reports and receiving records to validate that tasks are fully understood and consistently performed.

IV. **OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS**

A. **Diversion Program**

A comprehensive and effective diversion prevention program is not in place

Due to the nature of their job responsibilities, healthcare professionals have access to controlled substances at hospitals; therefore, it is imperative that hospitals have an effective diversion program in place to prevent and detect diversion of controlled substances. Employees who take and pilfer controlled substances not only harm themselves but also jeopardize patient care and safety.

The Pharmacy has implemented several control processes for preventing diversion of controlled substances such as a segregation of duties for purchasing and receiving, reviews of receiving documents, restricting access to controlled substance inventory and requiring two personnel to witness returns and resolve any inventory discrepancies. Also, implementation of CII Safe systems has greatly improved controls for handling controlled substances and retention of electronic records for transactions.

However, we noted that a number of critical elements of a diversion prevention program are not in place or are not routinely performed to sufficiently prevent and detect diversion and abuse of controlled substances, including the following:

1. Education and Training

Pharmacy provides training on its policies and procedures on handling and administering controlled substances to Pharmaceutical Services personnel upon hire and on an ad-hoc basis to Nursing Professionals. However, there is no on-going training and education program in place on the controlled substances diversion program that includes:

- An orientation for all new health professionals who can access, administer and handle controlled substances on the organization's policies and procedures and diversion prevention program;
- On-going awareness training and education for managers, supervisors and staff on compliance policies and procedures for safe handling of controlled substances, signs and behavior indicating possible diversion, their obligation to report when they have knowledge of diversion and reporting methods.

Absence of a sufficient education and training program increases the likelihood of improper drug handling practices, diversions going undetected or unreported and increased risk of harm to patients.

Management Corrective Action

Pharmacy, in conjunction with Nursing and Medical Staff will assess existing educational training processes and materials. Based on this assessment, a proposal for a comprehensive and on-going drug diversion training and educational program for all health professionals will be developed and presented to senior management for review and approval. These actions will be taken by March 31, 2014.

2. Diversion Detection and Monitoring

Diversion of controlled substances can occur in numerous ways and can be difficult to detect due to numerous medications access points; therefore, it is important that a methodical and systematic diversion program be established based on existing risks and controls in the organization.

The Medical Center currently does not have an effective diversion and monitoring program in place. Due to lack of resources within Pharmacy, there is limited oversight to validate that existing diversion detection and monitoring processes in the Nursing Units are being followed. Therefore, there is limited assurance on whether these monitoring controls are in place within the Nursing Units. Furthermore, during FY 2013 proactive diversion reports to facilitate the monthly audits by Nursing were not consistently provided to Nursing Managers on a monthly basis by Pharmacy.

It was noted that Pharmacy had developed a detailed narcotic auditing and monitoring program in 2006; however, this was not fully implemented due to lack of sufficient resources within Pharmacy for performing the audits.

Lack of comprehensive diversion detection and monitoring program increases the risks that diversions will go undetected and cause potential harm to patients.

Management Corrective Action

- a) Pharmacy will modify existing procedures for the monthly Nursing Unit inspection to include a verification to ensure monthly monitoring audits of controlled substances are being performed by the Nursing Unit Managers. Procedures will be modified and new inspection process will be implemented by November 1, 2013.
- b) Pharmacy will assess the sufficiency of the existing monitoring and detection programs for high risk areas such as OR and Anesthesia and determine whether additional oversight and monitoring is warranted. The assessment will be completed by March 31, 2014.

B. Regulatory Compliance

Authority to approve purchases of Schedule II controlled substances has not been properly delegated.

When ordering Schedule II controlled substances, DEA regulations require that a Form 222 is completed and signed by the DEA Registrant or someone to whom the Registrant has granted authority through a power of attorney (POA). For the UCSF Medical Center, the DEA Registrant is the Chief Executive Officer (CEO).

The POAs reviewed had been signed by the prior Chief Operating Officer and/or the Director of Pharmaceutical Services rather than the Medical Center CEO.

Management Corrective Action

Effective August 5, 2013 new Power of Attorney (POA) forms have been prepared and signed by the CEO of the Medical Center.

C. Receiving

Internal controls need to be strengthened to improve the accuracy and completeness of controlled substance receiving data.

Upon delivery of individual orders of control substances, quantities received are matched to invoices, receiving information is entered into the CII Safe system and the deliveries are placed in designated secured areas. Additionally, for Schedule II controlled substances, a staff member completes the DEA 222 form denoting quantity of drugs received.

