



UTHealth

The University of Texas
Health Science Center at Tyler

Office of Internal Audit

July 24, 2018

Dr. Kirk A. Calhoun, President
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Dr. Calhoun,

We have completed the Audit of Controlled Substance Contracts that was part of our Fiscal Year (FY) 2018 Audit Plan as a risk-based audit. The objective of this audit was to evaluate the Institution's processes for managing controlled substance contracts. The scope of the audit was as of FY 2018.

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 management and other personnel and hope the information presented in our report is helpful.

Sincerely,

Stephen Ford
AVP, Chief Audit Executive

Enclosure

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Controlled Substance Contracts Audit

July 24, 2018

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Report

Background

The Controlled Substance Contracts Audit was completed as part of the Fiscal Year (FY) 2018 Audit Plan as a risk-based audit.

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.). More than 40% of all U.S. opioid overdose deaths in 2016 involved a prescription opioid, with more than 46 people dying every day from overdoses involving prescription opioids. The CDC reported that from 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids. Furthermore, overdose deaths involving prescription opioids were 5 times higher in 2016 than in 1999.

The CDC reports that the most common drugs involved in prescription opioid overdose deaths include Oxycodone, Hydrocodone and Methadone.

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. The article reports that the number of prescriptions dispensed in 2016 was 236 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.

Recent CDC guidelines specify that prescribers should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program data. It further specifies that prescribers should review this data when starting opioid therapy for chronic pain and periodically during the therapy for chronic pain from every prescription to every three (3) months.

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 and overprescribing of controlled substances, as well as to obtain critical controlled substance history information.

It is imperative to note that here in Texas during the 2017 legislative session, the Texas legislature passed House Bill 2561, which provided for the following changes regarding the PMP:

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- 1) Effective September 1, 2017, Texas-licensed pharmacies are required to report all dispensed controlled substances records to the PMP no later than the next business day after the prescription is filled. The 85th Texas Legislature changed this requirement, which previously allowed for 7 days to send the information. The reporting requirement applies to all Schedule II, III, IV, and V controlled substances; and
- 2) Beginning September 1, 2019, pharmacists and prescribers (other than a veterinarian) will be required to check the patient's 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.

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.

There has been a recent push in best practices to rename the previously utilized “controlled substance contracts” terminology to “controlled substance agreements” in order to remove the legal connotation. Therefore, from hereafter within the report, and in our recommendations, the term controlled substance agreements will be utilized.

Objective

The objective of this audit was to evaluate UT Health Science Center at Tyler's (UTHSCT) processes for managing controlled substance agreements.

Scope and Methodology

The scope of the audit was as of FY 2018.

To achieve the audit objective we:

- Reviewed applicable regulations, guidance and UTHSCT policies;
- Performed a walkthrough of controlled substance agreement-related processes at each clinic identified as prescribing controlled substances;
- Reviewed processes for managing controlled substance agreements at each identified clinic against best practices;
- Obtained and reviewed a report of prescribed controlled substances for the audit period, provided by Information Technology (IT); and

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- Selected a sample of patients purported to have a controlled substance agreement at each clinic, to review documentation within the selected patient's electronic medical record (EMR).

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

Our audit revealed that UTHSCT does not have an Institutional policy that addresses its controlled substance agreement requirements and processes. Accordingly, we tested the controlled substance agreement processes against best practices.

We selected a total of 95 patients for testing, 80 who were identified on the IT report as requiring a controlled substance agreement and 15 patients who were identified on the Clinic's recent Urine Drug Screen (UDS) report. Our testing revealed two (2) categories of patients: those selected patients identified on the reports as requiring a controlled substance agreement who had a controlled substance agreement on file (49 patients), and those selected patients identified on the reports as requiring a controlled substance agreement, but who at the time of our fieldwork did not have an agreement on file (46 patients).

Our review of the 46 patients identified on the reports as requiring a controlled substance agreement, but who did not have an agreement, revealed 19 instances where the reports erroneously identified the patient as requiring an agreement and 27 instances where the EMR did not contain the required agreement.

