



An Audit Report on

# Controlled Substances Management at The University of Texas at Tyler

- UT Tyler HSC's Inpatient and Outpatient pharmacies had effective processes for tracking, securing, and disposing of controlled substances.
- Safeguards were in place to appropriately limit access to controlled substances, preventing potential diversion.

Lisa R. Collier, CPA, CFE, CIDA  
State Auditor

The University of Texas at Tyler Health Science Center's (UT Tyler HSC) Inpatient and Outpatient Pharmacies had adequate processes to ensure that controlled substances were properly tracked and secured from ordering through dispensing and, as applicable, disposal. They also implemented safeguards to appropriately limit access to controlled substances.

In addition, UT Tyler HSC ensured that the annual inventory of controlled substances was conducted as required; however, it should strengthen its monitoring over the weekly inventories.

- [Background](#) | p. 3
- [Audit Objective](#) | p. 16

*This audit was conducted in accordance with Texas Government Code, Sections 321.013 and 321.0132.*

## LOW

### **ORDERING, ADMINISTERING, AND DISPENSING CONTROLLED SUBSTANCES**

UT Tyler HSC had effective processes to track the receipt, administration, and dispensing of controlled substances.

[Chapter 1 | p. 7](#)

## MEDIUM

### **INVENTORY COUNTS**

UT Tyler HSC's pharmacies conducted the required annual inventory. However, required weekly inventories were not consistently conducted.

[Chapter 2 | p. 11](#)

## LOW

### **DRUG DISPOSAL AND RETURNS**

UT Tyler HSC established processes to help ensure that the risk of drug loss or diversion is minimized during the drug disposal and return processes.

[Chapter 3 | p. 13](#)

## LOW

### **SECURITY AND ACCESS CONTROLS**

UT Tyler HSC implemented physical and user access controls to safeguard and prevent diversion of its controlled substances.

[Chapter 4 | p. 15](#)

For more information about this audit, contact Audit Manager Hillary Eckford or State Auditor Lisa Collier at 512-936-9500.

October 2024 | Report No. 25-004

---

## Summary of Management's Response

---

Auditors made recommendations to address the issues identified during this audit, provided at the end of certain chapters in this report. UT Tyler HSC agreed with the recommendations.

---

## Ratings Definitions

---

Auditors used professional judgment and rated the audit findings identified in this report. The issue ratings identified for each chapter were determined based on the degree of risk or effect of the findings in relation to the audit objective(s).

**PRIORITY**: Issues identified present risks or effects that if not addressed could *critically affect* the audited entity's ability to effectively administer the program(s)/function(s) audited. Immediate action is required to address the noted concern(s) and reduce risks to the audited entity.

**HIGH**: Issues identified present risks or effects that if not addressed could *substantially affect* the audited entity's ability to effectively administer the program(s)/function(s) audited. Prompt action is essential to address the noted concern(s) and reduce risks to the audited entity.

**MEDIUM**: Issues identified present risks or effects that if not addressed could *moderately affect* the audited entity's ability to effectively administer the program(s)/function(s) audited. Action is needed to address the noted concern(s) and reduce risks to a more desirable level.

**LOW**: The audit identified strengths that support the audited entity's ability to administer the program(s)/function(s) audited or the issues identified do not present significant risks *or* effects that would negatively affect the audited entity's ability to effectively administer the program(s)/function(s) audited.

For more on the methodology for issue ratings, see Report Ratings in Appendix 1.

## Background Information

---

### The University of Texas at Tyler Health Science Center

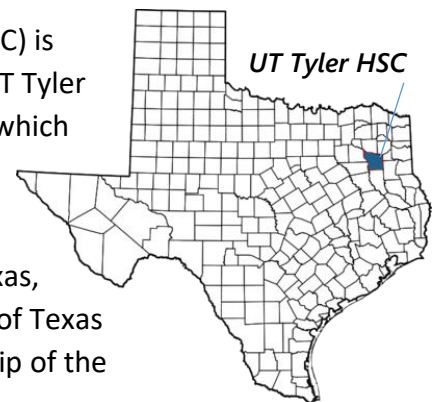
---

#### Hospital

The University of Texas at Tyler Health Science Center (UT Tyler HSC) is one of the five campuses of The University of Texas at Tyler. The UT Tyler HSC campus includes the UT Health North Campus Tyler Hospital, which contains an emergency room, various clinics, and inpatient and outpatient pharmacies.

