January 8, 2014

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Dr. Calhoun:

The Pharmacy Inventory Audit was completed as part of our FY 2014 Audit Plan. The objective of this audit was to determine if effective and efficient controls are in place over the procurement, security and distribution of drugs. We found that overall processes and controls are adequate over the procurement, security and distribution of UT Health Northeast’s drug inventory. In the course of our work, opportunities were identified for improving physical security of facilities and controls over prescription pad stock.

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,

Kris I. Kavasch
Executive Director of Internal Audit

Enclosure

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Pharmacy Inventory Audit

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Audit Report

Executive Summary

The Pharmacy Inventory Audit was completed as part of our FY 2014 Audit Plan. We determined that overall the UT Health Northeast Inpatient and Retail Pharmacies have effective and efficient controls in place over the procurement, security and distribution of drug inventory to properly safeguard and control these assets. Although internal control weaknesses identified for the Inpatient and Retail Pharmacies were immediately corrected by management during the course of the audit, there are institution-wide process deficiencies that need to be addressed that in part caused these control weaknesses. We believe the following recommendations will help to resolve these weaknesses and strengthen controls institution-wide:

- The Chief of Police needs to implement policies and procedures for effectively performing the Police Department’s responsibilities in administering badge reader security access and the issuance of mechanical keys. Procedures need to be implemented for empowering departmental managers to be able to properly monitor who has access to institutional facilities within their areas of authority. Higher risk institutional areas need to be identified and access to those areas need to be properly restricted to employees or contractors with a valid business purpose to have access to the areas. Contractors’ responsibilities and procedures for ensuring security of institutional facilities need to be defined, documented and communicated to the contractors. A member of internal management should be assigned with responsibility for monitoring the contractors’ adherence to facility security requirements.

- The Executive Director of Facilities Operations needs to implement procedures for notifying the Police Department when new facilities are considered to be complete and ready for operations. The Chief of Police needs to collaborate with the management of the operations within the new facilities to promptly and effectively deactivate badge reader access and obtain any keys issued from personnel or contractors who needed access to the new facilities while under construction but have no need for access after operations begin.

- The Senior Vice President, Clinical and Academic Affairs and Physician-In-Chief needs to ensure policies and procedures are fully developed and implemented to provide guidance and consistency in ordering and controlling prescription pad stock used by UT Health Northeast providers.
**Background**

UT Health Northeast has an Inpatient Pharmacy and a Retail Pharmacy that function to provide drugs for its operations and patients. Both pharmacies are located within the main campus facilities. During FY 2013, the Inpatient Pharmacy functioned within an approximate annual drug inventory budget of $3.9 million and at August 31, 2013 reported a drug inventory value of approximately $837,000. The Inpatient Pharmacy functions to provide drugs for the institution’s hospital inpatients, on-site and off-site clinics, emergency center, surgery, ancillary and certain contracted services within the facility. The Inpatient Pharmacy operates with eleven full time employees (including the Director) and three part time employees. These employees are pharmacists and pharmacy technicians and have varying responsibilities in the ordering, stocking, maintenance, and dispensing of drug inventory for the area.

During FY 2013, the Retail Pharmacy functioned within an approximate annual drug inventory budget of $1.2 million and at August 31, 2013 reported a drug inventory value of approximately $113,000. The Retail Pharmacy functions like other retail pharmacy operations but serves only UT Health Northeast outpatients due to its participation in the 340B drug program. The Retail Pharmacy operates with seven full time employees and one part time employee (including the Supervisor, pharmacists and pharmacy technicians) who have varying responsibilities in the ordering, stocking, maintaining, and dispensing of drug inventory for the area.

**Audit Objective**

The objective of the audit was to determine if effective and efficient controls are in place over the procurement, security and distribution of drugs.

**Audit Scope and Methodology**

We began by identifying the key functions over drug supply inventories that are important for proper controls to be in place including physical security, information technology security, purchasing, storage, dispensing to operational areas, destruction and wastage, and monitoring controlled substance inventory. We limited procedures to operations of the Inpatient and Retail Pharmacies in respect to drug inventory processes and controls. This audit did not cover procedures or controls for dispensing drugs to patients for either pharmacy but did cover the Inpatient Pharmacy’s distribution of drug inventories to operational areas of the facility. The audit did not cover processes and controls over the maintenance and distribution of drug samples which are provided by the pharmaceutical companies.

