The University of Texas Medical Branch
Audit Services

Audit Report

Pharmacy Inventory Management

Engagement Number 2023-012

May 2024

The University of Texas Medical Branch
Audit Services
301 University Boulevard, Suite 4.100
Galveston, Texas 77555-0150

Pharmacy Inventory Management Audit

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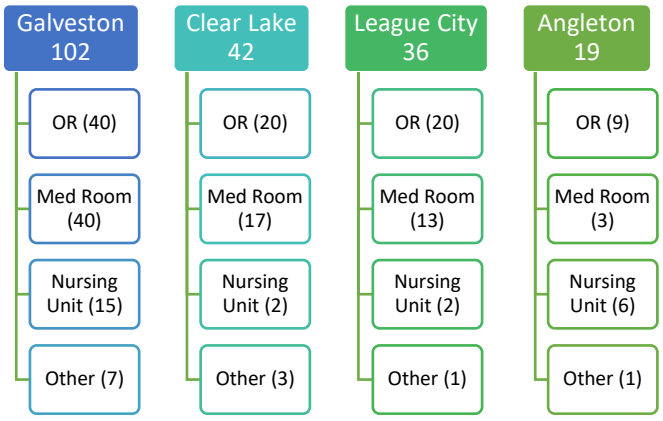
Background

The University of Texas Medical Branch at Galveston (UTMB Health) consists of four hospital campuses that provide pharmaceutical care to patients, which include controlled substances. The Pharmacy department within UTMB Health is responsible for inpatient services, inpatient medication distribution, investigational drug services, drug information, education, outpatient services, purchasing and inventory control, financial monitoring, quality and compliance, and pharmacy informatics. Each campus is responsible for maintaining effective controls to safeguard controlled substance inventory and prevent/detect diversion.

Drug diversion refers to the illegal distribution or abuse of prescription drugs or use for purposes not intended by the prescriber. There have been multiple incidents of diversion reported recently from Texas health care institutions resulting in substance abuse and overdose deaths. These cases emphasize the importance of an effective internal control environment related to the safeguarding of inventory for controlled substances as well as preventing and detecting diversion.

UTMB Health's Pharmacy inventory is controlled through various information systems. Morris & Dickson is the primary pharmaceutical distributor used for ordering controlled substances and other medications. The Controlled Substance Ordering System (CSOS) is utilized for compliance with the Drug Enforcement Agency (DEA) to order controlled substances through vendors to ensure reporting all controlled substances to the DEA occurs. These orders are delivered by the UTMB wholesaler, received by UTMB Health Pharmacy, and then stored in the Pyxis System, which is an automated medication dispensing system. The Pyxis machine provides secure medication storage on patient care units, along with electronic tracking of the use of narcotics and other controlled medications.

The following diagram represents the 199 Pyxis machines containing controlled substances and their respective locations at each of the UTMB Health hospitals.



Due to the significant health risk presented with controlled substances, UTMB Health is subject to rules and regulations of multiple outside agencies, primarily the DEA and Texas State Board of Pharmacy. In fiscal year 2023, risks related to the pharmacy inventory environment were identified as high-risk resulting in Audit Services including an audit engagement for this area in its fiscal year 2023 audit plan. This engagement was carried forward to fiscal year 2024 to ensure coverage of this high-risk area.

In September 2023, UTMB Health implemented a Diversion Prevention Task Force Committee, which is a multi-disciplinary team comprised of Pharmacy, Compliance, Legal, Anesthesiology, and Nursing that was established to provide oversight for the diversion prevention program. The committee meets quarterly and is responsible for evaluating practices and procedures, as well as providing recommendations for process enhancement. Additionally, the committee will manage the investigation of all reports of suspected drug diversion and will provide guidance for an appropriate course of action.

In October 2023, UTMB Health implemented a Controlled Substance Diversion Committee under the direction of the Diversion Task Force Committee. This committee meets on a monthly basis. This committee will develop policy and practice updates to fulfill state and federal regulatory requirements and will be responsible for taking action on the operational standards and diversion surveillance.