The North Campus Tyler hospital is operated by UT Health East Texas, a joint venture between Ardent Health Service and The University of Texas System. Ardent, a for-profit company, maintains majority ownership of the joint venture and manages day-to-day operations.

Although UT Health East Texas is managed by Ardent, the North Campus Tyler hospital is considered a state entity as part of The University of Texas System.



---

### Management of Controlled Substances

---

UT Tyler HSC is registered as a hospital with the Drug Enforcement Administration (DEA). The registration allows UT Tyler HSC's pharmacies to legally handle controlled substances in Schedules II through V.

The Inpatient and Outpatient (retail) pharmacies are located in separate areas within the hospital. Each is responsible for ordering and managing its own inventory in accordance with applicable requirements and processes.

#### Inpatient Pharmacy

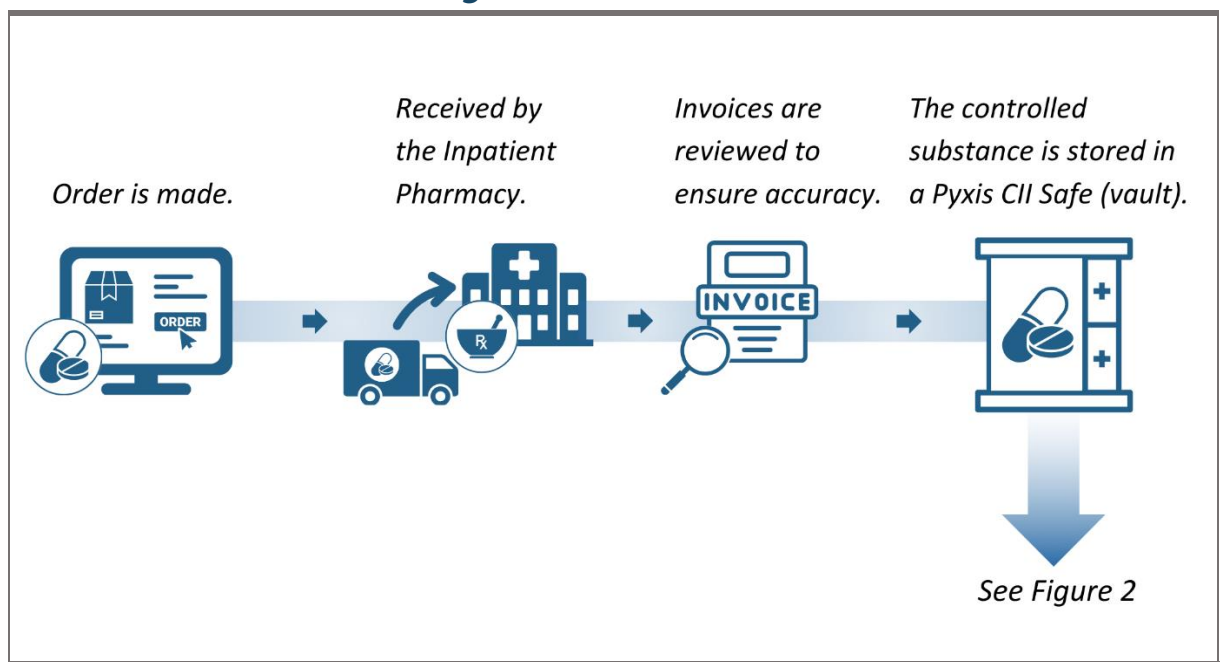
The Inpatient Pharmacy, managed by a Pharmacy Director, is responsible for ordering and managing controlled substances used at the North Campus Tyler hospital. The pharmacy uses an integrated inventory management system—called the Pyxis System—to track controlled substances through ordering and

receiving, distribution to the automated dispensing machines, administration to patients, and on-site disposal (within the Pharmacy or in patient care areas) or returns (through a reverse distributor<sup>1</sup>).

Figure 1 shows the Inpatient Pharmacy’s process from when an order for a controlled substance is made to securing the controlled substances in its inventory.