To achieve the objective, we performed the following procedures, among others:

- Held interviews with Pharmacy management and key staff members to gain an understanding of policies and procedures and controls in place over drug inventories
- Physically observed access security and reviewed key and badge reader access reports to locations and equipment where the institution’s drug inventory is maintained
• Reviewed security access to the key information technology systems used for the institution’s drug inventory including Computer RX, ScriptPro, Meditech Pharmacy module, and Pyxis
• Reviewed processes and documentation in place for ordering, receiving and stocking drug inventory, including controlled and non-controlled drugs
• Reviewed processes and documentation in place for maintaining drugs in the stockrooms and the methods for annual and ongoing inventory counts
• Reviewed the methods for managing and destroying expired or damaged drugs and return of stock to the vendor or manufacturer
• Reviewed institutional processes for the acquisition and storage of prescription pad stock

The scope of our audit was September 1, 2012 through December 31, 2013. We conducted our audit in accordance with guidelines set forth in The Institute of Internal Auditors’ International Standards for the Professional Practice of Internal Auditing.

Audit Results

Physical Security of Pharmacy Locations
We performed physical inspections of Inpatient and Retail Pharmacy locations where drug inventory is maintained. We reviewed security for the badge reader and mechanical key access, surveillance cameras and other security equipment and related records. Based on the work performed, we believe physical security controls are adequate to protect drug inventory maintained within the institution's Pharmacy locations, due to the fact that there is more than one layer of physical security in place. However, we found that the Campus Police, who are responsible for badge reader access administration and mechanical key issuance, have not adequately maintained badge reader and mechanical key security access controls and records for the Inpatient and Retail Pharmacies to assure this important layer of physical security is operating to provide proper protection of the facilities and drug inventory. In response to Audit's concerns, the Director of the Pharmacy immediately collaborated with the UT Health Northeast Chief of Police to update the badge reader security access to the Inpatient and Retail Pharmacies. In addition, the Inpatient and Retail Pharmacy locks were changed and keys were issued to authorized personnel. The Police Department updated records in the key system to appropriately document the keys issued to Pharmacy personnel.

Although we believe Pharmacy management has appropriately resolved the immediate security concerns for the Inpatient and Retail Pharmacies, there are several weaknesses within badge reader security access and key issuance processes that, in part, caused the deficiencies that need to be resolved including:

• The Inpatient Pharmacy management as well as other departmental management, who are responsible for safeguarding institutional facilities and assets within their areas of authority, have not been assigned responsibility for monitoring access lists. Also, there is no process in place for routinely providing badge reader access lists and mechanical key
records to allow departmental management to effectively monitor who has physical access to their areas.

- The Police Department has not identified higher-risk areas within the institution in which access to contractors and employees needs to be restricted based upon job responsibilities and in collaboration with departmental management adequately restricted these areas.
- There are no well-defined responsibilities or documented procedures in place for on-site contractors to promptly report to the Police Department their employees that have been terminated and no longer need access to institutional facilities. Also, there is no internal management assigned with the responsibility to ensure contractors comply with facility security requirements.
- The Police Department does not have their own departmental procedures in place to consistently and effectively manage the badge reader security access and the issuance and control of institutional keys.

**Recommendation #1:** The Chief of Police needs to implement policies and procedures for effectively performing the Police Department’s responsibilities in administering badge reader security access and the issuance of mechanical keys. Procedures need to be implemented for empowering departmental managers to be able to properly monitor who has access to institutional facilities within their areas of authority. Higher risk institutional areas need to be identified and access to those areas need to be properly restricted to employees or contractors with a valid business purpose to have access to the areas. Contractors’ responsibilities and procedures for ensuring security of institutional facilities need to be defined, documented and communicated to the contractors. A member of internal management should be assigned with responsibility for monitoring the contractors’ adherence to facility security requirements.

**Management’s Response:** The UT Health Northeast Chief of Police concurs with the issues identified and will implement process changes to resolve them. IHOP Policy 08.20 Key and Prox Card Control Policy outlines the maintenance and control of keys and prox cards to UT Health Northeast employees and/or contractors. This policy was last updated in April of 2012 and is need of review and updates. A review is ongoing to update this policy to correctly reflect the responsibilities in administering badge reader security access and the issuance of mechanical keys. Also being reviewed in this policy is the identification of the high risk institutional areas and the process to identify who has access to those areas and how that is reviewed. Contractors’ responsibilities in facility security will be identified in this policy and a procedure developed to ensure internal management monitors the activity. The following procedure options are in the process of being reviewed and plans are for one of the three options to be implemented to ensure departmental managers have the information to properly monitor who has access to facilities under their authority:

1. Develop a folder on the “T” drive in which reader and key reports will be deposited for managers to review. These reports will be made available at least quarterly, so managers may modify or delete access to individuals and send required updates to Key Control.
2. Another option will be to purchase software to integrate into the Police Department’s current access control database to electronically send reports directly to managers for review. The key technician is investigating this option at this time.

