Office of Internal Audit

UT Southwestern Medical Center

The University of Texas Southwestern Medical Center
Pharmacy Controlled Substances Audit

Internal Audit Report 15:10

March 2, 2015

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Executive Summary

Background

Controlled substances include narcotics, stimulants, depressants, and hallucinogens. Due to the abuse potential and risk associated with these drugs, the U.S. Department of Justice (DOJ) and the Drug Enforcement Agency (DEA) developed regulatory requirements governing their manufacture, distribution and dispensing. These requirements include special handling, inventory controls, and documentation requirements. Additionally, the DEA Office of Diversion Control released a series of "significant documents" which include a practitioner manual and pharmacist manual that further outlines elements of the CSA and procedures to appropriately comply.

The Department of Pharmacy Services (Pharmacy) is responsible for ensuring compliance with all regulatory requirements in regards to the handling of controlled substances within the University of Texas Southwestern Medical Center (Medical Center) hospitals and clinics. Each pharmacy location holds its own license with the Texas State Board of Pharmacy (TSBP), DEA, and the Department of Public Safety (DPS).

Pharmacy provides integrated pharmaceutical services to the Medical Center hospitals and clinics. In addition to the traditional medication dispensing functions, Pharmacy offers daily clinical services, hospitalist services and annual training for over 20 pharmacy students and three residents. The Department has a central pharmacy at each hospital that manages the dispensing of medications for hospital patients; three clinic pharmacies that supply medications for patients receiving cancer treatment; and two retail pharmacies that dispense medications to customers as prescribed by their provider:

- Clements University Hospital Central Pharmacy
- Zale Lipshy University Hospital Central Pharmacy and OR Satellite Pharmacy
- Ashton Infusion Center Pharmacy
- Simmons Cancer Center Infusion Pharmacy
- Simmons Cancer Center Infusion Pharmacy at Richardson/Plano
- Simmons Cancer Center Retail Pharmacy
- Campus Retail Pharmacy at Aston Center

The Pyxis CIISafe System (CIISafe) is the central storage for all controlled substances and is used to track and monitor controlled substance inventory at the central pharmacies. Pyxis MedStations (Pyxis) are automated dispensing units located throughout the hospitals and clinics. Controlled substances from the CIISafe are distributed to Pyxis as needed. CIISafe and Pyxis are equipped with the necessary features to handle controlled substances; including username and fingerprint access, inventory, receiving, dispensing, return, disposal and audit trails of all activities performed. Pyxis are not used at the retail pharmacy locations. Instead, certain controlled substances with higher potential for abuse are stored in locked cabinets. See Appendix B for statistics on the volume of controlled substances inventory on hand as of December 31, 2014.

Scope and Objectives

The Medical Center Office of Internal Audit has completed its Pharmacy Controlled Substances Audit. This was an operational risk based audit and part of the fiscal year 2015 Audit Plan.

The audit scope included processes related to the overall handling of controlled substances and activities from May 1, 2014 to December 31, 2014. The review included all hospital, clinic and retail pharmacy locations with controlled substances inventory. Controlled substances in ambulatory clinics, animal

Executive Summary

research and clinical research locations were not included in the scope of this audit but will be reviewed separately. Audit procedures included interviews with stakeholders, review of policies and procedures and other documentation, data analytics and substantive testing.

We conducted our examination according to guidelines set forth by the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing.

The primary objectives of the audit were to determine whether:

- Controlled substances are stored and safeguarded in compliance with the federal regulations and Medical Center policies.
- Appropriate internal controls for the procurement of controlled substances are in place and are operating effectively.
- Controlled substances transported between pharmacies or operational areas are appropriately approved and safeguarded.
- Inventory monitoring procedures are in place to identify and resolve discrepancies and ensure regulatory discrepancy reporting is performed on a timely basis.
- Wastage is physically safeguarded and properly destroyed or disposed.
- The Medical Center is in compliance with DEA or other requirements and internal policies.

Conclusion

Included in the table below is a summary of the observations noted, along with the respective disposition of these observations within the Medical Center internal audit risk definition and classification process. See Appendix A for Risk Rating Classifications and Definitions.

High (1)	Medium/High (1)	Medium (3)	Low (2)	Total (7)

Specific strengths identified during the audit include:

- Pharmacy operations were well documented and compliant with federal regulations.
- Licensing with the DEA, TSBP and DPS for operating and ordering controlled substances is current and appropriate.
- Controlled substances storage is compliant with federal regulations and Medical Center policies at the hospitals and clinics.
- Controlled substances transported between pharmacies or operational areas were supported by evidence of sufficient review and safeguarding.