Figure 1

***UT Tyler HSC’s Inpatient Pharmacy’s Process for Ordering and Storing Controlled Substances***



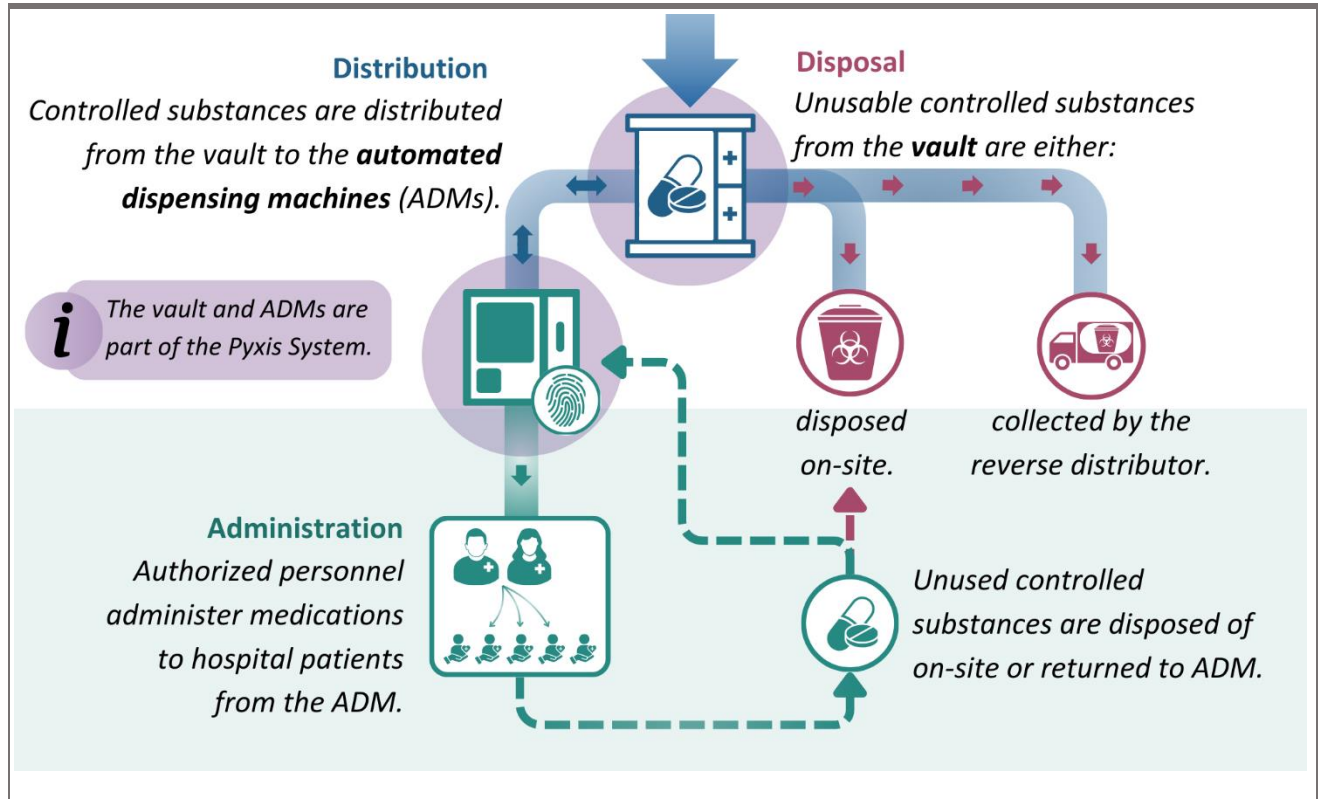
Source: UT Tyler HSC.

<sup>1</sup> A reverse distributor is a vendor authorized by the U.S. Drug Enforcement Agency (DEA) to collect controlled substances from other DEA registrants (such as pharmacies and hospitals) and to either return the controlled substances to the manufacturer or arrange for their destruction.

Figure 2 shows the Inpatient Pharmacy’s process for the distribution, administration, and disposal of controlled substances.

Figure 2

### UT Tyler HSC’s Inpatient Pharmacy’s Process for Distributing, Administering, and Disposing Controlled Substances



Source: UT Tyler HSC.

