



UT Tyler
THE UNIVERSITY OF TEXAS AT TYLER

Internal Audit Department

September 22, 2023

Dr. Kirk Calhoun
President
The University of Texas at Tyler
3900 University Blvd.
Tyler, TX 75799

Dr. Calhoun,

We have completed the Controlled Substance Agreements Audit as part of our Fiscal Year (FY) 2023 Audit Plan. The objective of the engagement was to evaluate The University of Texas at Tyler Health Science Center's (UT Tyler HSC) processes for executing and managing controlled substance agreements in accordance with its new policy post-Epic implementation. The scope of the audit was limited to UT Tyler HSC's clinics as of June 7, 2023.

This audit was conducted in accordance with guidelines set forth in *The Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing* and Generally Accepted Government Auditing Standards. We appreciate the assistance provided by management and other personnel and hope the information presented in our report is helpful.

Sincerely,

Stephen Ford
Vice President, Chief Audit Executive

Enclosure

cc:

Dr. Julie Phillee, Executive Vice President, Health Affairs, Vice Provost
Dr. Steven Cox, Senior Vice President, Clinical Affairs
Dr. My-huyen Tran, Associate Professor of Family Medicine, Associate Program Director
Mr. Dwain Morris, Executive Vice President, Administration, Chief Business Officer
Mr. Daniel Deslatte, Senior Vice President, Business Affairs, Chief Operating Officer – Health Affairs
Dr. Emmanuel Elueze, Vice President for Medical Education and Professional Development
Mr. Donald Baker, Market President of UT Health East Texas
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Controlled Substance Agreements Audit



September 22, 2023

INTERNAL AUDIT DEPARTMENT
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AUDIT OBJECTIVE

The objective of the engagement was to evaluate The University of Texas at Tyler Health Science Center's (UT Tyler HSC) processes for executing and managing controlled substance agreements in accordance with its new policy post-Epic implementation.

OBSERVATIONS

A total of *150 patients were selected for testing from the controlled substance report provided by IT, for which 32 were in fact identified as requiring a controlled substance agreement upon testing. Testing revealed three (3) categories of patients: those selected patients identified on the report as requiring a controlled substance agreement who had a controlled substance agreement on file (27), those selected patients identified on the report as requiring a controlled substance agreement and upon testing did in fact require an agreement, but who at the time of fieldwork did not have an agreement on file (5), and those selected patients identified on the report as requiring a controlled substance agreement, but who upon testing did not require an agreement (118).

This report consolidates our findings for the Institution without reference to individual clinics.

It is noted that the audit testing was performed against items required by Institutional Policy #5777477 "Controlled Substance" effective August 2019. Please note that this policy states "Providers must execute a controlled substance agreement with any adult patient (18 years old and older) whose treatment with a Schedule II, III drug, Tramadol, Benzodiazepine, Barbiturates, or Carisoprodol is intended for longer than 90 days. It is further noted that this policy states "This policy does not apply to patients undergoing active cancer treatment, palliative care or end-of-lifecare."

It is further noted, according to Texas House Bill 3284, effective March 1, 2020, pharmacists and prescribers (other than a veterinarian) are required to check the patient's prescription monitoring program (PMP) history before dispensing or prescribing opioids, benzodiazepines, barbiturates, or carisoprodol.

As part of testing for items required per Policy #5777477 "Controlled Substance," the below listed 13 questions were answered. Please note Question #1 pertains to the 32 patients selected from the IT report who in fact required a controlled substance agreement upon testing. Questions #2 through #10 and #13 pertain to each of the 27 selected patients who in fact had a controlled substance agreement on file. Per Texas House Bill 3284, noted above, questions #11 and #12 of our testing were reviewed for all controlled substances prescribed and not solely those long-term prescriptions that required an agreement as specified in the Controlled Substance policy.

1. Was the agreement entered for any adult patient (18 years old and older) whose treatment with a controlled substance listed on Schedule II, III, Tramadol, Benzodiazepine, Barbiturates, or Carisoprodol is intended for longer than 90 days, excluding patients undergoing active cancer treatment, palliative care or end-of-life care (5 exceptions);
2. Was the patient's agreement renewed within one (1) year (7 exceptions);
3. Was the agreement signed by both parties (1 exception);
4. Did the agreement use the UT Tyler HSC controlled substance agreement template (5 exceptions);
5. If there was a change in the primary care provider while the patient was bound by a controlled substance agreement, was a new controlled substance agreement executed (1 exception);

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6. If there was a change in pharmacy while the patient was bound by a controlled substance agreement, was a new controlled substance agreement executed (7 exceptions);
7. Did the patient undergo urine drug screens (UDSs) and/or pill counts annually per UT Tyler HSC Controlled Substance policy (12 exceptions);
8. Were there any UDS violations noted (2 exceptions);
9. If the patient failed two (2) or more UDSs and/or pill counts was the agreement terminated (1 exception);
10. Was a PMP site check conducted upon initiation of the controlled substance agreement (3 exceptions);
11. Was a PMP site check conducted prior to the dispense of the controlled substance prescription, at every patient visit subsequent to the signed agreement, or if not on an agreement (17 exceptions);
12. Was a printout of each PMP report scanned into the patient’s electronic medical record (EMR) and/or documented in the EMR (60 exceptions); and
13. Was the controlled substance agreement scanned into the EMR within 10 business days of agreement execution (10 exceptions).

