UTHealth
The University of Texas
Health Science Center at Tyler

Office of Internal Audit

October 21, 2020

Dr. Kirk A. Calhoun, President
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11937 U. S. Hwy 271
Tyler, TX 75708

Dr. Calhoun,

We have completed the Controlled Substance Agreements Audit that was part of our Fiscal Year (FY) 2020 Audit Plan. The objective of this audit was to evaluate the Institution's processes for executing and managing controlled substance agreements in accordance with its new policy.

This audit was conducted in accordance with guidelines set forth in The Institute of Internal Auditor's *International Standards for the Professional Practice of Internal Auditing.* We appreciate the assistance provided by everyone we worked with on this audit and hope the information presented in our report is helpful.

Sincerely,

Stephen Ford
AVP, Chief Audit Executive

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Controlled Substance Agreements Audit

October 21, 2020

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Report

Background

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

According to information on the U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC) website, prescription opioids continue to contribute to the opioid overdose epidemic in the United States (U.S.). In addition, the website notes that the number of drug overdose deaths decreased by 4% from 2017 to 2018, but the number of drug overdose deaths was still 4 times higher in 2018 than it was in 1999. Nearly 70% of the 67,367 overdose deaths in 2018 involved an opioid. The CDC reported that in 2018, approximately 128 people died every day from an opioid overdose.

The CDC reports that the most common drugs involved in prescription opioid overdose deaths include Oxycodone, Hydrocodone and Methadone. However, it is reported that Tramadol and Fentanyl overdose deaths have seen a dramatic increase in the past couple of years. The CDC website states that it is committed to fighting the opioid overdose epidemic and supporting states and communities as they continue work to identify outbreaks, collect data, respond to overdoses, and provide care to those in their communities. It further states, that Overdose Data to Action (OD2A) is a 3-year cooperative agreement through which the CDC funds health departments in 47 states, Washington DC, two territories, and 16 cities and counties for surveillance and prevention efforts. It explains that these efforts include timelier tracking of nonfatal and fatal drug overdoses, improving toxicology to better track polysubstance-involved deaths, enhancing linkage to care for people with opioid use disorder and risk for opioid overdose, improving prescription drug monitoring programs, implementing health systems interventions, partnering with public safety, and implementing other innovative surveillance and prevention activities.

According to an article published by CNN in June of 2018, the number of opioid prescriptions dispensed by doctors steadily increased from 112 million prescriptions in 1992 to a peak of 282 million in 2012. With actions taken across the U.S. in recent years, the CDC reports that the number of opioid prescriptions dispensed in 2018 was down to 168 million.

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. 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.

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.

The use of controlled substance agreements is designed to promote best practices in the management of patients who are prescribed controlled substances for long-term use. The best practices are aimed at reducing the potential for drug abuse or diversion.

Objective

The objective of this audit was to evaluate the Institution's processes for executing and managing controlled substance agreements in accordance with its new policy.

Scope and Methodology

The scope of the audit was from September 1, 2019 through March 1, 2020 for UT Health Science Center at Tyler (UTHSCT).

To achieve the audit objective, we:

- Reviewed applicable regulations, guidance, and *UTHSCT 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 UTHSCT policy #5777477 "Controlled Substance";
- Obtained and reviewed a report of prescribed controlled substances for the audit period, provided by Information Technology (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 electronic health record (EHR).

* It is noted 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." However, it is further noted that this policy states "This policy does not apply to patients undergoing active cancer treatment, palliative care or end-of-life care."

The audit was conducted in accordance with the guidelines set forth in The Institute of Internal Auditor's *International Standards for the Professional Practice of Internal Auditing*.

Audit Results

We selected a total of 165 patients for testing from the prescribed controlled substance report provided by IT, of which 113 were in fact identified as requiring a controlled substance agreement upon testing. Our 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 (58 patients), 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 our fieldwork did not have an agreement on file (55 patients), and those selected patients identified on the report as requiring a controlled substance agreement, but who upon testing did not require an agreement (52 patients).

