Office of Internal Audit

UT Southwestern Medical Center

Ambulatory Clinics Controlled and Non-Controlled Substances Audit

Internal Audit Report 20:03

January 21, 2021

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Executive Summary

Background

The UT Southwestern Medical Center (UT Southwestern) operates 53 non-hospital based ambulatory clinics managed by either their respective academic clinical departments or the Ambulatory Operations leadership team and are organized by medical specialties across multiple geographic clinic locations in the Dallas and Ft. Worth metro area. Each clinical location is responsible for managing its own medication procurement, receiving and inventory management to support patient clinical needs.

Medications are classified as controlled substances or non-controlled substances. The Drug Enforcement Administration (DEA) definition of a controlled substance is: Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. An updated and complete list of the schedules is published annually in *Title 21 Code of Federal Regulations (C.F.R.) §§1308.11 through 1308.15*. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential and likelihood of causing dependence when abused. Non-controlled medications include over-the-counter drugs as well as prescription medications that are not regulated by the Controlled Substances Act.

Eight ambulatory clinics procure and store schedule III through V controlled substances. Two of these clinics procure and store schedule II controlled substances. All eight clinics also procure, receive and store non-controlled substances.

The clinics procure controlled substances internally through the Department of Pharmacy. Non-controlled substances are ordered through preferred vendors. Each ambulatory clinic manages non-controlled medication inventory individually based on estimated inventory needs and budget considerations. As controlled and non-controlled substances are administered to patients based on the physician order, the administration is documented in Epic and tracked through the Medication Administration Record (MAR). A waste medication disposal system is used which captures partially administered or unused controlled substances and renders them non-retrievable and unusable.

Pyxis MedStations (Pyxis) are automated dispensing medication units in place for the two clinics that procure and store schedule II controlled substances. Pyxis units are equipped with the necessary features for securing and managing controlled substances, including controlled security access, automated inventory management and disposal controls as well as automated audit trails to document user activities. The other ambulatory clinics store controlled substances in locked cabinets and manually log inventory updates.

Executive Summary

Scope and Objectives

The Office of Internal Audit has completed its Ambulatory Clinics Controlled and Non-Controlled Substances audit. This was a risk based audit and part of the fiscal year (FY) 2020 Audit Plan. The audit scope period was September 2019 through October 2020 for ambulatory clinics that manage controlled and non-controlled substances. The review included assessing the adequacy and effectiveness of processes, oversight and monitoring controls for ambulatory clinic controlled substance processes as follows:

- Controlled substance storage in the clinics is in compliance with UT Southwestern policies.
- Appropriate internal controls are in place for controlled substance procurement, receiving and inventory management.
- Inventory monitoring procedures are in place to identify and resolve discrepancies in a timely manner.
- Physical security controls are in place for the disposal of drug wastage.

Audit procedures included interviews with stakeholders, review of policies and procedures and other documentation, substantive testing and data analytics. We conducted our examination according to guidelines set forth by The Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing.*

Conclusion

The decentralized nature of the ambulatory clinics in securing both controlled substance and non-controlled substance medications requires improvement to reduce the risk of loss or medication theft. In addition, improved monitoring will assist in verifying that expected process and procedures are in place and operating as intended.

Specifically, for non-controlled substances, each clinic is responsible for developing internal processes to manage procurement and inventory and these processes are incomplete. Centralized monitoring of these processes is not performed to ensure consistent practices are in place to reduce the risk of loss or medication theft. For ambulatory clinics that store controlled substances outside of the Pyxis system, monitoring procedures are incomplete to independently verify accurate inventory counts are in place. Independent clinic visits are needed to confirm accuracy of reported inventory counts. Finally, physical access and system access for both controlled substances and non-controlled substances medications requires improvement to ensure only minimum necessary access is granted to medications.

Executive Summary

Included in the table below is a summary of the observations along with their respective disposition within the UT Southwestern internal audit risk definition and classification process. See Appendix A for Risk Rating Classifications and Definitions. There were no priority or high rated issues identified in the audit.

Priority (0)	High (0)	Medium (6)	Low (0)	Total (6)

Key improvement opportunities risk-ranked as Medium are listed below.

