Executive Summary

Athletics Pharmacy Controls
Intercollegiate Athletics
Project Number: 23.009

Audit Objective

The objective of this audit was to determine whether there are adequate controls in The University of Texas at Austin (UT Austin) Intercollegiate Athletics (Athletics) pharmacy over the acquisition, storage, and issuance of medications to prevent drug diversion.

Conclusion

Athletics maintains effective physical safeguards to prevent unauthorized access to medication and controlled substances. However, there are opportunities to strengthen controls surrounding Athletics’ medication inventory, collection, and distribution processes.

Audit Observations

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Risk Level</th>
<th>Estimated Implementation Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventory Process</td>
<td>High</td>
<td>January 2024</td>
</tr>
<tr>
<td>Controlled Substance Collection</td>
<td>High</td>
<td>September 2023</td>
</tr>
<tr>
<td>Student-Athlete Prescription Logs</td>
<td>Medium</td>
<td>May 2023</td>
</tr>
</tbody>
</table>

Engagement Team

Mr. Jason Boone, CFE, Auditor III
Mr. Patrick McKinney, CIA, Director

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1 Each observation has been ranked according to The University of Texas System Administration (UT System) Audit Risk Ranking guidelines. Please see the last page of the report for ranking definitions.
Detailed Audit Results

Athletics maintains effective physical safeguards to prevent unauthorized access to medication and controlled substances. Prescription medications are stored in locked cabinets within an access-controlled room, and the limited number of schedule III and IV\(^2\) controlled substances on site are stored in a locked box inside of the cabinets. These safeguards help mitigate the risk of drug diversion.

**Observation #1 Inventory Process**

Athletics does not maintain an inventory of medications and controlled substances dispensed or on hand and does not have a process to accurately determine the distribution of medications without manually reviewing each individual student-athlete’s medical notes. The lack of an inventory tracking system prevents Athletics from reconciling substances on hand to supporting documentation (e.g., purchase invoices, destruction logs, or medical records). As a result, Athletics cannot verify quantities on hand are accurate, identify missing medications, or readily notify the Drug Enforcement Agency if controlled substances are lost or diverted. The risk of drug diversion increases without accurate records of pharmaceutical acquisition, use, and disposal, which could result in health, legal, and financial implications.

Athletics is in the process of developing an inventory database for use in the electronic medical record (EMR) system. The EMR system will be able to generate inventory reports through tracking of medication acquisition and dispensing. Athletics also plans to conduct periodic inventory counts. In addition to mitigating diversion risks, these process improvements will help ensure Athletics is compliant with federal rules related to controlled substances. Chapter 21, Code of Federal Regulations (CFR), Part 1304, requires practitioners to maintain complete and accurate records of controlled substances on hand.

**Recommendation:** Athletics should complete and implement their inventory database to maintain an accurate record of medications, including controlled substances. Periodic physical inventory counts should be conducted and reconciled to supporting documentation to verify the accuracy of records. Athletics should review CFR requirements for maintaining an inventory of controlled substances to determine whether their system complies with all applicable requirements.

**Management’s Corrective Action Plan:** The inventory database has been developed in Smartabase to track all prescription medications, including controlled substances. In addition, as a secondary control, we will continue the existing process of performing manual inventory of controlled substances. Physical inventory will be reconciled bi-annually per DEA inventory requirements.

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\(^2\) The Controlled Substances Act classifies controlled substances into five schedules based on a substance’s accepted medical use and risk of dependence or abuse. Schedule I substances are considered most risky and schedule V substances the least risky.
In addition, we intend to replace existing pharmacy cabinet locks that open with unique PIN with locks that utilize EID proxy (or similar) for cabinet access and monitoring. We are currently awaiting ISO input for approved locks.

**Responsible Person:** Chief Medical Officer

**Planned Implementation Date:** Inventory database implemented in June 2023. Remainder of recommendation implemented by January 31, 2024.