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

We answered the following 13 questions for each of the 49 patients who had a controlled substance agreement on file:

- 1) Was the agreement entered for a controlled substance listed on Schedule II, III or other (0 exceptions);
- 2) Was the current agreement in place for more than one (1) year at the time of our testing (40 exceptions);
- 3) Had the patient's agreement exceeded the one (1) year limit at any point in time (40 exceptions);
- 4) Was the agreement signed by both parties (1 exception);
- 5) Did the agreement use the UTHSCT template in effect at the time of contracting (see Issue #2 on page 8);
- 6) 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 per best practice (6 exceptions);

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- 7) If there was a change in pharmacy or medication while the patient was bound by a controlled substance agreement, was a new controlled substance agreement executed when necessary (4 exceptions);
- 8) Did the patient undergo UDSs and/or pill counts per best practice (24 exceptions);
- 9) If the patient failed two (2) or more UDSs and/or pill counts was the agreement terminated per best practice (0 exceptions);
- 10) Was a PMP site check conducted upon initiation of the controlled substance agreement (37 exceptions);
- 11) Was a PMP site check conducted at least every six (6) months per best practice (21 exceptions) **Please note: Recommendation #1 on page 7 recommends the PMP site check be performed at every patient visit in order to be in compliance with the requirement of Texas House Bill 2561, which becomes effective September 1, 2019;*
- 12) Was a printout of each PMP report scanned into the patient's electronic medical record per best practice (39 exceptions); and
- 13) Was the controlled substance agreement scanned into the outpatient electronic medical record within 10 business days of agreement execution (0 exceptions).

In addition, we noted the following exceptions not included in the 13 attributes above:

- 1) One (1) of the selected patients we tested had a discrepancy in their PMP, but the discrepancy was not noted in the EMR;
- 2) Fourteen of the selected patients we tested had required information missing from their controlled substance agreement;
- 3) Six (6) of the selected patients where we identified a violation in the patient's UDS, however, the violation wasn't noted in the EMR; and
- 4) Several patients who transferred in from an outside clinic were noted as having a controlled substance agreement in their transfer summary paper work, however, these patients did not have a copy of the agreement in their EMR.

Policies and Procedures

Issue #1: Currently, UTHSCT does not have an Institutional policy that addresses controlled substance agreements.

Recommendation #1: UTHSCT develop and implement an Institutional policy that addresses its controlled substance agreement requirements and ensure regular clinical staff education upon its implementation. The policy should be based upon best practices and include the following parameters and minimum requirements:

- 1) Clinics execute a controlled substance agreement with any patient whose treatment with a Schedule II or III drug is intended for longer than 90 days;
- 2) State that the policy does not apply to cancer treatment, palliative care or end-of-life care;
- 3) A standard controlled substance agreement to be utilized by all clinics;
- 4) Agreement be signed and dated by both the prescribing provider and the patient;

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- 5) Agreement be for a term of one (1) year and require annual renewal;
- 6) Agreement be scanned into the patient's EMR within 10 business days of agreement execution;
- 7) A urine drug screen (UDS) and/or pill count be performed at the time of the agreement and at least every six (6) months thereafter;
- 8) Each provider register with the Texas PMP;
- 9) A PMP check be performed at the time of agreement and at every patient visit thereafter by either the provider or their designee(s);
- 10) The PMP check be scanned into and/or documented in the patient's EMR;
- 11) State that a violation of the agreement may result in termination of the agreement and the discontinuation of the prescription(s); and
- 12) Clearly define the parameters, if any, for allowing an alternative prescriber to provide the patient with the agreed upon controlled substance(s) on a temporary basis (e.g. prescriber listed on the executed agreement will be on vacation for a short period and an alternative prescriber from the same clinic is available to cover during their absence).

Ranking: High

Management's Response: Agreed

Implementation Date: February 1, 2019

Issue #2: Currently, UTHSCT does not have a standard controlled substance agreement to be utilized by all clinics.

Recommendation #2: UTHSCT develop and implement a standard controlled substance agreement template that meets the minimum requirements of the UTHSCT Institutional policy in Recommendation #1 above and also includes the following minimum requirements.

- 1) State that the patient may only obtain the controlled substance(s) from the prescriber on the agreement;
- 2) State that the patient may only obtain the controlled substance(s) from a designated pharmacy agreed to by both the patient and the prescriber;
- 3) State that it is the responsibility of the patient to be discreet about possessing the controlled substance(s) and to protect the substance(s) from theft or loss; and
- 4) State that the prescriber may limit the number and frequency of prescription refills.

Ranking: High

Management's Response: Agreed

Implementation Date: February 1, 2019

Issue #3: Currently, UTHSCT is not able to accurately or completely identify all patients who require a controlled substance agreement, all patients who are currently on a controlled substance

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agreement, or all patients who have had a controlled substance agreement terminated for a violation.

Recommendation #3: UTHSCT implement processes that allow its clinics, providers and leadership to readily and accurately identify all patients who require a controlled substance agreement, all patients who are currently on a controlled substance agreement, and all patients who have had a controlled substance agreement terminated for a violation. This tracking and monitoring will be imperative upon implementation of the Institutional policy in Recommendation #1 above.

Ranking: High

Management's Response: Agreed

Implementation Date: February 1, 2019

Conclusion

Our audit identified a number of 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.



Stephen Ford
AVP, Chief Audit Executive