**It is noted that of the 150 selections made from the controlled substance report provided, 77 of the selected patients captured within the report were actually prescribed controlled substances by historical providers at non-HSC clinics. In addition, there were prescriptions from HSC clinics included on the report for cancer treatment, palliative care, end of life care, and Schedule IV and V Controlled Substances that were not required by the policy to have a Controlled Substance Agreement.*

This audit identified the following opportunities for improvement		
1	High	<i>Develop a Complete and Accurate Tracking Report</i>
2	High	<i>Execute a Signed Controlled Substance Agreement as per Policy</i>
3	High	<i>Implement a process for Documenting the Prescription Monitoring Program Checks in the EMR</i>
4	Medium	<i>Inadequate Documentation of Controlled Substance Agreement Requirements</i>
5	Medium	<i>Policies and Agreement Requiring Updates</i>

#1: Develop a Complete and Accurate Tracking Report

High: Lack of an accurate and complete tracking report does not allow for appropriate monitoring and review to be in accordance with the Institutional Policy.

UT Tyler HSC is not able to provide a tracking report that identifies all patients who, in accordance with the terms of its policy, require a controlled substance agreement, or a complete and accurate report of all patients who have a controlled substance agreement uploaded within the EMR. Best business practice would require an accurate and complete tracking report relating to who is required to have or is currently on a controlled substance agreement. Of the 150 patients selected from the current report, 118 did not require an agreement upon testing. 77 were identified as having a historical provider and the controlled substance was prescribed by a prior physician. It was also noted that 51 patients were identified as having an MRN on the report provided by IT that pulled in information from Meditech to Epic conversion and did not match the unique MRN within the current EMR. In some instances, utilizing the MRN on the report for our testing revealed that no patient could be found using that record or multiple individuals were returned.

Opportunity for Improvement #1: UT Tyler HSC Management should consider implementing processes that will allow its clinics, providers, and leadership to readily and accurately identify all patients who require a controlled substance agreement, as per the language in its policy, in order to monitor which patients will need an agreement upon their next appointment.

Management Response: UT Tyler HSC management will develop and implement processes that will allow providers, clinics and leadership to readily and accurately identify all patients who require a controlled substance agreement, as per the language in its policy, in order to monitor which patients will need an agreement upon their next appointment

Responsible Person(s): Clinic managers and leadership

Anticipated Implementation Date: May 31, 2024

Opportunity for Improvement #2: UT Tyler HSC Management should consider implementing processes that will allow its clinics, providers, and leadership to readily and accurately identify all patients who are currently on a controlled substance agreement, to identify the patients that need to be in compliance with the 13 testing attributes listed above and to provide continuous monitoring for the attributes that are outstanding for identified patients.

Management Response: "UT Tyler HSC management will develop and implement processes that will allow its providers, clinics, and leadership to readily and accurately identify all patients who are currently on a controlled substance agreement, to identify the patients that need to be in compliance with the 13 testing attributes listed in the audit, and to provide continuous monitoring for the attributes that are outstanding for identified patients."

Responsible Person(s): Clinic managers, providers, and leadership

Anticipated Implementation Date: May 31, 2024

Opportunity for Improvement #3: UT Tyler HSC Management should ensure patient MRN information within the report matches what is listed in the current EMR, Epic, for each patient.

Management Response: Data report will be reviewed for accurate MRN/patient. The data report for recent audit was obtained via IT report, which captured some data from the transition period between Meditech to EPIC. Moving forward, we will request for Epic report.

Responsible Person(s): Clinic leadership

Anticipated Implementation Date: May 31, 2024

#2: Execute a Signed Controlled Substance Agreement as per Policy

High: Lack of an agreement does not adhere to Texas requirements and is a violation of Institutional Policy.

As noted in the sample testing results above, five (5) patients identified as needing a controlled substance agreement per Institutional policy, do not have an agreement on file. In addition to the Institutional policy, per Texas Administrative Code Rule §170.3, most recently amended July 13, 2020, a written pain management agreement between the physician and patient is required for extended drug therapy.

