THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center®

MDA24-102 Pharmacy Controlled Substances

November 7, 2024

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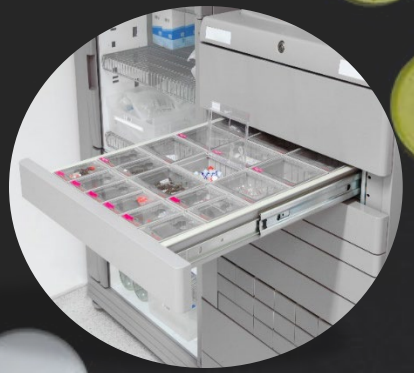

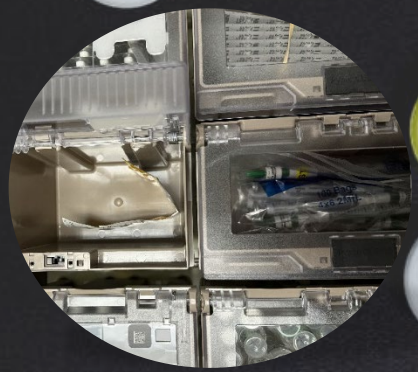

Executive Summary

Internal Audit conducted a review to assess controls in place over ordering, receiving, and accounting for controlled substances located in various Pharmacy locations, including the vault, Houston Area Locations (HALs), and surgical areas. This also included a review of the process established to account for waste and transfers to other locations.

The Division of Pharmacy has robust procedures for handling of controlled substances including, but are not limited to, inventory distribution, storage and security, and waste. Additionally, the Division oversees the institution's multiple pharmacy locations, both on and offsite, including retail and non-retail locations.

Our review identified that controls are in place for the processes in handling of expired/waste medication, and operating room suites. However, we identified areas of opportunity to strengthen processes and controls:

The U.S. Department of Justice, the Drug Enforcement Agency (DEA), and the Texas Department of Public Safety identify a controlled substance as a substance that, due to its abuse potential, is subjected to extensive licensing, registration, storage, security, use, and disposal requirements. The DEA requires that pharmacies maintain complete and accurate records for each controlled substance received, sold, delivered, or disposed.

RISK CATEGORY	OPPORTUNITIES	RISK CONSIDERATIONS
Operational	Ensure appropriate user access to Pyxis stations	• Personnel may have unauthorized/unnecessary access to controlled substances
Operational	Ensure sufficient Segregation of Duties	• Controlled substances may be mishandled/diverted
Compliance	Consistently use Original DEA Form	• Penalties or fines may result from noncompliance
Fraud	Ensure dual acknowledgements consistently occur	• Controlled substances may be mishandled/diverted
Operational	Consider options for integrating EyeCon with Epic	• Errors or irregularities may result from manual data entry

Further details are outlined in the Detailed Observations section. Less significant issues were communicated to management separately.

Management Summary Response:
Management agrees with the observations and recommendations and has developed action plans to be implemented on or before March 31, 2025.

Appendix A outlines the objective, scope, and methodology for the engagement.

The courtesy and cooperation extended by the personnel in the Division of Pharmacy are sincerely appreciated.

Ann Lovelady, CIA, CHIAP, CFE, CRMA, CCSA
AVP & Chief Audit Officer *Ad interim*
November 7, 2024

DETAILED OBSERVATIONS

1. Ensure Appropriate User Access to Pyxis Stations — RANKING: HIGH

Per institutional policy, system access is restricted to authorized personnel in accordance with their scope of practice. We identified 36 non-pharmacy personnel with inappropriate access to Pyxis stations in Pharmacy areas. Additionally, an Informatics end user who was not in Pharmacy held a "Pharmacist" user role. In these instances, management acknowledged these individuals' access was given in error and were corrected promptly. Finally, 18 Pharmacists had dormant accounts, as their job roles did not require them to access Pyxis stations on a regular basis. Pharmacy Operations grants Pyxis station access based on the employee's job title and work area. Inappropriate access increases the risk of drug diversion.

Recommendation
Management should enhance controls over user access to include and not be limited to routine monitoring and deactivate dormant accounts.

Management Action Plan
We will work with Pharmacy Analytics to build a report that pulls information from both the Institutional Active Directory and Pyxis ES server to reconcile area assignments in Pyxis. Once the report is built, we will develop a SOP that outlines audit steps to include pharmacy operations and nursing leadership to review and correct area assignments as needed. Our plan is to audit area assignments twice a year.