There was one significant (high risk) issue identified related to Physical Security Access. Other key improvement opportunities risk-ranked as medium/high and medium are also summarized below.

- **Physical Security Access** – Badge access, punch code access and key access to physical locations is not adequate to prevent loss or theft of controlled substances. Previous diversion incident of Schedule II drugs was identified due to lack of monitoring and security measures.

- **Discrepancies Resolution** – Discrepancies (i.e. where controlled substance inventory on hand does not agree to system totals) were not resolved timely which could result in undetected diversion.

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- **Pyxis Station System Access Review –** A process was not in place to review the appropriateness of employees assigned Pyxis access.

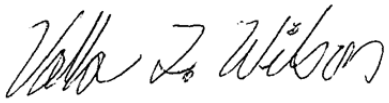
- **Physical Wastage –** The process to dispose of liquid controlled substances at the Clements and Zale Lipshy hospitals is not in compliance with Environmental Protection Agency (EPA) guidelines. Additionally, the process for disposal of tablets and patches could result in diversion.

- **Retail Inventory Monitoring –** Procedures were found to have control gaps for ensuring accurate controlled substance inventory records at the retail locations.

Management has plans to address the issues identified in the report and in some cases have already implemented corrective actions. These responses, along with additional details for the key improvement opportunities listed above and other lower risk observations are listed in the Detailed Observations and Action Plans Matrix (Matrix) section of this report.

We would like to take the opportunity to thank the departments and individuals included in this audit for the courtesies extended to us and for their cooperation during our review.

Sincerely,



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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: High ● 1. **Improve Physical Security Access for Controlled Substances** Physical access to pharmacy and Pyxis station locations, and cabinets securing Schedule II drugs, is not adequate to prevent loss or theft of controlled substances. • **Simmons Cancer Center & Retail:** o Access is controlled through key punch codes and door keys assigned to Pharmacy personnel. Pharmacy management requested removal of the generic key punch master code that allows access to an unknown number of people with knowledge of the code. o A diversion of approximately 2,340 Schedule II drugs occurred during July and August 2014 as a result of inadequate physical security and monitoring controls. The diversion was appropriately reported to the applicable authorities. • **Aston Retail**: o Access is controlled by assigned door keys. The main door should remain locked to control access to only authorized Pharmacy personnel, however current practice is to leave the door propped open during business hours. Installation of a badge reader access system is planned in the near future. o Access to the cabinet securing Schedule II drugs is controlled by keys assigned only to the Pharmacists. The cabinet was observed standing open and unlocked during	1. Determine the appropriate physical access authorities for pharmacy and non-pharmacy personnel regarding the punch code. 2. Determine the appropriate physical access authorities for pharmacy and non-pharmacy personnel regarding key access. 3. Determine the appropriate physical access authorities for pharmacy and non-pharmacy personnel regarding badge access. 4. Establish a process to periodically review physical access to the pharmacy areas monthly in order to identify and correct inappropriate access for badges, punch codes and keys.	**Management Action Plans:** 1. Badge access is approved and will replace punch code access at the Simmons Cancer Center retail and infusion pharmacies. 2. The door to enter the Aston Retail Pharmacy is now kept shut at all times. The Schedule II cabinet within the Ashton Retail Pharmacy is now locked at all times and accessible only to the pharmacists with assigned keys. The spare key is now kept in a box with a combination lock. 3. The Associate VP Ancillary Services will coordinate with the Campus Police Department to establish the appropriate level of access for officers to pharmacy locations. 4. The Pharmacy Director will request a listing of badge access and badge activity reports monthly from the Police Department Access Control Manager in order to review and correct inappropriate access. **Action Plan Owners:** 1. Simmons Cancer Center Pharmacy Manager 2. Retail Pharmacies Operations Manager 3. Associate VP Ancillary Services 4. Pharmacy Director

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
business hours. Additionally, an extra key to the cabinet was kept at an unsecured area accessible by anyone within the pharmacy. • **Clements, Zale Lipshy, Aston Infusion Clinic, Richardson/Plano Clinic:** Access is controlled by badge access. Analysis revealed: o 71 employees at Clements, 84 at Zale Lipshy, 69 at Aston Infusion and five at Richardson had inappropriate access because they were either terminated or employed by another department. o Two Shred It vendor employees have badge access. o Campus Police Officers also have unrestricted access to enter pharmacy locations. Pharmacy management has requested the removal of the inappropriate access rights. There was not a process in place for management to periodically review badge access reports.		**Target Completion Dates:** 1. March 31, 2015 2. Completed 3. March 31, 2015 4. March 31, 2015