Ambulatory Operations Observations

- **#1. Improve Oversight and Implement Standardized Ambulatory Clinics Non - Controlled Substances Procedures** - Each clinic is responsible for developing their procedures for internal processes for managing non-controlled substance procurement and inventory management and no monitoring of these processes is in place. Proper oversight and monitoring controls are necessary to ensure consistent practices and reduce the risk of loss or medication theft.
- **#2 Enhance Physical and Logical System Access to Improve Medication Security -** Physical access to medication rooms and system access to Pyxis stations, securing controlled and non-controlled substances, is not periodically evaluated to ensure only employees who require medication access maintain access to reduce the risk of loss or medication theft.
- **#3 Enhance Clinic Monitoring Process for Controlled Substances -** Ambulatory clinic controlled substance inventory management procedures are incomplete for clinics using locked cabinets and manually tracking inventory balances. Independent clinic visits to confirm accuracy of inventory counts are not occurring increasing the risk of inappropriate use of medications and risk of theft.

Ambulatory Clinic Observations

- **#4 Improve Pyxis Activity Monitoring Processes -** The two ambulatory clinics using the Pyxis system are not reviewing the medication discrepancy and load/refill reports to monitor daily Pyxis activities for unusual activities, increasing the risk of discrepancies going undetected.

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- **#5 Improve Epic Medication Administration Documentation -** A clinic is not documenting medication administration appropriately within the Epic MAR as required per Ambulatory policy AMB 6.15 "*Controlled Substances*" to aid in the reconciliation of Pyxis activity to patient medication administration increasing the risk of inaccurate medication records and incomplete medication reconciliation.

- **#6 Improve Patient Owned Medication Security Procedures** - A clinic receives and stores patient owned medications for patients until they arrive for their scheduled patient visit. Unused medications are stored for an extended period of time increasing the risk of medication loss or theft.

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

Sincerely,

Valla F. Wilson, Vice President and Chief Audit Executive, Office of Internal Audit

Audit Team:
Mia Dinh, Staff Auditor II
Teresa Labbé, Staff Auditor I
Melinda Lokey, Director, Internal Audit
Angeliki Marko, Supervisor, Internal Audit

Executive Summary

cc: Daffodil Baez, Assistant Director Clinical Operations, Ambulatory Services
Steven Bloom, M.D., Chair, Department of Obstetrics & Gynecology
DeAnne Carmichael, Manager, Pharmacy Operations
Sharron Coffie, Director, Opioid Safety, Health System Quality Office
Brian Cohen, Assistant Vice President, Pharmacy Services, University Hospitals
William Daniel, M.D. Vice President & Chief Quality Officer, Health System Quality Office
Arnim E. Dontes, Executive Vice President, Business Affairs
John Forbes, Department Administrator, Department of Urology
Leah A. Hurley, J.D., Vice President for Legal Affairs
Hicham Ibrahim, M.D., M.B.A., Associate Vice President and Chief Medical Officer, Ambulatory Services
Diana Julian, Director, Ambulatory Operations
Kyle Kerr, Manager Pharmacy Operations
Anne Lai Howard, J.D., Director and Managing Attorney, Medical Risk Management, Legal Affairs
Christopher Madden, M.D., Vice President and Chief Operations Officer, UT Southwestern Medical Group
Kristin Martin-Cook, Clinic Practice Manager, Department of Psychiatry
Christopher McLarty, D.N.P., APRN, ACNP-BC, Associate Vice President and Chief Nursing Officer, Ambulatory Services
Mark Meyer, Health System Chief Financial Officer, Health System Affairs
Rebecca Napier, Department Administrator, Department of Surgery
Felicia Neal, Manager Clinical Practice, Department of Urology
Phuong Nguyen, Manager, Pharmacy Operations
Adolfo Ortuzar, Director, IR Operations and Compliance, Academic and Administrative Information Resources
Dennis Pfeifer, Assistant Vice President and Chief Technology Officer, Health System
Dawn Quantrell, Clinic Manager, Department of Psychiatry
Mark Rauschuber, Associate Vice President and Chief Information Officer, Health System
Natalie Ramello, J.D., Vice President and Institutional Chief Compliance Officer, Office of Compliance
Claus Roehrborn, M.D., Chair, Department of Urology
Thomas Spencer, Ph.D., Assistant Vice President, Information Resources Operations and Compliance
Renuka Sundaresan, Director, Ambulatory Operations, Ambulatory Services
Allison Sunleaf, Clinic Manager, Obstetrics & Gynecology
Amie Swindle, Director, Patient Health & Safety
Carol Tamminga, M.D., Chair, Department of Psychiatry
Seth Toomay, M.D., Associate Vice President and Health System Chief Medical Officer
Anju Varghese, Manager, Ambulatory Safety Outcomes & PI
Janice Walton, Department Administrator, Department of Obstetrics & Gynecology
John Warner, M.D., M.B.A., Executive Vice President Health System Affairs & Chief Executive Officer, University Hospitals
Herbert J. Zeh, III, M.D., Chair, Department of Surgery