**Observation #2 Controlled Substance Collection**
Occasionally, Athletics accepts and destroys a variety of controlled substances turned in by student-athletes when the substances are no longer needed. Student-athletes have turned in substances ranging from schedules II-V. The pharmacy has not maintained complete records of the medications collected for destruction, thus increasing the risk of drug diversion. Furthermore, Athletics is not registered and approved to collect unused controlled substances from patients. CFR prohibits the collection of controlled substances by individual practitioners or other registrants not registered as a collector.

**Recommendation:** Athletics should discontinue accepting unused controlled substances from student-athletes, and the pharmacy should destroy any controlled substances that have already been accepted.

**Management’s Corrective Action Plan:** Unused controlled substances are no longer collected for destruction. Rather, an instructional document will be provided to anyone wishing to dispose of unused controlled substances. Stock prescription medications, including controlled substances that are expired, will be transported to a local location registered for destruction per DEA guidance. Unused and expired stock medications will be destroyed on a monthly basis. Department policy has been amended to reflect this change.

**Responsible Person:** Chief Medical Officer

**Planned Implementation Date:** September 1, 2023

**Observation #3 Student-Athlete Prescription Logs**
Athletics does not maintain sufficiently-detailed documentation to demonstrate that student-athlete prescriptions are received from the pharmacy and delivered to student-athletes. HEB pharmacy fills student-athlete prescriptions for non-controlled medicines, and a third-party delivers them to Athletics. Often, athletic trainers will pick up these prescriptions from Athletics and deliver them to student-athletes. Prescription logs are not always signed to confirm accurate receipt from HEB, and signatures have not been consistently required when medications are picked up by student-athletes or athletic trainers.
During this engagement, Athletics created an updated log that requires athletic trainers to specify whether they are picking up medication for a student-athlete, taking it to a different clinic, or returning it.

**Recommendation:** Athletics should continue to document the individual who picks up/delivers student-athlete prescriptions.

**Management’s Corrective Action Plan:** Prescription log has been updated to specify disposition of individual receiving prescription medication (if on behalf of student-athlete/patient) or if returning medication to the HEB pharmacy.

**Responsible Person:** Chief Medical Officer

**Planned Implementation Date:** Implemented May 2023

**Additional Risk Consideration**

Current procedures do not require student-athletes to confirm receipt of prescriptions delivered by athletic trainers. While prescriptions delivered by athletic trainers do not contain controlled substances, there is an increased risk of financial loss when Athletics does not have confirmation that medications are received by student-athletes. Athletics should consider a method to verify student-athletes receive medications delivered by trainers. A dollar threshold or criticality of medication could be considered if it is unfeasible to verify receipt of all medication deliveries.

**Conclusion**

Athletics maintains effective physical safeguards to prevent unauthorized access to medication and controlled substances. However, there are opportunities to strengthen controls surrounding Athletics’ medication inventory, collection, and distribution processes.

**Table: Controls Assessment**

<table>
<thead>
<tr>
<th>Audit Objective</th>
<th>Controls Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective 1: Physical Safeguards</td>
<td>Satisfactory with Medium Risk Opportunity</td>
</tr>
<tr>
<td>Objective 2: Inventory Management</td>
<td>Ineffective with High Risk Opportunity</td>
</tr>
<tr>
<td>Objective 3: Student-Athlete Medication</td>
<td>Satisfactory with Medium Risk Opportunity</td>
</tr>
<tr>
<td>Objective 4: Destruction and Disposal</td>
<td>Ineffective with High Risk Opportunity</td>
</tr>
<tr>
<td>Objective 5: Pharmacy Purchasing</td>
<td>Effective</td>
</tr>
</tbody>
</table>

**Background**

Athletics provides a prescription medication program that allows team physicians to dispense and administer prescription medications to student-athletes for sport-related injuries and common illnesses. Athletics contracts with HEB Pharmacy to purchase stocked pharmaceuticals and specific prescription drugs that are delivered to student-athletes through the Athletics pharmacy.
Athletics also maintains a small in-house inventory of Schedule III and Schedule IV controlled substances that are primarily used to relieve pain in the event of serious injuries.