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium/High 🟡 2. **Improve Discrepancy Resolution Process** Discrepancies were not consistently resolved in a timely manner. A discrepancy occurs when there are inconsistencies in patient information, incorrect inventory counts, or incomplete provider records for transactions involving controlled substances. Analysis of 1,244 discrepancies generated over the course of 90 days revealed: • 236 (18%) general Pyxis discrepancies were not resolved within the 24 hour timeframe as required by policy. • 60 (5%) general Pyxis discrepancies remained unresolved. • 66 (5%) operating room Pyxis station discrepancies were not resolved within the 72 hour timeframe as required by policy. In addition, Anesthesiologists and operating room users create about 70 discrepancies per month but are not resolving their own discrepancies as required by Pharmacy policy. Instead, central pharmacy personnel follow up to resolve these discrepancies causing unnecessary delays. Additionally, documentation by the central pharmacy was not signed and dated to support the timeliness of their discrepancy resolution. Delays in resolving discrepancies increase the risk that controlled substances diversion will not be detected.	1. Establish a process to retrain nurses and providers on how to use the Pyxis stations to resolve discrepancies. 2. Establish a process to ensure Anesthesiology providers take accountability to resolve their discrepancies. Also consider having a designated individual perform on site reviews and random visits at the operating room areas to improve the discrepancy resolution process. 3. Include the dates and name of the reviewer in all resolution documentation for Anesthesiology discrepancies.	**Management Action Plans:** 1. The Pharmacy Director will collaborate with the Nursing Educators and Pyxis team to retrain nurses and providers on proper discrepancy resolution procedures and timeliness standards. In addition, laminated instruction cards will be made available at each Pyxis for user reference. 2. The Associate VP, Chief Operations Officer will coordinate with the Chair of Anesthesiology and Pain Management to ensure proper accountability for discrepancy resolution is established. 3. The OR Technician Coordinator is now signing and dating all resolution documentation. **Action Plan Owners:** 1. Pharmacy Director 2. Associate VP Chief Operations Officer 3. OR Technician Coordinator **Target Completion Dates:** 1. May 31, 2015 2. May 31, 2015 3. Completed

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium 3. **Establish Pyxis Stations System Access Review** A process was not in place to review the appropriateness of employees assigned Pyxis access. Current pharmacy procedures require employees to complete Pyxis training and a New User Pyxis form. Supervisors must verify, grant access, and return the form to the central pharmacy for review and filing. However, there was not a completed form on file for 15 of the 22 current employees tested. Without proper review, Pyxis access may not be granted appropriately and unauthorized employees may access controlled substances stored in the Pyxis stations.	Reinforce the required record keeping process and establish a periodic review to ensure Pyxis access is provided only to employees who completed required training.	**Management Action Plans:** The current procedures to forward New User Pyxis forms to central pharmacy will be reinforced. In addition, the Pharmacy Director will coordinate with the My Learning team to obtain a report to confirm required training has been completed by all new Pyxis users. He will also determine with the Pyxis team a report of users with the trail of who granted access can be obtained. **Action Plan Owners:** Pharmacy Director **Target Completion Dates:** May 31, 2015.
Risk Rating: Medium 4. **Improve Physical Wastage Methods** The processes to dispose of controlled substances at the Clements and Zale Lipshy hospitals need improvement. Management disclosed that liquid waste is disposed down the sink and tablets and patches are thrown in Sharps containers. Disposal of controlled substances down the sink is a violation of EPA guidelines. Disposal of tablets and patches in Sharps containers does not effectively safeguard controlled substances from diversion. A pilot program is in place at certain locations to appropriately dispose of controlled substances in compliance with EPA and DEA requirements.	Expand the pilot program to all locations in order to manage controlled substance physical wastage in compliance with federal guidelines and protect against diversion.	**Management Action Plans:** Pharmacy will be phasing in the pilot system waste receptacles over the next six months to approximately 70 areas. **Action Plan Owners:** Pharmacy Director **Target Completion Dates:** August 31, 2015