Responsible Executive: Rosanna Morris
Division/Department Executive: Ryan Roux
Owner: Lauren Scott
Due Date: March 31, 2025

2. Ensure Sufficient Segregation of Duties — RANKING: MODERATE

We identified nine instances where an order (internal transfer) from a Retail Pharmacy location to the Vault was submitted and received by the same individual as documented in Epic. These instances indicated a lack of segregation of duties, and an increased risk of drug diversion. We did observe compensating controls such as weekly counts to monitor inventory that would help identify when an order was not received. Additionally, no indication of drug diversion was noted based on the procedures performed.

Recommendation
Management should ensure that duties are sufficiently segregated for all controlled substance orders, including internal transfers.

Management Action Plan
We will add language to our existing controlled substance ordering and receiving SOPs to include that the ordering and receiving individual must be different. We will also create an SOP specific to ordering and receiving controlled substances from the vault. We will implement a retrospective audit process to ensure compliance.

Responsible Executive: Rosanna Morris
Division/Department Executive: Ryan Roux
Owner: Lori Bertrand
Due Date: December 31, 2024

3. Consistently Use Original DEA 222 Form — RANKING: MODERATE

Per DEA guidance, an original signed DEA Form 222 must be used when transferring controlled substances. However, we noted in one instance a faxed copy was used to request a controlled substance transfer from the supplier (vault) to The Proton Therapy Center (PTC). A provider who is a DEA registrant performed the request for PTC while on leave. According to management, this provider should have registered a Power of Attorney with the DEA to submit the original form, therefore ensuring original forms will be submitted to the supplier (vault). When DEA requirements are not followed, noncompliance may result in fines or penalties.

Recommendation
Management should enhance controls to ensure that in the absence of the DEA registered provider the original DEA forms are submitted as required.

Management Action Plan
We will work with institutional DEA registrants that are responsible for controlled substances at their respective locations to ensure a Power of Attorney is established with the DEA using the provided DEA Form (https://www.deaecom.gov/poa.html). We will also create an SOP that is given to non-pharmacy DEA registrants that outlines their responsibilities and includes identifying a Power of Attorney.

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4. Ensure Dual Acknowledgements Consistently Occur — RANKING: MODERATE

Management's current practice is to have two individuals acknowledge receipt of controlled substance orders by signing the invoice. Our review indicated two invoices that did not contain dual signatures as required. In another instance where no drugs were received, the invoice had no signatures, although still required. When evidence of the dual acknowledgements is not present, there is a risk that it did not occur, therefore increasing the risk of drug diversion.

Recommendation
Management should ensure that current practice are consistently followed, including documentation of signature review.

Management Action Plan
Pharmacy operations that receive controlled substances will update SOPs to ensure two individuals are signing the invoice, even if the invoice states a zero quantity was shipped. Re-education of SOPs will be provided to all staff involved in receiving controlled substances.

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5. Consider Options for Integrating Eyecon with Epic — RANKING: MODERATE

Currently, in Retail Pharmacy (R2/R10) EPIC tracks beginning inventory as well as dispensed amounts. However, the remaining inventory is manually determined through physical counts using the Eyecon machine. The result of this count is manually entered into EPIC. The manual count and data entry increases the risk that errors or irregularities may occur. Automated integration between EPIC and Eyecon would minimize potential errors and increase efficiency of these processes. This was also observed by Retail Pharmacy management in a recent gap analysis performed prior to our audit.

Recommendation
Management should consult with the Epic Team on possible strategies that would allow for the integration of Eyecon with Epic.

Management Action Plan
Our Epic team explored a workaround to avoid building a true interface with Eyecon, but that effort was unsuccessful. We will submit an IT prioritization request to the Pharmacy Optimization group to build the interface (to be reviewed on 10/28/2024). If the interface is prioritized as a project we will submit for further, IT governance approval.

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Appendix A

Objective, Scope and Methodology

The objective of the review is to assess the controls in place over ordering, receiving, administering, and accounting for controlled substances located in various Pharmacy locations, including the vault (main campus), Houston Area Locations, and surgical areas. The period of review was Fiscal Year 2024 to date, and any related periods.

Our procedures included, but not limited to, the following:

- Performed on-site observations and interviewed key personnel across multiple locations to gain an understanding of key processes and controls.
- Reviewed relevant institutional policies and federal/state guidance related to controlled substances.
- Reviewed and tested purchasing documentation (invoices, receiving reports, etc.) for controlled substances from external vendors.
- Assessed reconciliations and evaluated resolution of discrepancies identified.
- Reviewed activities such as internal transfers, handling of expired drugs, and destruction of damaged controlled substances.

Our internal audit was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing*. The internal audit function at MD Anderson Cancer Center is independent per the *Generally Accepted Government Auditing Standards (GAGAS)* requirements for internal auditors.

Number of Priority Findings to be monitored by UT System: *None*
A Priority Finding is defined as "*an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.*"