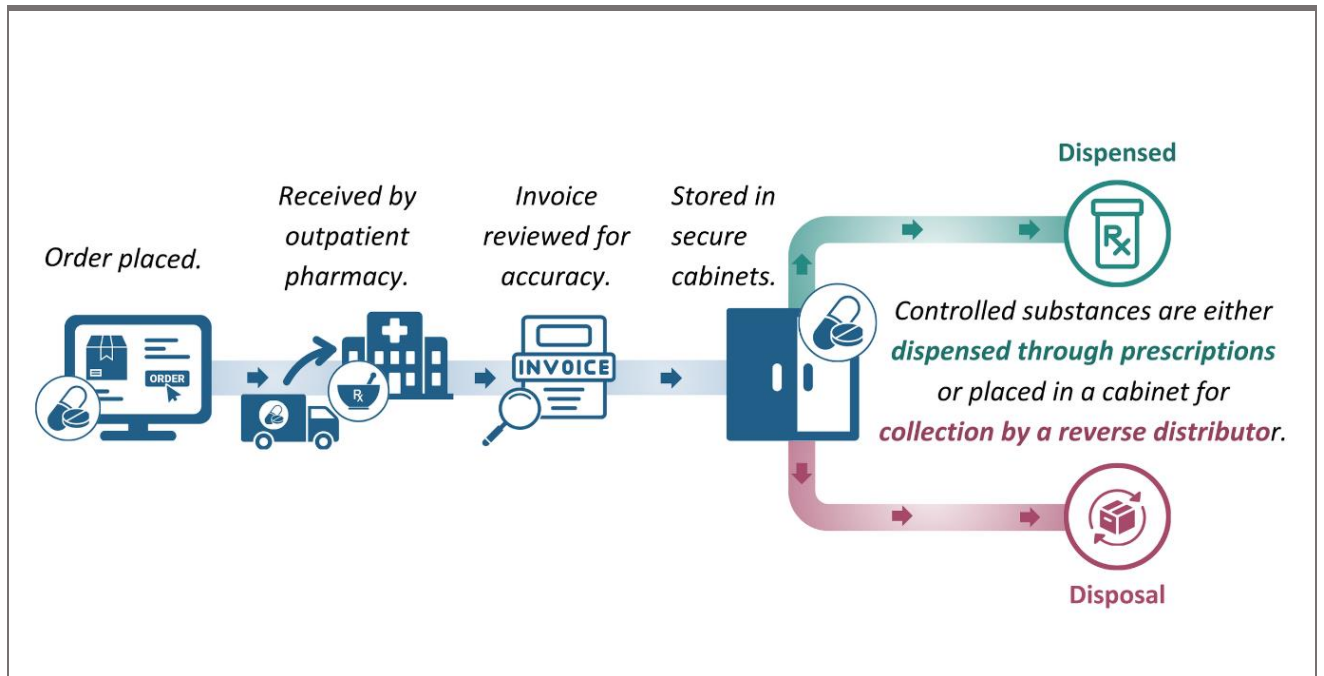
### Outpatient Pharmacy

The Outpatient Pharmacy, managed by a Pharmacy Manager, uses the Computer Rx system to track controlled substances from ordering and receiving to filling prescriptions for patients, and to return unusable items to a reverse distributor.

Figure 3 shows the Outpatient Pharmacy’s process for tracking and dispensing controlled substances.

Figure 3

### *UT Tyler HSC Outpatient Pharmacy’s Process for Ordering, Receiving, Storing, and Dispensing Controlled Substances*



Source: UT Tyler HSC.



**LOW**

## Chapter 1 Ordering, Administering, and Dispensing Controlled Substances

The University of Texas at Tyler Health Science Center's (UT Tyler HSC) Inpatient and Outpatient Pharmacies had adequate processes to ensure that controlled substances were properly tracked and secured from ordering through dispensing.

Those processes included recording all controlled substances received, verifying invoices, adequately securing and controlling access to stored controlled substances, and complying with Texas Prescription Monitoring Program requirement to check the patient's prescription history before dispensing certain controlled substances.

---

### UT Tyler HSC effectively tracked the receipt of controlled substances.

---

During the audit period, UT Tyler HSC's Inpatient Pharmacy received 695 controlled substance orders and its Outpatient Pharmacy received 1,456 orders, all of which were accurately recorded in the respective inventory systems.