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response

Ambulatory Operations Observations

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium 🟡 **1. Improve Oversight and Implement Standardized Ambulatory Clinics Non - Controlled Substances Procedures** Each Ambulatory clinic is responsible for developing their internal policies and procedures for managing non-controlled substances including procurement, receiving and inventory management and no monitoring of these processes is in place to confirm appropriate controls are in place to safeguard non-controlled medications. Proper oversight and monitoring controls are necessary to ensure consistent practices and reduce the risk of loss or medication theft. During a walkthrough of seven ambulatory clinic locations in Q1 FY2021, we observed the following: • Inventory management is not in place in all clinics and medications placed into inventory and removed from inventory are not consistently documented and confirmed via secondary witness. • Medication logs used for recording medication inventory changes are not completed. In addition, there were incomplete medication logging formats, missing required fields for medications added and removed from inventory.	1. Develop an Ambulatory Medication Procurement and Inventory Management Policy for non-controlled substances, including: a. Procurement and inventory tracking b. Reporting procedures for discrepancies, c. Use of the Epic MAR to document medication administration, d. Clinic definition of the medication management clinical scope of practice, e. Routine clinic management validation of policy compliance f. Additional steps as applicable 2. Provide clinic personnel training on these medication SOPs and perform competency verification to ensure clinic personnel understand the procedures.	**Management Action Plans:** 1. 1a. A policy inventory was conducted of existing policies and required updates were identified. An Ambulatory Operations policy has been drafted and is being routed through the policy review and approval process. This policy includes requirements for defining roles and responsibilities in each clinic based on the medication management scope of practice, procurement and inventory tracking requirements, use of the Epic MAR to document medication administration, reporting procedures for discrepancies, missing and stolen medications and other key steps. 1b. Policy will be routed and approvals obtained through the Ambulatory Operations policy review structure. 2. Once the policy has been approved, an ambulatory training plan will be developed, including clinic leader tools, to verify competency understanding. 3. Best practice guidance to be provided to clinic and department leadership teams during an upcoming Ambulatory Operations meeting.

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
• Medications administered during ambulatory visits are not consistently documented in the Epic Medication Administration Record (MAR), which aids in the completion of the daily medication reconciliation. • Procedures for reporting medication discrepancies and reporting protocols for discrepancies are not documented.		**Action Plan Owners:** Director Ambulatory Operations, Ambulatory Services Associate Vice President and Chief Nursing Officer, Ambulatory Services **Target Completion Dates:** 1. A. Completed B. March 31, 2021 2. April 30, 2021 3. February 28, 2021