3. The last option will be to send the reports directly to managers. This option entails the technician having to manually generate the reports and send them. This will be the last option due to the time involved in the process.

**Implementation Date:** The Key and Prox Card Policy is in review at this time and option #1 is under consideration already with help from the IT Department. Option #2 is being researched to obtain the cost and time to implement. Policies will be updated and management will decide upon a course of action by February 28, 2014 and have procedures documented and activated by May 31, 2014.

**Physical Security of Satellite Locations**
We also performed physical inspections of satellite locations where drug inventory is maintained in Pyxis MedStations in clinical and medical operational areas. Similar to the procedures performed for the Inpatient and Retail Pharmacies, we reviewed security for the badge reader and mechanical key access and related records. Based on the work performed, we believe physical security controls are adequate to protect drug inventory maintained within the institution’s clinical locations, due to the fact there is more than one level of physical security in place. However, our testing included a recently opened clinical area that highlighted a weakness in the transition process between the construction phase and active operations. We found there is no defined process in place for ensuring badge reader or key access to newly constructed areas is consistently reviewed after the area is placed in service with the purpose of deactivating access for contractors and other start up personnel who no longer need access to the area after operations begin.

**Recommendation #2:** The Executive Director of Facilities Operations needs to implement procedures for notifying the Police Department when facilities are considered to be complete and ready for operations. The Chief of Police needs to collaborate with the management of the operations within the new facilities to promptly and effectively deactivate badge reader access and obtain any keys issued from personnel or contractors who needed access to the new facilities while under construction but have no need for access after operations begin.

**Management’s Response:** The UT Health Northeast Chief of Police and Executive Director of Facilities Operations concur that communication processes could be improved to strengthen physical security over newly constructed or renovated facilities. The Chief of Police will develop a process for collaborating with the manager of facility construction identified by the Executive Director of Facilities Operations for effectively managing the badge reader cards, badge reader access, and keys issued during construction and upon completion of new construction or renovations. There is currently a process in place for Physical Plant to issue access badges to contractors for access to some areas of the facilities on a day to day basis, which appears to be working well.
Implementation Date: A method for managing construction workers’ badge reader and key access to facilities will be implemented by January 31, 2014.

Information Technology Security
We reviewed users with active security access to the Computer RX, ScriptPro, Meditech Pharmacy, and Pyxis information systems. We focused our review on identifying any users with active access who should not have access and on users with inappropriate levels of access given their job responsibilities.

The Computer RX system is the Retail Pharmacy's complete medication management information system that provides for an accurate perpetual inventory, reordering, point of sale integration, billing, and reporting. The ScriptPro drug dispensing system is located within and used by the Retail Pharmacy. It is essentially robotic equipment that dispenses medications by counting, bottling the drugs, and labeling the bottle. The system retains a count of drug inventory placed within and dispensed from the system and it is able to provide various management reports. Access to these systems is limited to pharmacists and pharmacy technicians. For Computer RX and ScriptPro we found no inappropriate access or access levels.

Used by the Inpatient Pharmacy, Meditech Pharmacy (PHA) is one of the integrated clinical modules in Meditech’s Health Care Information System that the institution uses for patient billing. The Meditech PHA module interfaces with the Pyxis system. For the Meditech PHA module, there were approximately thirty users whose access was active within the Meditech module that needed to be de-activated. This was not an unexpected outcome since the institution’s Information Technology Department for several years has had a practice in place of de-activating a user’s network (Active Directory) access rather than de-activating each application level access for the user. Audit concurs that this method renders the user’s access to the application inaccessible because the user is unable to attain network access. However, the UT Health Northeast Data Owner Policy requires each data owner to review access lists at least annually to be able to properly restrict access to the application or system. As a result, Audit recommended for the Director of the Pharmacy, who is the Data Owner of the Meditech PHA system, to submit a request to the Information Technology Department to de-activate the users who should not have access. The Director of the Pharmacy immediately issued the Information Technology Request. The Chief Information Officer prioritized the work to be completed by December 31, 2013 due to the lower risk. Audit tested a sample of users whose Meditech PHA system access was active but should have been de-activated and found that all tested had either been de-activated or deleted from Active Directory, so we agree that risks are lower and the lower prioritization by the Information Technology Department is reasonable.