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

We answered the following 13 questions as part of our testing. Please note Question #1 pertains to the 113 patients selected from the IT report who in fact required a controlled substance agreement upon testing. Questions #2 through #13 pertain to each of the 58 selected patients who in fact had a controlled substance agreement on file:

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 (55 exceptions);
2) Was the patient's agreement renewed within one (1) year (7 exceptions);
3) Was the agreement signed by both parties (2 exceptions);
4) Was the signed agreement on the current UTHSCT template (12 exceptions);
5) If there was a change in primary care provider while the patient was bound by a controlled substance agreement, was a new controlled substance agreement executed (2 exceptions);
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, as necessary (0 exceptions);
7) Did the patient undergo urine drug screens (UDSs) and/or pill counts, per UTHSCT policy, during the audit period (14 exceptions);

8) Were there any UDS violations noted (7 exceptions);
9) If the patient failed two (2) or more UDSs and/or pill counts was the agreement terminated (0 exceptions);
10) Was a PMP site check conducted upon initiation of the controlled substance agreement (27 exceptions);
11) Was a PMP site check conducted prior to the dispense of a controlled substance at every patient visit subsequent to the signed agreement (22 exceptions);
12) Was a printout of each PMP report scanned into the patient's EHR and/or documented in the EHR (7 exceptions); and
13) Was the controlled substance agreement scanned into the EHR within 10 business days of agreement execution (0 exceptions).

Findings and Recommendations

Issue #1: UTHSCT 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. Of the 165 patients selected from the current report, 52 did not require an agreement upon testing.

Recommendation #1: UTHSCT implement 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.

Ranking: High

Management's Response: Agreed. Most deficiencies identified in the audit report are directly connected to the inability of our current EHR (Meditech) to create and maintain an actual controlled substances patients' registry. This will be rectified with the implementation of EPIC as our new EHR, scheduled for April 23, 2021. Implementation date will be set as 6 months after EPIC go-live date.

Implementation Date: October 23, 2021

Issue #2: UTHSCT is not able to provide a tracking report that identifies all patients, accurately and completely, who currently have a signed controlled substance agreement in their EHR.

Recommendation #2: UTHSCT implement processes that will allow its clinics, providers and leadership to readily and accurately identify all patients who are currently on a controlled substance agreement, in order 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 the identified patients.

Ranking: High

Management's Response: Agreed. As stated above, most deficiencies identified in the audit report are directly connected to the inability of our current EHR (Meditech) to create and maintain an actual controlled substances patients' registry. This will be rectified with the implementation of EPIC as our new EHR, scheduled for April 23, 2021. Implementation date will be set as 6 months after EPIC go-live date.

Implementation Date: October 23, 2021

Issue #3: As noted in the sample testing results above, 55 patients identified as needing a controlled substance agreement per Institutional policy, do not have an agreement on file.

Recommendation #3: UTHSCT should execute 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.

Ranking: High

Management's Response: Agreed. It was noted that several clinics at UTHSC – Tyler are not fully compliant with our controlled substance policy and protocols established by UTHSC – Tyler, Texas Medical Board and other agencies governing Controlled Substance Management. Also, CSM (Controlled Substance Module) that is a part of each outpatient clinical encounter template is not as widely used as initially anticipated. We decided that Department Chairs in charge of above-mentioned clinics will plan and implement corrective actions in order to bring their clinics and providers to be fully compliant with our current and approved Policies and Protocols. The leadership from Performance Improvement Council and Controlled Substances Stewardship (Drs. Seferovic and Tran) will be available to support each Department Chair if they request the assistance. Implementation date for corrective actions on a departmental/clinical level is April 30, 2021.

Implementation Date: April 30, 2021

Issue #4: Currently, UTHSCT is not able to provide a historical tracking report for PMP checks performed through DrFirst. In addition, PMP checks performed through DrFirst software are not captured in the patient's EHR for verification that the checks were performed. As a result, the PMP checks performed through DrFirst do not have an audit trail.

Recommendation #4: UTHSCT implement a process for documenting the PMP checks performed in the EHR. As part of the EPIC implementation process, Management should work to ensure PMP checks performed through DrFirst are automatically captured in the EHR.

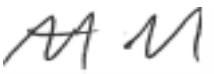
Ranking: High

Management's Response: Agreed. Meditech cannot capture PMP checks performed through DrFirst software. This will be rectified with the implementation of EPIC as our new EHR, scheduled for April 23, 2021. Implementation date will be set as 6 months after EPIC go-live date.

Implementation Date: October 23, 2021

Conclusion

Our audit identified areas where the controlled substance agreement controls and processes in place at UTHSCT could be strengthened. The above recommendations have been made to improve these areas.



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