UT Tyler HSC also complied with additional requirements applied to Schedule II controlled substances (see text box for more information). Specifically, all of the Schedule II controlled substance orders received—245 in the Inpatient Pharmacy and 507 in the Outpatient Pharmacy—were ordered by authorized personnel, either the Pharmacy Director or Pharmacy Manager, in accordance with applicable requirements.

### Invoice Verification

Both pharmacies implemented an invoice verification process to ensure that appropriate staff accurately review and inventory controlled substance orders received. This process also reinforces the separation of duties through dual signatures on invoices.

Overall, the Outpatient Pharmacy complied with its policies and procedures requiring two signatures or initials on all invoices. Specifically, all 27 invoices tested for the Outpatient Pharmacy contained initials from the Pharmacy Manager and 26 (96 percent) of those invoices contained 2 signatures.

The Inpatient Pharmacy does not have documented policies and procedures describing who should review and sign the invoices during the invoice review process. All 25 invoices tested for the Inpatient Pharmacy contained at least 2 signatures. Two (8 percent) invoices did not include an initial or signature by the Pharmacy Director. Having a documented policy for the invoice review process could help the Inpatient Pharmacy ensure consistency for those reviews.

---

## UT Tyler HSC had effective distribution, administration, and dispensing processes.

---

### Inpatient Pharmacy

At the Inpatient Pharmacy, controlled substances are securely stored in an automated medication dispensing system (vault) with access restricted to authorized staff. The pharmacy distributes these substances from the vault to

#### Schedule II Controlled Substances

**Controlled Substances** are drugs, substances, and certain chemicals used to make drugs that are classified into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential.

**Schedule II controlled substances** are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. Only the Pharmacy Director and outpatient Pharmacy Manager have ordering authority for Schedule II controlled substances.

Sources: United States Drug Enforcement Administration (DEA) and UT Tyler Health Science Center.



automated dispensing machines (ADMs), which are accessible only to authorized personnel (see text box).

The Inpatient Pharmacy appropriately tracked the movement of controlled substances to and from the pharmacy's vault and ADMs for all 7,637 distribution records during the audit period. Additionally, all 25 patient records tested showed that the controlled substances removed from the ADMs were either administered to the patient and/or appropriately disposed.

In addition, for 24 of 25 transactions tested, the Inpatient Pharmacy maintained documentation demonstrating compliance with UT Health East Texas's<sup>2</sup> *Procedure Guidelines for a Diversion Program Policy*, which requires a form signed by both the person removing the controlled substance from the vault and the person delivering it to the ADMs.

### Outpatient Pharmacy

At the Outpatient Pharmacy, controlled substances are stored in locked cabinets, accessible only via proximity cards. The pharmacy also tracks filled prescriptions in its inventory system. In addition, for all 14 applicable filled prescriptions tested, the Outpatient Pharmacy checked the patient's prescription history in accordance with the Texas Prescription Monitoring Program before dispensing opioids, benzodiazepines, barbiturates, or carisoprodol to patients.

#### Automated Dispensing Machine (ADM)

An ADM is a computerized pharmacy system designed for drug storage and decentralized dispensing of medication used in the health care setting, and it is located at the point of care (for example at a Nursing Unit).

Source: UT Health East Texas.

---

## Recommendation

---

UT Tyler HSC should develop and implement written policies and procedures for the Inpatient Pharmacy invoice review process.

---

<sup>2</sup> UT Health East Texas was created as result of a joint venture between Ardent Health Services and The University of Texas System. UT Health East Texas operates the hospital, including the Inpatient and Outpatient pharmacies within UT Tyler HSC (see the Background Section for additional information).

---

## Management's Response

---

A Standard Operating Procedure (SOP) has been developed and implemented to outline these steps for UT Tyler Health Science Center Pharmacy on 09/03/2024. Pharmacy Management will communicate this SOP to ensure the Inpatient Pharmacy invoice review process effectively addresses the noted items above.

**MEDIUM**

## Chapter 2 Inventory Counts

UT Tyler HSC's Inpatient and Outpatient Pharmacies conducted annual inventories in accordance with requirements. However, UT Tyler HSC did not ensure that weekly inventories of the automated dispensing machines (ADMs) were consistently conducted as required.