The Inpatient Pharmacy has placed Pyxis MedStations and anesthesia systems within certain clinical and medical operational areas to help with control and dispensing of drug inventory. The Pyxis system is an automated drug dispensing system supporting decentralized medication management. Barcode scanning helps to ensure accurate medication dispensing with features to prevent loading of the wrong medication and active alerts to provide an added safety precaution for high risk medications. Pyxis consoles, which are for performing administrative functions of
the system, are located within the Inpatient Pharmacy and access is restricted to Pharmacy personnel. Although the Inpatient Pharmacy does not maintain inventory other than for controlled drugs on a perpetual inventory system, this system provides a perpetual inventory of drugs that are stocked within the equipment. When reviewing user access to the Pyxis MedStations and console an important concern we identified was that one Information Technology Systems Specialist who assisted with the initial system installation had an inappropriate level of administrative rights and user access to the system. Although this access may have been needed initially during installation, it should have been de-activated after the installation was complete. Upon notification by Audit, the Director of the Pharmacy indicated this user’s access was not deactivated due to inadvertent oversight and she immediately had this access deactivated. There were a few users with access to the Pyxis MedStations where certain access levels were not needed for their job responsibilities. Upon notification, the Director of the Pharmacy immediately made corrections to the access levels for these users. The levels of inappropriate access identified were for the most part caused when building the user templates or by copying templates (roles) when the system was initially set up and did not appear to be any intentional step to inappropriately expand access for certain users. Audit verified the changes needed were appropriately made to the users’ access. After information technology user security access changes noted were made to systems reviewed, we believe user security access is appropriate for the Pyxis system.

Drug Inventory Purchases
We reviewed processes and controls in place for ordering drug inventory for the Inpatient and Retail Pharmacies and found duties were properly segregated and documentation was in place to reflect proper authorization and control of these transactions. We physically observed the ordering, receiving and stocking of drug inventory within the pharmacies and Pyxis MedStations. We physically observed processes for dispensing drugs using the ScriptPro robotic equipment. We tested a sample of drug purchases from both pharmacies and found all were properly authorized, accurate in amount and properly supported. For drugs tested that were maintained on a perpetual inventory system we were able to validate the appropriateness of the purchases based on the Pharmacy’s par levels. We were also able to validate that the inventory systems were adequately documenting the purchase within the inventory stock. For drugs tested that were maintained on a periodic inventory method, which were mainly Inpatient Pharmacy drugs that are not stored within the Pyxis equipment or Retail Pharmacy compounding supplies, we found these were properly authorized and adequately supported purchase transactions. As we expected, since these drugs are on a periodic system we were unable to compare the purchase to inventory par levels or balances. Processes and controls over the purchasing, receiving and stocking of drug inventory were found to be adequate to properly manage and control the transactions and drug inventory.

Drug Inventory Maintenance and Storage
The Inpatient and Retail Pharmacies maintain their inventory in physically secure locations and equipment. Both pharmacies have assigned responsibilities and have implemented processes and controls for keeping their drug stock orderly, well-labeled and for removing expired or damaged drug inventory.
For controlled substances, the Retail Pharmacy performs ongoing counts of these drugs and compares the results to the perpetual inventory records. Inpatient Pharmacy pharmacists and technicians physically count and verify controlled substances stored within the Pyxis narcotics safe and the MedStations when they are restocked as supported by Pyxis system controls which are set to require counts. Although the Pyxis system is not set to require dual counting, manual procedures are in place for the stocking of controlled substances in the Pyxis MedStations by two employees who perform and sign off on the task, including one employee from Pharmacy and one from Nursing. Management uses various system reports available to evaluate purchases and usage to help make decisions for par levels and to identify any unusual variances in expectations, which must be investigated. In May of each year, both pharmacies perform an annual physical count of all controlled substances and maintain an official inventory record of the count as required by federal regulations. In addition, the Inpatient Pharmacy performs quarterly counts of controlled substances and compares the results to the perpetual inventory records. Also, the Inpatient and Retail Pharmacies perform an annual count of all drugs within their locations for the purpose of presenting an inventory dollar value for the institution’s financial records. Additionally, Internal Audit or Accounting routinely performs test counts annually to verify the appropriateness and accuracy of the physical count.