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **2. Enhance Physical and Logical System Access to Improve Medication Security** Periodic evaluation for physical access to medication rooms containing controlled and non-controlled substances is not in place to ensure only required employees have access. In addition, Pyxis system access is not periodically reviewed to ensure only employees who need access have access to the system. Employees who move into new roles and no longer need access are not removed from Pyxis system access in a timely manner. Terminated employees are automatically removed from access at the time of termination. The clinics are not routinely reviewing badge access and Pyxis access to confirm appropriate access after the initial access is granted, increasing the risk of medication loss or theft. A review of two ambulatory clinics using the Pyxis system, identified twenty-six employees with access to Pyxis stations that no longer require access to these stations.	1. Evaluate alternative storage options for clinics not using the Pyxis system to secure controlled substances and provide automated inventory tracking and monitoring. 2. Review, update, and remove badge and Pyxis system access for employees in the the clinics who should not have access. 3. Develop a periodic user access review process to the clinic medication room and update employee access accordingly. 4. Perform periodic review of the Pyxis access reports to ensure access is appropriate based on the employees' roles at the clinics. 5. Implement procedures across the ambulatory clinics to periodically monitor badge access and Pyxis system access for appropriate access.	**Management Action Plans:** 1. An evaluation was performed previously and a determination was made for the clinics that would need Pyxis based on a risk/benefit analysis. Periodic evaluation will be performed to assess risks for clinics storing controlled substances outside of Pyxis machines. 2. We reviewed the list of the employees with badge and Pyxis access to medications and removed the employee access. 3. The clinics have implemented procedures to review employee badge access monthly. 4. The clinics have implemented periodic review of Pyxis user's access using reports provided by the Pharmacy team. 5. The updated Ambulatory Operations policy will include requirement for periodic review of badge access and Pyxis system access.

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
Six ambulatory clinics are not using Pyxis machines to secure controlled substances, rather they are using locked cabinets and relying on manual inventory tracking and monitoring. In one clinic, a review of employee badge access to controlled substance inventory areas identified five out of 48 employees had inappropriate access to the controlled substances due to a change in their role.		**Action Plan Owners:** 1. Associate Vice President and Chief Nursing Officer, Ambulatory Services 2. Clinic Managers 4. 3. Clinic ManagersClinic Manager 5. Director Ambulatory Operations, Ambulatory Services Associate Vice President and Chief Nursing Officer, Ambulatory Services **Target Completion Dates:** 1. April 30, 2021 2. Completed 3. Completed 4. January 31, 2021 5. March 31, 2021

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium 🟡 **3. Enhance Ambulatory Clinic Monitoring Process for Controlled Substances** Ambulatory policy AMB 6.15 "*Controlled Substances*" is incomplete and does not include inventory tracking and monitoring procedures for clinics using the Pyxis system. In addition, the policy does not include independent monitoring to confirm accuracy of reported controlled substance inventory counts, increasing the risk of medications loss or theft. For clinics storing controlled substances in locked cabinets, the Patient Safety team receives monthly self-assessment documentation from each clinic, completed by the clinic employees, and copies of inventory logs. The inventory logs are reviewed for missing information or discrepancies. Independent validation of these results via on site clinic visits are currently not occurring. One clinic uses the Pyxis system and is not completing and reporting daily inventory counts to identify controlled substance discrepancies or missing medications in a timely manner.	1. Update Ambulatory policies for the clinics and include: a. Completion of daily inventory counts, b. Periodic monitoring of inventory for clinics not using Pyxis machines, and c. Review of key Pyxis reporting for discrepancies. 2. Establish an Ambulatory Controlled Substance Committee to monitor and review medication discrepancies to identify and address trends. 3. Develop monitoring procedures across all ambulatory clinics to confirm established procedures are performed as expected. 4. Update clinic monitoring procedures for clinics not using the Pyxis system to include periodic verification of clinic assessment results via onsite clinic visits and inventory counts.	**Management Action Plans:** 1. The Ambulatory Patient Safety controlled substances monitoring activities are moving over to the Opioid Safety team and existing processes will be updated to ensure consistent policies, including wastage and monitoring. Policies will be updated to reflect the application of current Pyxis standards across the ambulatory clinics to ensure consistency across the Health System. Clinic monitoring will include confirmation of daily inventory counts, blind counts for medication dispensing and MAR documentation. 2. The Controlled Substance Oversight Committee is reviewing a request to establish an Ambulatory Controlled Substance Committee. The committee charter and objectives will be defined as well as determining whether non-controlled substances will be included in the committee's scope, or if additional independent monitoring should be performed. 3. We are updating procedures and will include monitoring activities for clinics using Pyxis. 4. We are updating procedures and will include on-site periodic verification of clinic assessment results as part of the overall monitoring activities.