All pharmacies must conduct an annual inventory, as required by Title 22 of the Texas Administrative Code. In addition, UT Tyler HSC's policies require inventories of the controlled substances in the ADMs at least once weekly.

While the weekly inventories could help the pharmacies quickly identify any missing inventory, the risk of drug loss or diversion is mitigated in part by the established processes for tracking and storing controlled substances discussed in Chapter 1.

---

**UT Tyler HSC should strengthen its oversight to ensure that weekly inventories are conducted as required.**

---

**Weekly Counts.** During the audit period, weekly inventories were not consistently completed for 12 ADMs identified as having controlled substances. Compliance rates with the weekly inventory requirements ranged from 58 percent to 95 percent. The noncompliance identified occurred in part because UT Tyler HSC does not ensure adequate coordination between appropriate departments so that required inventory counts are completed as required.

---

### Recommendation

---

UT Tyler HSC should ensure effective coordination between the appropriate departments and staff so that weekly controlled substance inventories are completed in accordance with applicable requirements.

---

## Management's Response

---

UT Tyler HSC will ensure weekly controlled substances counts are completed in accordance with applicable requirements with the inclusion of the Director of Nursing and Nurse Manager being embedded in the review process.

**LOW**

## Chapter 3 Drug Disposal and Returns

UT Tyler HSC established processes to help ensure that the risk of drug loss or diversion is minimized during the drug disposal and return processes.

UT Tyler HSC may dispose of damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances either (1) on-site, or (2) by transferring a controlled substance to a reverse distributor<sup>3</sup> for off-site destruction.

UT Tyler HSC's Inpatient Pharmacy complied with requirements for controlled substances on-site disposals (see text box). Specifically, from September 1, 2022, through March 31, 2024, all 3,388 disposed controlled substance transactions were performed in the presence of a witness, as required.

**UT Tyler HSC's pharmacies tracked controlled substances that were returned.**

UT Tyler HSC's pharmacies used a reverse distributor, when it identified controlled substances for a return, such as expired medications. They stored the controlled substances to be returned in designated secured bins until they were collected. In addition, to comply with Code of Federal Regulations requirements, both the Inpatient and Outpatient pharmacies record in their

### **Inpatient Pharmacy Disposal Requirements**

When controlled substances, such as damaged items, are identified for disposal, two witnesses must be present. The disposal is recorded in the inventory system, which automatically generates a warning indicating that a witness is required for this transaction.

At the nursing units, the disposal of controlled substances exceeding the administered dose must be witnessed by two authorized individuals.

Sources: Code of Federal Regulations, Title 21, Part 1317; UT Tyler HSC; and UT Health East Texas.

<sup>3</sup> A reverse distributor is a vendor authorized by the U.S. Drug Enforcement Agency (DEA) to collect controlled substances from other DEA registrants (such as pharmacies and hospitals) and to either return the controlled substances to the manufacturer or arrange for their destruction.

respective inventory systems applicable information about the returned drug such as name, quantity, and the reason for return.

During the audit period, the reverse distributor made six pickups for controlled substances at the Inpatient Pharmacy and six pickups at the Outpatient Pharmacy. Both Inpatient and Outpatient Pharmacies completed the required U.S. Drug Enforcement Administration form for all Schedule II controlled substances returned via the reverse distributor.

In addition, all 106 controlled substance return transactions from the Inpatient Pharmacy and all 61 transactions from the Outpatient Pharmacy were accurately tracked in their respective inventory systems.

**LOW**

## Chapter 4 Security and Access Controls

---

UT Tyler HSC implemented physical and user access controls to safeguard its controlled substances.

---

UT Tyler HSC's controls are designed to help prevent the diversion of controlled substances in both its inpatient and outpatient pharmacies, as well as in patient care areas. Those controls include the use of proximity cards, biometric identification (fingerprint scans), and security cameras. Additionally, UT Tyler HSC ensured that only authorized personnel had access to the pharmacies and areas where controlled substances are stored. UT Tyler HSC also appropriately restricted access to its ordering and inventory systems, as well as the automated dispensing machines, to current employees only.

For both its physical security and information technology controls, UT Tyler HSC also ensured that the access permissions appropriately aligned to the users' roles.