Audit Services performed test work to validate the accuracy of receiving information in the CII Safe system by comparing system information with relevant DEA 222 forms and invoices. Several inaccuracies and inconsistencies were identified including:

- Incorrect vendor names;
- Incorrect or missed invoice numbers;
- Combined quantities from several invoices entered into CII safe, thereby limiting the ability to match quantities to individual invoices;
- Incorrect or missed DEA 222 form numbers; and
- Incorrect DEA 222 form used for recording received Schedule II controlled substances.

Incorrect or inconsistent entry of data limits the audit trail and the ability to account for all controlled substances received.

Management Corrective Action

Education and training of Pharmacists/Narcotic Technicians that are accountable for the record keeping and receiving will be performed to reinforce the requirement for accurate data entry. The Pharmacy Manager responsible for verification of invoices to CII safe entries will be required to verify the accuracy of other data elements in addition to quantities received. Additionally, the process to perform a periodic spot checking for data accuracy will be developed. These actions will be taken by December 31, 2013.

D. Inventory and Physical Security

1. *Existing inventory practices do not provide effective controls for controlled substances that are not frequently used.*

Pharmacy conducts a full physical inventory count on a biennial basis in accordance with the DEA regulations. Pharmacy also has an established procedure of conducting a blind count² of controlled substances whenever they are “accessed” (i.e. any movement of quantity while removing, replenishing or wasting). However, controlled substances which are not accessed regularly only count during the biennial inventory count and therefore the detection of theft/loss of those controlled substances would occur at that time.

Infrequent physical inventory precludes the ability to detect loss/theft of controlled substances in a timely manner.

Management Corrective Action

Effective December 31, 2013 Pharmacy will perform a full physical inventory count annually.

² Blind counts involve the taking of a physical inventory by a person who does not know quantities that the CII Safe system shows as on hand.

2. *Physical security can be enhanced with the installation of surveillance cameras.*

Surveillance cameras have become a cost effective way of monitoring activities in critical and sensitive areas. In addition, video records provide indisputable evidence and serve as a deterrent for improper activity.

Currently, access to the narcotic storage areas is obtained via a key that is held by the Pharmacist in charge but is available for use by the Pharmacists/Narcotic technicians. No logs are maintained on who accessed the narcotics store room, creating potential security vulnerability. Installation of surveillance cameras would help monitor that access is appropriate and would be a deterrent.

Management Corrective Action

Pharmacy will work with Human Resources to determine if cameras can be installed without violating terms of existing collective bargaining agreements and/or University policies. If HR confirms that cameras can be installed, Pharmacy will develop a plan and have cameras installed in areas (where deemed necessary) storing controlled substances by June 30, 2014.

E. Policies and Procedures

1. *There are no standard operating procedures which sufficiently define requirements for handling controlled substances within Pharmacy.*

Pharmacy has developed and documented several policies and procedures which define the process and control requirements for handling controlled substances; however, these processes and requirements are mainly for Pyxis Medstations or non-Pyxis controlled substances used by nursing staff.³ There are not similar policies and procedures for Pharmacy personnel who handle controlled substances within Pharmacy. Additionally, elements of the drug diversion program such as independent review of the Pyxis vs. CII Safe Compare Report and validation of controlled substances received to shipping records are being performed by Pharmacy personnel but procedures for resolving of discrepancies are not fully defined and documented. This has caused inconsistencies in practices across the three locations that maintain and handle controlled substances.

The absence of operating procedures which clearly define requirements and accountability for handling controlled substances increases the risk that responsibilities and routine tasks are not consistently performed for handling controlled substances within Pharmacy.

³ Pharmacy Policies and Procedures “Narcotic and Controlled Substances” (Policy# 110.300)
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Management Corrective Action

Pharmacy will update existing operating procedures to define requirements and accountability for handling controlled substances within Pharmacy. For the processes which include reviewing/reconciliation of documents/reports, requirements to retain 'evidence of review' will be included. These actions will be taken by December 31, 2013.

2. Existing policies and procedures do not sufficiently cover requirements for the new system developed for controlled substances used by anesthesiologists.

Pharmacy recently installed 4 PAS stations as a pilot program at the Orthopedic Institute at Mission Bay for evaluation purposes. PAS was designed to assist with the storage and oversight of medications used by anesthesiologists in the OR suites.

Existing Pharmacy and Nursing policies and procedures for controlled substances are written for administering controlled substances in Pyxis Medstation or non-Pyxis units. As a result, there are no applicable policies and procedures that clearly define requirements for controlled substances stored in and removed from PAS.

The absence of policies and procedures which clearly define control requirements for handling controlled substances in PAS increases the risk that controlled substances stocked in/dispensed from PAS are not handled properly or fully accounted for.

Management Corrective Action

Pharmacy will review and modify existing policies and procedures in order to ensure that control requirements for PAS used by Orthopedic Institute are sufficiently covered and will incorporate these control requirements in the diversion education and training program for anesthesiologists. These actions will be taken by March 31, 2013.

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