Opportunity for Improvement: UT Tyler HSC Management should consider executing a controlled substance agreement for each of the identified patients. In addition, Management should continue training efforts and share best practices amongst the clinics to ensure all clinics are aware of the controlled substance agreement requirements specified by Institutional policy and put into practice.

Management Response: Previous education regarding controlled substance agreement has been provided. Ongoing education and reminders will be provided to providers and clinic managers. This can also be a part of provider/staff orientation.

Responsible Person(s): Clinic managers and leadership

Anticipated Implementation Date: May 31, 2024

#3: Implement a Process for Documenting the Prescription Monitoring Program Checks in the EMR

High: Without documentation of initial and routine PMP checks, it is not possible to ensure these reviews are being conducted.

Currently, UT Tyler HSC is not able to provide a tracking report for PMP checks completed through Epic. As a result, PMP checks performed through Epic do not have an audit trail. Per the Texas Administrative Code Rule §170.3, before prescribing opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic pain, a physician must review prescription data and history related to the patient contained in the Prescription Drug Monitoring Program (relating to Prescription Monitoring Program Check).

Opportunity for Improvement: UT Tyler HSC Management should consider implementing a process for documenting PMP checks performed in Epic. As part of the Epic implementation process, Management should work to ensure PMP checks performed are automatically documented in the EMR.

Management Response: We will discuss with EPIC IT regarding time stamp of PDMP checks within the chart when accessed/reviewed. The time stamp of the PDMP review is noted in the history report of PDMP website, however, not readily accessible within Epic EHR. An Epic Report can be generated to review the PDMP checks, however, there are some inaccuracies on this list as well.

Responsible Person(s): Clinic managers and leadership, Epic IT.

Anticipated Implementation Date: May 31, 2024

#4: Inadequate Documentation of Controlled Substance Agreement Requirements

Medium: Missing information and unacknowledged requirements could lead to unfollowed policies.

As documented in the sample testing above, 12 patients were missing required UDS and/or pill count documentation, there were 2 UDS violations, and 1 failed UDS that had occurred 2 or more times. Per Policy #5777477 “Controlled Substance,” a urine drug screen and/or pill count must be performed at the time of the agreement and at least annually thereafter. The policy also states that confirmatory evaluation should be obtained in setting of discordant urine drug screen results. Further, it was noted that within the Controlled Substance Agreement document, there was missing information and/or unacknowledged requirements. The Controlled Substance policy mentions that providers will complete and include in the EMR a controlled substance agreement/informed consent.

Opportunity for Improvement: UT Tyler HSC Management should consider training and processes to ensure documentation is uploaded in accordance with the Controlled Substance policy and each line item is complete and agreed to on the Patient Agreement and Informed Consent for Controlled Substance Therapy form.

Management Response: Pending review of Controlled substance policy. Ongoing education to providers and clinic leadership regarding expectation and completion of Controlled substance agreement.

Responsible Person(s): Providers and Clinic leadership.

Anticipated Implementation Date: 6 months after approval of updated policy

#5: Policies and Agreement Requiring Updates

Medium: By not reviewing policies on a timely basis, policies could remain outdated or incorrect.

In performing a review of applicable policies to this audit, two (2) UT Tyler HSC policies from HSC PolicyStat were past their review date. Policies identified were Policy #5777477 “Controlled Substance” and Policy #7131313 “Electronic Controlled Substance Prescribing.” It is noted that Policy #5777477 “Controlled Substance” lacked a reference to House Bill 3284, which as of March 1, 2020, requires each physician to perform a PMP check before prescribing opioids, benzodiazepines, and carisoprodol. It was further noted that Policy #5777477 “Controlled Substance” includes an outdated attachment of the Texas Administrative Code Rule §170.3 Minimum Requirements for the Treatment of Chronic Pain. Policies should be reviewed and updated on a timely basis. It was noted upon review of the “Patient Agreement and Informed Consent for Controlled Substance Therapy” form template attached to Policy #5777477 “Controlled Substance,” that the controlled substance being prescribed is not specified. If prescribed multiple controlled substances, it cannot be differentiated as to which agreement correlates to the related drug or if an agreement is for a current or discontinued controlled substance.

Opportunity for Improvement: A review of the identified policies should be performed, a reference added for House Bill 3284 in Policy #5777477 “Controlled Substance,” and to also update the policy to include the revised Texas Administrative Code Rule §170.3 Minimum Requirements for the Treatment of Chronic Pain as an attachment. Leadership should also consider a revision to the current Patient Agreement and Informed Consent for Controlled Substance Therapy form template to include the controlled substance being prescribed and agreed upon by the provider and patient.