## Appendix 1

# Objective, Scope, and Methodology

### Objective

The objective of this audit was to determine whether The University of Texas at Tyler has processes and related controls to ensure that it manages controlled substances in accordance with applicable requirements.

### Scope

The scope of this audit included a review of processes and controls in place at The University of Texas at Tyler Health Science Center's (UT Tyler HSC) Inpatient and Outpatient pharmacies from September 1, 2022, through March 31, 2024.

The scope also included a review of significant internal control components related to management of control substances at both pharmacies.

The following members of the State Auditor's staff performed the audit:



- Bianca F. Pineda, CIA, CFE, CGAP (Project Manager)
- Chase Dierschke, CIA (Assistant Project Manager)
- Kamil Helou
- David Hinojosa, CIA, CFE
- David Johnson Jr.
- Armando S. Sanchez, CFE
- Robby Webb
- Ann E. Karnes, CPA (Quality Control Reviewer)
- Hillary Eckford, CIA, CFE (Audit Manager)

---

## Methodology

---

We conducted this performance audit from February 2024 through September 2024 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 based on our audit objectives. In addition, during the audit, matters not required to be reported in accordance with *Government Auditing Standards* were communicated to UT Tyler HSC management for consideration.

### Addressing the Audit Objective

During the audit, we performed the following:

- Interviewed UT Tyler HSC management and staff to gain an understanding of processes and internal controls for managing controlled substances.
- Identified the relevant criteria:
  - The Controlled Substances Act (United States Code, Title 21, Chapter 13, Subchapter I).
  - The Code of Federal Regulations, Title 21 Food and Drugs, Chapter II Drug Enforcement Administration, Department of Justice.
  - Texas Administrative Code, Title 22, Section 170.3(C).
  - UT Health East Texas's and UT Tyler HSC's policies and procedures.
- Observed the physical security controls in place to safeguard controlled substances.
- Tested physical access to areas where controlled substances were stored, as well as user access to UT Tyler HSC's Pyxis and Computer Rx inventory systems and ordering systems, such as AmerisourceBergen and QuVa.

### Samples Tested

Auditors tested nonstatistical samples to determine if UT Tyler HSC complied with applicable federal and state requirements, as well as its own policies for the ordering, administering, and dispensing of controlled substances. The following tests were performed for the audit period from September 1, 2022, through March 31, 2024:

- Tested a sample of invoices from the Inpatient and Outpatient pharmacies to determine whether controlled substance orders were verified by appropriate staff.
- Tested a sample of patient records to determine if the controlled substance removed from the automated dispensing machine (ADM) was administered to the patient and/or appropriately disposed.
- Tested delivery transactions to verify whether there were signatures of both the person removing controlled substances from the Inpatient Pharmacy’s vault and the person delivering to the automated dispensing machines.
- Tested a sample of prescriptions filled by the Outpatient Pharmacy to determine if it complied with the Texas Prescription Monitoring Program requirement to check the patient’s prescription history before dispensing certain controlled substances.

Figure 4 provides details about the populations and samples selected for the testing described above.

Figure 4

### *Populations and Samples Selected*

Description	Population	Sample Size	Methodology
Controlled substance orders and adjustments:			
Inpatient Pharmacy	720	24 random and 1 risk-based	Combination of Sampling Techniques <sup>a</sup>
Outpatient Pharmacy	1,507	25 random and 2 risk-based	
Inpatient Pharmacy patient administration records	46,020	25 random	Nonstatistical Random <sup>b</sup>
Inpatient Pharmacy delivery transactions (from the vault to the ADMs)	3,766	25 random	Nonstatistical Random <sup>b</sup>

Description	Population	Sample Size	Methodology
Outpatient Pharmacy prescriptions filled for controlled substances	4,456	25 random and 3 risk-based	Combination of Sampling Techniques <sup>c</sup>

<sup>a</sup>Auditors selected a nonstatistical sample of 24 orders from the Inpatient Pharmacy and 25 orders from the Outpatient Pharmacy primarily through random selection so the sample could include a cross section of controlled substance orders. Auditors selected additional orders to test to ensure that the sample included coverage of all staff involved in handling orders. The test results as reported do not identify which items were randomly selected or selected using professional judgment; therefore, it would not be appropriate to project the test results to the population.