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium 🟡 5. **Enhance Retail Inventory Monitoring Procedures** Procedures were found to have control gaps for ensuring accurate controlled substance inventory records at the retail locations. The following was noted: • Procedures are not in place to review inventory adjustments for appropriateness. • At the Aston retail location, negative inventory balances were noted in the Pioneer Rx inventory system. Additionally, minor discrepancies between inventory balances on hand and system totals were identified. • Retail Pharmacy Management segregates and secures controlled substances removed from inventory for scheduled pickup by the return vendor. However, a reconciliation is not performed between controlled substances removed from inventory for return and the confirmation report from the vendor of items received. Lack of monitoring and reconciliation of controlled substance movement or inventory changes increases the risk of undetected diversion and inaccurate inventory records.	1. Establish a process to monitor and reconcile all controlled substance movement in and out of the Pioneer Rx system at the Simmons Cancer Center retail and Aston retail pharmacies. 2. Update the system inventory records to agree with inventory balances on shelf at Aston retail pharmacy. 3. Establish a process to reconcile the controlled substances removed from Pioneer Rx system with the controlled substances picked up by the vendor at Simmons Cancer Center retail and Aston retail pharmacies.	**Management Action Plans:** 1. A Pioneer RX monthly drug movement report has been identified and is now being used to review changes and adjustments by drugs and users. 2. The system inventory records for Aston Retail are now updated to reflect actual current inventory balances. Head Pharmacist will perform monthly inventory reviews to ensure records are accurate. 3. A record will now be kept reconciling the controlled substances removed from Pioneer Rx with the controlled substances picked up by the vendor. **Action Plan Owners:** 1. Retail Pharmacies Operations Manager 2. Completed 3. Aston Retail Pharmacist in Charge & Simmons Cancer Center Pharmacist in Charge **Target Completion Dates:** 1. Completed 2. Completed 3. Completed

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Low 6. **Update Pharmacy Written Procedures** Current Pharmacy controlled substance practices do not agree with some of the written procedures for the following: • Ordering and receiving at the Simmons Cancer Center pharmacies. • Validation of wastage of controlled substances on a sample basis using the refractometer. • The DEA requirement for the timely reporting of loss or theft is not detailed in the written procedures. Pharmacy controlled substances written policies and procedures have been in place since 2010 and some updates were performed in 2013. Without consistency of policies and procedures with the actual practices, processes performed may not be correct.	Re-evaluate and update the written procedures to reflect current practices, as necessary.	**Management Action Plans:** Procedures will be updated as necessary to reflect current practices. The validation of wastage of controlled substances using the refractometer will be reestablished and will remain in the procedures. **Action Plan Owners:** Pharmacy Operations Manager **Target Completion Dates:** August 31, 2015

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Low  7. **Improve Controlled Substance Receiving and Loading Processes** Segregation of physical receiving and loading processes needs improvement. We identified the following: • At Aston Infusion clinic, a pharmacist signature is not always evidenced on the controlled substances invoices as required by policy. • At Aston Infusion and Simmons Cancer Center at Richardson/Plano, the same individual who physically receives also loads the controlled substances into Pyxis. A load report is not printed in order for the Pharmacist to perform an independent review. These clinics have minimum quantities of controlled substances and inventory monitoring is performed by their supervising pharmacies. However, without an independent review of received orders, the possibility of loss or theft of controlled substances is increased.	Ensure pharmacists at Aston Infusion and Simmons Cancer Center at Richardson/Plano verify controlled substances received and quantities loaded in the Pyxis stations match, by signing the invoices and performing an independent review.	**Management Action Plans:** The Load report is now printed and both the pharmacist and another individual sign the invoice witnessing that all drugs were loaded into Pyxis. **Action Plan Owners:** Simmons Cancer Center Pharmacy Manager Aston Infusion Clinic Pharmacist in Charge **Target Completion Dates:** Completed

Appendix A – Risk Classifications and Definitions

As you review each observation within the Detailed Observations and Action Plans Matrix of this report, please note that we have included a color-coded depiction as to the perceived degree of risk represented by each of the observations identified during our review. The following chart is intended to provide information with respect to the applicable definitions and terms utilized as part of our risk ranking process:

	Degree of Risk and Priority of Action	
Risk Definition - The degree of risk that exists based upon the identified deficiency combined with the subsequent priority of action to be undertaken by management.	**High**	The degree of risk is unacceptable and either does or could pose a significant level of exposure to the organization. As such, immediate action is required by management in order to address the noted concern and reduce risks to the organization.
	Medium/High	The degree of risk is substantially undesirable and either does or could pose a moderate to significant level of exposure to the organization. As such, prompt action by management is essential in order to address the noted concern and reduce risks to the organization.
	Medium	The degree of risk is undesirable and either does or could pose a moderate level of exposure to the organization. As such, action is needed by management in order to address the noted concern and reduce risks to a more desirable level.
	Low	The degree of risk appears reasonable; however, opportunities exist to further reduce risks through improvement of existing policies, procedures, and/or operations. As such, action should be taken by management to address the noted concern and reduce risks to the organization.

It is important to note that considerable professional judgment is required in determining the overall ratings presented on the subsequent pages of this report. Accordingly, others could evaluate the results differently and draw different conclusions.

It is also important to note that this report provides management with information about the condition of risks and internal controls at one point in time. Future changes in environmental factors and actions by personnel may significantly and adversely impact these risks and controls in ways that this report did not and cannot anticipate.

Appendix B – Pharmacy Controlled Substances Data