In addition to the afore mentioned systems, UTMB Health has also implemented FairWarning, which is a controlled substance tracking and diversion detection software used to monitor alerts and detect suspicious behavior patterns that may indicate inappropriate access or drug diversion. FairWarning analyzes medication dispenses from Pyxis, administration, excessive waste, unusual access of controlled substances, inventory discrepancies, unusual waste, and other data from Epic, UTMB Health's electronic health record, to identify undocumented events. UTMB Health Pharmacy is researching additional methods to enhance the use and monitoring of the FairWarning alert system more efficiently. Additionally, further research has been undertaken into Pyxis machine functionality to enable the "too close" warning for scheduled and override removals of controlled substances. An alert will occur in Pyxis when a controlled substance is removed before the allotted time to administer the medication to the patient.

The Pharmacy department is also working with the Design and Construction department to install surveillance cameras in all locations where controlled substances are stored. This large undertaking will require extensive planning and budgeting between multiple UTMB Health teams. Currently, fifteen cameras are surveilling Pyxis stations with controlled substances on the Galveston Campus and nine at League City and Clear Lake combined. The cameras are operated by the UTMB Health Police Department and utilized to review stored footage when necessary.

Objective, Scope and Methodology

Objective

The objective of this engagement was to assess the effectiveness of internal controls over controlled substance medications to provide assurance relative to safeguarding inventory, preventing/detecting diversion, and ensuring compliance with outside agencies.

Scope of Work and Methodology

The scope of work included policies, procedures, internal controls, and system access related to controlled substances medications at the Angleton Danbury, Clear Lake, Galveston, and League City campuses.

The methodology used to assess the effectiveness of these controls included reviews of policies and procedures, inquiry-based process walkthroughs, physical observations, detail testing of monitoring reports, and full population testing of monitoring reports using data analytics.

Executive Summary

UTMB Health Pharmacy has made significant efforts to strength the internal controls surrounding detection and prevention of controlled substances which included implementing oversight task forces and committees to prevent and monitor issues. However, Audit Services identified additional opportunities to improve monitoring review processes involving controlled substances overrides and discrepancies. Additionally, the Pharmacy department can develop and improve the standard operating procedures institution wide surrounding controlled substances from the time the inventory reaches the institution to the time of administration, waste, or return.

Detailed Results

Override Monitoring

Override monitoring is a critical control for the Pharmacy department, as the override function allows a person to remove a medication from the Pyxis machine before a pharmacist reviews the order. The purpose of the override function is to allow access to medications in cases where the order is not yet entered into the system, and taking time to enter it would endanger the patient. While the function is necessary in some emergent cases to administer the medication promptly while the order is being processed, it can be abused to pull medications in non-emergent situations. To mitigate the risk of utilizing the override function for non-emergent or unapproved transactions, all campuses should be monitoring overrides of controlled substances daily with appropriate follow up, when necessary, to document the unjustified utilization of the override function. Monitoring provides security to deter drug diversion for all medication use to match the correct patient with the correct drug, the correct dosage and at the prescribed time.

These measures, along with complete documentation, are generally accepted as a standard for safe medication practices.

Audit Services assessed the daily monitoring controls in place for review of override transactions and determined they are not operating as intended at all campuses. Additionally, the tracking mechanisms used for documenting investigations required as a result of unjustified overrides are inconsistent across campus, with some being nonexistent. For the League City, Angleton Danbury, and Clear Lake campuses daily monitoring of overrides is occurring and a tracker or log is being used to document follow-up communication, as necessary. To further enhance consistencies and best practices across the university there are opportunities for all campuses to formalize the tracking procedures. During review of the Galveston campus, Audit Services concluded the monitoring controls in place for daily review of override transactions are not operating as intended, and the Galveston campus does not maintain a tracking mechanism to follow-up with nurse/nurse managers in instances when an override discrepancy has been identified. During testing of the override monitoring reports for the Galveston campus, more than 50% of the reports reviewed contained transactions that indicated an additional follow-up was necessary to resolve the discrepancy; however, no additional information was available to determine whether the transactions had been resolved.

Discrepancy Monitoring

Discrepancies can be generated in a multitude of ways. The primary reason for a discrepancy to occur would be from controlled substances being removed from a Pyxis machine and not immediately administered or not wasted in the machine accurately. To mitigate the risk of controlled substance inventory discrepancies, daily reconciliations take place by the pharmacist at each location. The Pharmacy Managers then verify the reconciliations. Discrepancies should be tracked until resolved or elevated to the appropriate task force for further review. Additionally, all medications should be administered in a timely manner.