We tested a sample of Inpatient and Retail Pharmacy higher dollar and controlled drugs and found for the inventory retained on a perpetual inventory system drug amounts recorded in the records agreed to the amounts on-hand. This test helped to validate the accuracy of Computer RX and Pyxis drug inventory records maintained in the Retail and Inpatient Pharmacies. We believe controls and processes are adequate within the Inpatient and Retail Pharmacies to safeguard and monitor the institution’s drug inventory. However, it is important to note that although we deemed processes and controls to be adequate, the Inpatient Pharmacy has a significant portion of its inventory maintained on a periodic system which somewhat weakens controls over these inventories since a count is not readily available that would allow for close monitoring of these non-controlled drugs. The Director indicates she believes the process in place within the Inpatient Pharmacy ensures adequate stock with minimal overstock or wastage. She indicates she has considered the costs and Information Technology Department expertise and assistance for interfaces and day-to-day system maintenance to move the Inpatient Pharmacy to a fully perpetual inventory system. She perceives the costs will far exceed the benefit of doing so within the current level of operations.

Drugs Expired, Damaged, Destroyed
The Inpatient and Retail Pharmacies have controls and procedures in place for promptly identifying and for pulling expired or damaged drugs from the shelves or drug dispensing equipment. Ongoing review for expired medications is performed daily by pharmacists and technicians as drugs are being stocked or dispensed. The institution currently uses one reverse distributor vendor, for returning drugs to the manufacturer and for destroying drugs as needed. Expired or damaged drugs are secured properly and adequately documented prior to pick-up by the reverse distributor. Adequate records are maintained for drugs removed from the facility by the reverse distributor and for projected credits to be received from the vendor or manufacturer.
After the drugs are removed from the Inpatient or Retail Pharmacy, it is the reverse distributor’s responsibility to properly control and manage the drugs for return or destruction in accordance with applicable laws and regulations.

**Prescription Pads**

Prior to the institution's implementation of electronic prescriptions, the Pharmacy was responsible for ordering all prescription pads for the institution and distributing these to the providers who needed them. However, after the institution implemented the electronic prescription system, the purchase of prescription pad stock was decentralized from the Pharmacy to the areas in which the medical providers who need the prescription pads were assigned. The Pharmacy still orders prescription pad stock for its own use for verbal provider orders and a minimal amount of blank stock for distribution to providers should they run low or completely out of stock prior to ordering. Although the Pharmacy has a basic departmental policy relative to prescription pad control that is applicable to clinical areas, employees within areas that order prescription pads do not appear to be well-informed about the policy or its requirements. The policy includes high-level policy statements concerning the control of prescription pads but due to the following concerns we do not believe policies and procedures over prescription pads are adequate to effectively control these supplies:

- The policy does not include or reference the detailed federal regulations concerning Medicaid security requirements for prescription pads used for Medicaid patients. With no institutional requirement to use certain approved vendors for these purchases and decentralized purchasing of these supplies by employees who may not be knowledgeable about the applicable regulations, there is an increased risk that prescription pads may be ordered and used that do not meet federal guidelines.
- Procedures for ensuring the security of prescription pad stock when ordering, receiving, distributing to the medical providers and maintaining inventory within the department have not been formally developed. Lack of proper controls within the departments that order and maintain inventories of these supplies increases the risk for theft and resulting fraudulent prescriptions.
- Formal procedures have not been developed for controlling and monitoring prescription pads kept in exam rooms and other medical areas for provider use. Inadequate guidance for management and control of prescription pads maintained within the clinical settings increases the risk for theft and resulting fraudulent prescriptions.

**Recommendation #3:** The Senior Vice President, Clinical and Academic Affairs and Physician-In-Chief needs to ensure policies and procedures are fully developed and implemented to provide guidance and consistency in ordering and controlling prescription pad stock used by UT Health Northeast providers.

**Management’s Response:** A policy and procedure for prescription pad stock will be developed with input from pharmacy, patient care services, and medical staff. Approval of the policy will be obtained from the nursing leadership council and the medical executive committee.
Implementation Date: A draft policy and procedure will be completed by January 31, 2014 and sent to the nursing leadership council for review at their February meeting. After approval by nursing leadership the policy will be sent to the medical executive committee. Plans are for the policy to be finalized and approved by the medical executive committee by March 31, 2014.

Conclusion
Based on the work performed, we believe that overall the Inpatient and Retail Pharmacies have effective and efficient controls in place over the procurement, security and distribution of UT Health Northeast’s drug inventory. However, we believe that implementation of the recommendations noted above will improve weaknesses identified in the areas of physical security of facilities and prescription pads.

Kris I. Kavanagh, Executive Director of Internal Audit
Summary of Significant Findings

According to The University of Texas System, a significant finding is one that may be material to the operation, financial reporting, or legal compliance of the university if corrective action has not been fully implemented. This would include an internal control weakness that does not reduce the risk of irregularity, illegal act, error, inefficiency, waste, ineffectiveness, or conflict of interest to a reasonably low level.

In view of the above requirements, the Pharmacy Inventory Audit had no significant findings.