**Scope, Objectives, and Methodology**

This audit was conducted in conformance with The Institute of Internal Auditors’ *International Standards for the Professional Practice of Internal Auditing*. Additionally, we conducted the audit in accordance with Generally Accepted Government Auditing Standards and meet the independence requirements for internal auditors. 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 on our audit objectives.

The scope of this review includes fiscal year 2022 and current operations.

Specific audit objectives and the methodology to achieve the objectives are outlined in the table below.

<table>
<thead>
<tr>
<th>Audit Objective</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective 1: Determine whether physical safeguards prevent unauthorized access to medication and controlled substances.</td>
<td>• Conducted site visit to observe controlled substance storage and access procedures</td>
</tr>
<tr>
<td>Objective 2: Determine whether inventory management controls ensure accurate records and compliance with departmental requirements.</td>
<td>• Conducted interviews and walkthroughs with Athletics pharmacy personnel to understand how drugs are ordered, received, inventoried, and administered</td>
</tr>
<tr>
<td>Objective 3: Determine whether medications are properly documented, maintained, and dispensed to student-athletes.</td>
<td>• Reviewed the receiving and storing processes and examined prescription medication logs for completeness</td>
</tr>
<tr>
<td>Objective 4: Determine whether the disposal and destruction of pharmaceuticals complies with departmental and federal guidelines.</td>
<td>• Documented Athletics’ drug disposal process • Examined a sample of records related to the destruction/disposal of controlled substances</td>
</tr>
<tr>
<td>Objective 5: Determine whether the procurement process for pharmaceuticals complies with University requirements and provides for timely payments.</td>
<td>• Interviewed Athletics personnel to understand the pharmaceutical procurement process • Tested a sample of pharmaceutical purchases to determine whether adequate separation of duties existed and whether payments were made on time</td>
</tr>
</tbody>
</table>
Criteria

21 Code of Federal Regulations Part 1301 – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances
   § 1301.71, Security Requirements Generally
   § 1301.75, Physical Security Controls for Practitioners

21 Code of Federal Regulations Part 1304 – Records and Reports of Registrants
   § 1304.04, Maintenance of Records and Inventories
   § 1304.11, Inventory Requirements

21 Code of Federal Regulations Part 1306 – Prescriptions

21 Code of Federal Regulations Part 1317 – Disposal
   § 1317.05, Registrant Disposal
   § 1317.30, Authorization to Collect from Non-Registrants
   § 1317.90, Methods of Destruction
   § 1317.95, Destruction Procedures

UT Austin Athletics Prescription Medication Policies and Procedures

UT Austin Handbook of Operating Procedures 7-1510: Controlled Substances in Research (references to Drug Enforcement Administration policies)

Observation Risk Ranking

Audit observations are ranked according to the following definitions, consistent with UT System Audit Office guidance.

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priority</td>
<td>If not addressed immediately, has a high probability to directly impact achievement of a strategic or important operational objective of The University of Texas at Austin (UT Austin) or the UT System as a whole.</td>
</tr>
<tr>
<td>High</td>
<td>Considered to have a medium to high probability of adverse effects to UT Austin either as a whole or to a significant college/school/unit level.</td>
</tr>
<tr>
<td>Medium</td>
<td>Considered to have a low to medium probability of adverse effects to UT Austin either as a whole or to a college/school/unit level.</td>
</tr>
<tr>
<td>Low</td>
<td>Considered to have minimal probability of adverse effects to UT Austin either as a whole or to a college/school/unit level.</td>
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In accordance with directives from UT System Board of Regents, Internal Audits will perform follow-up procedures to confirm that audit recommendations have been implemented.

**Report Submission**

We appreciate the courtesies and cooperation extended throughout the audit.

Respectfully Submitted,

Sandy Jansen, CIA, CCSA, CRMA, Chief Audit Executive

**Distribution**

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