In a review of an unreconciled dispense report from Epic, a controlled substance was dispensed from Pyxis but did not show as administered to the patient in Epic for over 8 hours. Additionally, during the detail testing of discrepancy transactions, a controlled substance was removed from Pyxis but was not recorded as wasted until over 27 hours later with a witness. Subsequent to these identified issues, the Pharmacy department worked interdepartmentally to update the non-IHOP 7.56 Administration of Controlled Substances Policy to establish a timeframe that doses are to be administered immediately after removal and will be flagged in the Pyxis system as delayed if not administered within the hour, as compared to the previous timeframe of 24 hours.

Additionally, Audit Services reviewed the monitoring controls in place for unreconciled dispenses and undocumented waste by reviewing reports generated from the Pyxis system. Through detail review of 27 undocumented waste monitoring reports for the League City, Clear Lake, and Angleton Danbury campuses, five of the reports reviewed did not contain a signature on the

report verifying a review was completed. The Galveston campus currently does not generate and monitor undocumented waste reports.

Operating Room Reconciliations:

Operating Room (OR) reconciliations are reconciliations performed after each operating room case comparing medications used during the medical event to supporting documentation and resolving any discrepancies that may be discovered in real-time.

In prior years, the Pharmacy department reconciliation technician would be available for a designated period. All cases lasting beyond the designated period will be reconciled the following morning to alert the anesthesia doctors from overnight of a discrepancy. However, a new procedure was introduced in fiscal year 2024 to mitigate discrepancies by placing OR pharmacy technicians in the OR rooms to prevent discrepancies in real-time, which decreased the unresolved discrepancy percentages from 19% in fiscal year 2023 to 13% in fiscal year 2024 (year to date).

Through detail review of the OR Reconciliation reports Audit Services identified inconsistent monitoring to ensure OR discrepancies are identified and resolved timely.

Recommendation 001 High – Override, Unreconciled Dispenses, Undocumented Waste, and Operating Room Reconciliation Monitoring

The Pharmacy department should develop and communicate institution wide procedures to reconcile and monitor override transactions, unreconciled dispenses, delayed waste, and operating room reconciliations. Additionally, the procedures should include key elements such as tracking and logging of follow-ups when discrepancies arise, escalating unresolved discrepancies, and documenting the results/outcomes.

Management's Response:

The Department of Pharmacy along with the Controlled Substance Diversion Prevention Committee and subsequently, the Diversion Prevention Task Force will:

Part A:

Update related Policies and Procedures to:

- Increase reconciliation of override transactions in non-high risk patient care areas (i.e., beyond OR) from 10% to 100% for schedule II and other targeted schedule III-IV controlled substances.
- Minimize current P&P timeframes to administer, waste, return, and/or transfer high risk control substances.
- Redefine resolved discrepancies to more stringent standards and include consequences for unresolved discrepancies.

- Minimize escalation times for unresolved discrepancies.

Implementation Date: May 30, 2024

Part B:
Include related competency-based training of updated policies and procedures in mandatory orientation and annual training for all employees handling high-risk controlled substances.

Implementation Date: July 31, 2024

Responsible Parties: AVP, Pharmacy Services

FairWarning Investigations:

FairWarning is a privacy monitoring technology that interfaces with EPIC and analyzes EPIC user activity to detect potentially inappropriate access to patient information and other privacy violations. The FairWarning software automatically sends the Quality Assurance Pharmacy a report of transactions that may require investigation. The Quality Assurance Pharmacy Supervisor is tracking open and active investigations from FairWarning, such as discrepancies of unreconciled dispense, excessive waste, delayed waste, and inventory discrepancies. There has been a delay in resolving these cases due to an absence of an enforceable policy or standard operating procedure to assist in the timely completion of FairWarning investigations.

Recommendation 002 High – FairWarning Investigations
The Pharmacy department should develop a workflow of the process for performing FairWarning investigations, implement an enforceable policy to assist with the timely completion of FairWarning Investigations, and communicate any unresolved discrepancies due to non-responsiveness to the Diversion Task Force Committee and the Controlled Substance Diversion Committee.

Management's Response:
The Department of Pharmacy along with the Controlled Substance Diversion Prevention Committee and subsequently, the Diversion Prevention Task Force will:

Part A:
Re-evaluate related available technologies and services in the market that will improve access and timeliness to diversion prevention and surveillance data and also re-evaluate related data analytics services in the market, if available. If no other options are available, the Department of Pharmacy will recruit and hire additional staff to provide timely and accurate data analytics.

Implementation Date: July 31, 2024

Part B:
Implement new drug diversion technology.