Management Response: Pending review for UT Health controlled substance policy. This is an opportunity to have a unified policy and protocol for all UT health clinics. The current controlled substance policy is due for review.

Responsible Person(s): Medical director and Clinic leadership

Anticipated Implementation Date: November 30, 2023

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BACKGROUND

The Controlled Substance Agreements Audit was completed as part of the Fiscal Year (FY) 2023 Audit Plan as a risk-based audit. This area was previously audited in FY 2018 and FY 2020. In FY 2018, the testing focused on the Institution's compliance with best practices. As a result of the FY 2018 audit, UT Tyler HSC implemented an Institutional policy governing this area. The testing for both the FY 2020 and FY 2023 audit focused on compliance with UT Tyler HSC PolicyStat ID 5777477, Controlled Substance.

According to a 2022 article on WebMD, experts estimate that more than 18 million people ages 12 and older have used prescription drugs for nonmedical reasons in the previous year. It was noted that's more than 6% of the U.S. population.

According to the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Preventions, more than 106,000 persons in the U.S. died from a drug-involved overdose in 2021, inclusive of illicit drugs and prescription opioids. Drug overdose deaths spiked after the start of the COVID-19 pandemic and during 2020 and 2021 claimed nearly 200,000 lives. It was noted that this surge has occurred alongside a rapidly changing U.S. drug supply. More potent synthetic opioids like Fentanyl are now playing a role in nearly 70 percent of deaths. It was further noted that Fentanyl is the most potent of all opioid drugs; as it is 50 to 100 times more potent than morphine, and morphine is 1.5 times more potent than Oxycodone.

The Federal Controlled Substances Act (CSA) became law on October 27, 1970. The CSA, part of the U.S. Drug Enforcement Agency (DEA), places drugs (or substances) into one (1) of five (5) schedules, from Schedule I through Schedule V. Schedule II through Schedule V drugs are currently acceptable for medical use. According to the DEA website, the placement of each substance into a schedule is based upon the substance's medical use, potential for abuse, and safety or dependence liability.

The Texas Prescription Monitoring Program (PMP), maintained by the Texas State Board of Pharmacy, is an electronic database used to collect and monitor prescription data for all Schedule II, III, IV, and V controlled substances dispensed by a pharmacy in Texas or to a Texas resident from a pharmacy located in another state. The PMP is designed to help eliminate duplicate prescriptions and overprescribing of controlled substances, as well as to obtain critical controlled substance history information.

As noted above within the report, according to Texas House Bill 3284, effective March 1, 2020, pharmacists and prescribers (other than a veterinarian) are required to check the patient's prescription monitoring program (PMP) history before dispensing or prescribing opioids, benzodiazepines, barbiturates, or carisoprodol.

The Texas Medical Board, through Texas Administrative Code (TAC) §170.3 "Minimum Requirements for the Treatment of Chronic Pain," states that the physician must use a written pain management agreement, entered into between the physician and the patient, if the treatment plan for chronic pain includes extended drug therapy.

STANDARDS

The audit was conducted in accordance with guidelines set forth in *The Institute of Internal Auditors' Standards for the Professional Practice of Internal Auditing* and Generally Accepted Government Auditing Standards.

SCOPE and PROCEDURES

The scope of the audit was limited to UT Tyler HSC’s clinics as of June 7, 2023.

To achieve the audit objective, we:

- Reviewed applicable state and federal regulations, Texas Medical Board literature, and UT Tyler HSC policy #5777477 “Controlled Substance;”
- Performed a walkthrough of controlled substance agreement-related processes at each selected clinic identified as prescribing controlled substances;
- Reviewed processes for managing controlled substance agreements at each of the selected clinics against UT Tyler HSC policy #5777477 “Controlled Substance;”
- Obtained and reviewed a report of prescribed controlled substances for the audit period, provided by IT; and
- Selected a sample of patients purported to have a controlled substance agreement at each selected clinic, to review documentation within the selected patient’s EMR.

OBSERVATION RANKINGS

Internal audit departments across The University of Texas System use a consistent process to evaluate audit results based on risk factors and the probability of a negative outcome.

Legend	
Priority	<i>A finding is defined as an issue that if not addressed immediately, has a high probability to directly impact achievement of a strategic or important operational objective of UT Tyler.</i>
High	<i>A finding that is considered to have a <u>medium to high probability</u> of adverse effects to UT Tyler as a whole or to a significant college or department.</i>
Medium	<i>A finding that is considered to have a <u>low to medium probability</u> of adverse effects to UT Tyler as a whole or to a college or department.</i>
Low	<i>A finding that is considered to have a <u>minimal probability</u> of adverse effects to UT Tyler as a whole or to a college or department. These findings are communicated separately to management.</i>