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
		Action Plan Owners: Director, Opioid Safety, Health System Quality Office Associate Vice President and Chief Nursing Officer, Ambulatory Services **Target Completion Dates:** 1. March 31, 2021 2. March 31, 2021 3. April 30, 2021 4. April 30, 2021

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
Ambulatory Clinic Observations		

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Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **4. Improve Pyxis Monitoring Processes** The two ambulatory clinics using the Pyxis system are not reviewing the medication discrepancy and load/refill reports in a timely manner to monitor daily Pyxis activities, increasing the risk of discrepancies going undetected. All discrepancies were resolved and there was no indication of theft or loss, however strengthening controls will assist in decreasing the risk of theft or loss.	1. Require the use of Pyxis discrepancy reports for identifying discrepancies and ensure procedures are in place for ensuring discrepancies are properly resolved. 2. Perform periodic review of the discrepancy and load/refills reports to ensure timely review of monitoring of Pyxis activities.	**Management Action Plans:** 1. Clinic leadership will coordinate with the Pharmacy department to obtain training on reviewing the Pyxis Discrepancy and Load/Refill reports. 2. The Pyxis Discrepancy and Load/Refill reports will be reviewed periodically and follow up actions performed as needed. **Action Plan Owners:** 1. Clinic Managers Manager Pharmacy Operations 2. Clinic Managers **Target Completion Dates:** 1. February 28, 2021 2. March 31, 2021

Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium 🟡 **5. Improve Epic Medication Administration Documentation** In one clinic, the clinic providers are not documenting medication administration within the Epic MAR as required per Ambulatory policy AMB 6.15 "*Controlled Substances*", increasing the risk of inaccurate medication records and incomplete medication reconciliation. The clinic providers are documenting medication administration in the patient records but they are not documenting in the MAR to aid in completion of the routine medication administration reconciliation. Since the clinic does not document within the Epic MAR, the Pharmacy team manually reviews medications administered within the Epic records to compare to Pyxis discrepancy reports. The manual nature of this process requires added time. For clinics that are documenting in the Epic MAR, this monitoring is automated and the Pharmacy team performs follow up on identified discrepancies.	Update clinic procedures to ensure compliance with the policy to document controlled and non-controlled medication administration in the Epic MAR module.	**Management Action Plans:** The Epic Sedation Narrator will be rolled out in early 2021, which will feed the medication information to the MAR module. Once the module is set up, we will complete training. In the meantime, clinic personnel are meeting with the Opioid Safety team to define monthly audit activities. **Action Plan Owners:** Clinic Manager Department Administrator Director, Ambulatory Operations **Target Completion Dates:** February 28, 2021 – Roll out of the Epic Sedation Narrator April 30, 2021 – Completion of training and implementation

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Detailed Observation and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **6. Improve Patient Owned Medication Security Procedures** A clinic receives and stores patient owned medications for patients until they arrive for their scheduled patient visit. Clinic inventory includes controlled substance medications that are no longer needed by patients or for patients that are no longer clinic patients. Unused medications are stored for an extended period of time increasing the risk of medication loss or theft.	1. Consult with Pharmacy personnel to dispose of unused medications for patients that are no longer clinic patients or for medications that are no longer needed by patients. 2. Develop patient confirmation statement to describe standard holding period for patient owned medications before disposal. Implement procedures to ensure all patients, who authorize delivery of medications to the clinic, sign the patient confirmation statement.	**Management Action Plans:** 1. We will contact the Pharmacy and Office of Safety and Business Continuity team to determine the appropriate disposal. 2. We will create the confirmation statement form to describe the holding period for all medication and have existing and new patients sign. **Action Plan Owners:** 1. Clinic Manager Director, Ambulatory Operations 2. Clinic Manager Director, Ambulatory Operations **Target Completion Dates:** 1. February 28, 2021 2. February 28, 2021

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.	**Priority**	An issue identified by Internal Audit that, if not addressed immediately, has a high probability to directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.
	High	A finding identified by Internal Audit that is considered to have a high probability of adverse effects to the UT institution either as a whole or to a significant college/school/unit level. As such, immediate action is required by management in order to address the noted concern and reduce risks to the organization.
	Medium	A finding identified by Internal Audit that is considered to have a medium probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action is needed by management in order to address the noted concern and reduce the risk to a more desirable level.
	Low	A finding identified by Internal Audit that is considered to have minimal probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. 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.