Implementation Date: October 31, 2024

Responsible Parties: AVP, Pharmacy Services

Physical Access Monitoring:
Badge access is required to enter the main pharmacy vault room. The main pharmacy vault room is used to store and maintain the controlled substance inventory prior to transferring to Pyxis machines. Access is granted only to a limited number of employees such as the pharmacy managers and pharmacy technicians stationed in the vault room. Additionally, Pyxis requires users to use their biometric fingerprint to log into the Pyxis system and the CII Vault Safe.

Through process walkthroughs, it was identified the vault room access listing is not monitored or verified to ensure only appropriate staff members have access to the vault. Audit Services identified 2.3% of badge holders have access to at least one or more pharmacies at League City, Galveston, Angleton Danbury, and Clear Lake campuses, but were not found in the active employee roster, the agency/non-UTMB roster in the Healthcare System Staffing System, or the employee directory.

Recommendation 003 High – Physical Access Monitoring
The Pharmacy department should implement a process to monitor badge access at all campus locations on a regular and consistent interval. In addition, the department should immediately remediate inactive or inappropriate users.

Management's Response:
Badge access is currently the responsibility of the DOP key control officers (KCO) per UTMB Health policy. Pharmacy Technician Specialists - Business Coordinators are designated KCO at each hospital campus and have standard work responsibilities to maintain access to pharmacy of all employees assigned to their respective campus. KCO responsibilities are currently being assigned to each Pharmacy Technician Specialists - Business Coordinators at all campuses to improve access control to respective pharmacies. In addition, the Pharmacy Technician Supervisor – HR Liaison and Lead Pharmacy Technicians are responsible for granting initial pharmacy access during new employee onboarding and removal of access during employee separation from the department. The Department of Pharmacy, Medication Safety Team, Pharmacy Technician Supervisor – HR Liaison, and Administrative Business Manager will

implement a periodic audit and accountability system for current related processes.

Implementation Date: June 30, 2024

Responsible Party: AVP, Pharmacy Services

System Access Monitoring

Through process walkthroughs, it was identified the pyxis system user access listing is not monitored or verified to ensure only appropriate staff members have access. Audit Services identified a total of 1.6% of Pyxis System users have access to at least one or more pyxis machines at League City, Galveston, Angleton Danbury, and Clear Lake campuses, but were not found in the active employee roster, the agency/non-UTMB rusher in the Healthcare System Staffing System or the employee directory. Additionally Audit Services identified .07% of the 1.6% were no longer employed at UTMB Health.

Recommendation 004 High – System Access Monitoring

The Pharmacy department should implement a process to monitor pyxis user access at all campus locations on a regular and consistent interval. In addition, the department should immediately remediate inactive or inappropriate users.

Management's Response:

The Department of Pharmacy's Medication Safety Team and Senior Pharmacy – Pharmacy Informatics will:

- Develop and implement processes for Pyxis access for non-pharmacy employees at the time of separation from UTMB. This process should be integrated into the related process for pharmacy employees.
- Implement a periodic audit and accountability system for current and proposed related processes.

Implementation Date: July 31, 2024

Responsible Party: AVP, Pharmacy Services

Retainment of Controlled Substance Order Forms:

The DEA Order Form (DEA Form 222) must be used for distributing Schedule II controlled substances. A pharmacy distributing controlled substances or dangerous drugs to another pharmacy (or doctor) must adhere to the following procedures:

Per the Code of Federal Regulation Section 1305.27 Preservation of electronic orders:

(a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement.

(b) A supplier must retain each original order filled and the linked records for two years.
(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location.

During the engagement, Audit Services identified that the DEA 222 forms were not maintained internally institution wide as required.
The CSOS ensures all controlled substance orders are reported to the DEA, but it does not eliminate the Federal Regulation recordkeeping requirement to retain the DEA 222 forms for two years.

Recommendation 005 Medium – Retainment of Controlled Substance Order Forms
The Pharmacy department should implement a process to ensure each campus pharmacy retains the original signed electronic DEA Order Forms for two years internally to ensure compliance with Federal Regulation recordkeeping requirements.

Management's Response:
The Department of Pharmacy's Medication Safety Team began saving all DEA 222 forms internally during the course of the audit and will continue to do so going forward. The Department of Pharmacy will implement a periodic audit and accountability system for record retention processes.