<sup>b</sup>A nonstatistical random sample is representative. This sample design was chosen so the sample could be evaluated in the context of the population. It would be appropriate to project those test results to the population, but the accuracy of the projection cannot be measured.

<sup>c</sup>Auditors selected nonstatistical samples of 25 prescription filled records from the Outpatient Pharmacy primarily through random selection so the sample could include a cross section of prescriptions filled for controlled substances. Auditors selected additional filled records to test to ensure that the sample included the three records with the highest number of prescriptions filled. The test results as reported do not identify which items were randomly selected or selected using professional judgment; therefore, it would not be appropriate to project the test results to the population.

### Data Analysis

Auditors performed data analysis to determine if UT Tyler HSC’s pharmacies effectively tracked, recorded, and complied with applicable requirements for controlled substances during the audit period. Specifically, auditors:

- Compared inventory and ordering system data to verify proper recording of controlled substance orders and reviewed all Schedule II orders to verify proper order authorization.
- Reviewed the Inpatient Pharmacy’s inventory system data to determine whether:
  - Controlled substances were appropriately tracked between the vault and ADMs.
  - The disposal of controlled substances was witnessed.
  - Weekly controlled substance counts were conducted in patient care areas.
- Compared inventory system data with reverse distributor records to confirm proper recording of returns and completion of required U.S. Drug Enforcement Agency forms for Schedule II controlled substances.

## Data Reliability and Completeness

Auditors determined that the following data sets were sufficiently reliable for the purposes of the audit:

- The Inpatient Pharmacy's inventory system data on controlled substances ordered, distributed, administered, disposed, and returned from September 1, 2022, to March 31, 2024.
- The Outpatient Pharmacy's inventory system data on controlled substances ordered, filled, and returned from September 1, 2022, to March 31, 2024.
- Data from the Inpatient and Outpatient pharmacies' ordering vendors, as well as data from their reverse distributor, on controlled substances ordered and returned from September 1, 2022, to March 31, 2024.

To determine reliability of the datasets used, auditors (1) reviewed the parameters used for data extraction and observed UT Tyler HSC staff during the extraction process, (2) analyzed the data for reasonableness and completeness, and (3) compared UT Tyler HSC's inventory system data to other applicable sources, such as vendor reports and reverse distributor data.

## Report Ratings

In determining the ratings of audit findings, auditors considered factors such as financial impact; potential failure to meet program/function objectives; noncompliance with state statute(s), rules, regulations, and other requirements or criteria; and the inadequacy of the design and/or operating effectiveness of internal controls. In addition, evidence of potential fraud, waste, or abuse; significant control environment issues; and little to no corrective action for issues previously identified could increase the ratings for audit findings. Auditors also identified and considered other factors when appropriate.



Copies of this report have been distributed to the following:

## **Legislative Audit Committee**

The Honorable Dan Patrick, Lieutenant Governor, Joint Chair

The Honorable Dade Phelan, Speaker of the House, Joint Chair

The Honorable Joan Huffman, Senate Finance Committee

The Honorable Robert Nichols, Member, Texas Senate

The Honorable Greg Bonnen, House Appropriations Committee

The Honorable Morgan Meyer, House Ways and Means Committee

## **Office of the Governor**

The Honorable Greg Abbott, Governor

## **The University of Texas System**

Members of The University of Texas System Board of Regents

Mr. James B. Milliken, Chancellor

## **The University of Texas at Tyler**

Dr. Julie V. Philley, President



This document is not copyrighted. Readers may make additional copies of this report as needed. In addition, most State Auditor's Office reports may be downloaded from our website: <https://sao.texas.gov>.

In compliance with the Americans with Disabilities Act, this document may also be requested in alternative formats. To do so, contact our report request line at (512) 936-9500 (Voice), (512) 936-9400 (FAX), or 1-800-RELAY-TX (TDD); or visit the Robert E. Johnson Building, 1501 North Congress Avenue, Suite 4.224, Austin, Texas 78701.

The State Auditor's Office is an equal opportunity employer and does not discriminate on the basis of race, color, religion, sex, national origin, age, or disability in employment or in the provision of services, programs, or activities.

To report waste, fraud, or abuse in state government, visit <https://sao.fraud.texas.gov>.