Implementation Date: June 30, 2024

Responsible Party: AVP, Pharmacy Services

Inventory Returns Recordkeeping:
Audit Services identified the Meds Pending Destruction Report and reverse distributors Service Event Inventory Report retained for recordkeeping purposes were not signed by the vendor representative, the pharmacy manager, or the technician to document and verify the return of controlled substance inventory for accuracy.

Record-keeping requirements for the Meds Pending Destruction Report are not addressed within Pharmacy non-IHOP Policy and Procedure 6.45 Controlled Substance Destruction.

Recommendation 006 Medium – Inventory Returns Recordkeeping
The Pharmacy department should develop oversight procedures to verify the return of controlled substances and to ensure signed copies of the reverse distributor vendors' Service Event Inventory Report and Meds Pending Destruction Report from the Pyxis system are retained for recordkeeping purposes.

Management's Response:
The Department of Pharmacy must comply with the current law and related pharmacy record retention policy. The Pharmacy will implement a periodic audit and accountability system for inventory returns recordkeeping processes.

Implementation Date: June 30, 2024

Responsible Party: AVP, Pharmacy Services

Storage of Controlled Substance Returns:

Per Texas Administrative Code 26, Health and Human Services Commission; Chapter 748 Minimum Standards for General Residential Operations; Sub Chapter L, Medication Division 3: Medication Storage and Destruction, Rule 748.211: Store medication covered by Schedule II of the Texas Controlled Substances Act under a double lock in a separate container.

The Pharmacy department stores controlled substances to be destroyed in the main pharmacy vault room within a secured destruction bin. The pharmacy buyers schedule UTMB Health's third-party vendor, Inmar, to pick up the controlled substances quarterly. During process walkthroughs, Audit Services observed an expired box of fentanyl stored on an open shelf within the pharmacy vault room due to fact the destruction bin reached maximum capacity. Due to a lack of operating procedures, pharmacy vault staff failed to notify pharmacy buyers the bin was full and an Inmar pick up was needed. At that time, pharmacy personnel were unaware pick-ups outside of the quarterly schedule were permitted and no communications regarding ad hoc pickups were made by pharmacy leadership. However, through inquiries, it was confirmed controlled substance pick-ups were permitted to be scheduled on an as-needed basis.

Recommendation 007 Medium – Storage of Controlled Substance Returns
The Pharmacy department should develop a process of communication to schedule the third-party vendor for an ad-hoc pickup when the waste bins are ready to be emptied. Additionally, the DOP should develop a process to ensure the controlled substances awaiting pick up for destruction are properly and adequately safeguarded according to Texas Administrative Code 26.

Management's Response:
The Department of Pharmacy's Medication Safety Team, Purchasing and Inventory Management Team, and Acute Care Pharmacy Operations Team at the Galveston Campus will:

Part A:
Eliminate the physical vault and convert to 100% storage and inventory control from the C2Safe as with all other campus pharmacies. This will eliminate the

associated risks of a physical vault, including, but not limited to access control, electronic inventory monitoring, physical inventory control, etc.

Implementation Date: August 30, 2024

Part B:
Implement a periodic audit and accountability system for current related processes.

Implementation Date: June 30, 2024

Responsible Party: AVP, Pharmacy Services

The Pharmacy department provides extensive guidance within the Pharmacy Institutional Handbook of Operating Procedures (IHOP) and Non-IHOP policies to support managing activities for the Controlled Substance Inventory.
Currently, no individual is designated to maintain the Pharmacy Intranet that maintains the policies, which resulted in outdated policies provided to Audit Services. This creates a potential risk of non-compliance with policies for staff when accessing the outdated policies for reference.

Recommendation 008 Medium – Policies and Procedures
The Pharmacy department should maintain one true source of information for individuals accessing the current Pharmacy non-IHOP policies. Additionally, a designation should be made for a UTMB Health pharmacy employee to review and monitor the expiration dates of policies. Finally, accountability guidelines should also be included within the policies and communication of new policies and/or policy changes be made.

Management's Response:
The pharmacy policies and procedures committee meet monthly to maintain all medication use related IHOP and departmental policies and procedures. The committee chair recognizes this finding as an exception and has already started implementation of corrective action (policy reconciliation).

Implementation Date: August 30, 2024

Responsible Party: AVP, Pharmacy Services

Conclusion

We greatly appreciate the assistance provided by Pharmacy staff and management and hope that the information presented in our report is beneficial.

This audit was conducted in conformance with The Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing*. Additionally, we conducted the audit in accordance with Generally Accepted Government Auditing Standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions on our audit objectives.

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