Pharmacy Services

Internal Audit Report No. I2016-204

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MELANIE D. JOE
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PHARMACY SERVICES

RE: Pharmacy Services Audit
    Report No. I2016-204

Internal Audit Services has completed the review of the Pharmacy Services and the final report is attached.

We extend our gratitude and appreciation to all personnel with whom we had contact while conducting our review. If you have any questions or require additional assistance, please do not hesitate to contact me.

Mike Bathke
Director
UC Irvine Internal Audit Services

Attachment

C: Audit Committee

I.   MANAGEMENT SUMMARY

In accordance with the fiscal year (FY) 2015-2016 audit plan, Internal Audit Services (IAS) reviewed the business operations, internal controls, and policy compliance in Pharmacy Services within the University of California, Irvine (UCI) Medical Center.   The review disclosed some internal control, compliance, and system access weaknesses that should be strengthened to minimize risks, ensure compliance with University policies and procedures and best business practices. Specifically, the following concerns were noted.

Controlled Substances Procurement – Internal controls were not adequate over the purchasing/ordering/receiving processes. Specifically, seperation of duties are lacking over purchasing and receiving medications located at the inpatient pharmacy. This observation is discussed in section V.1.

Automated Dispense Machines Access – Access controls over automated dispense machines need improvement. Further details related to this issue is provided in in section V.2.

Santa Ana Clinic Inventory – Non-controlled substances counted at year end do not take into account purchases, transfers, and deletions of expired drugs. Also, the physical inventory does not agree to the inventory list on file.   These observations are discussed in section V.3.

Cash Handling – Deposit reconciliations are not performed as part of the cash handling process. In addition, proper seperation of duties or mitigating controls were not in place as required by policy. Further details related to these issues are provided in section V.4.

Investigational Drugs – Controls over drug dispensing fees, billings and collections for investigational drugs need improvement. This observation is discussed in section V.5.

Overtime Approval – Overtime hours worked and paid are not approved in advance as required by policy. This observation is discussed in section V.6.

II.   BACKGROUND

The UC Irvine Medical Center maintains a licensed pharmacy which provides pharmaceutical services to patients hospitalized in the medical center, to outpatients seen in the ambulatory care clinics, and recently discharged inpatients. Pharmacy Services also provides specialized expertise in oncology, surgery and comprehensive investigational drug services including procurement, drug management and accountability.

Pharmacy Services is staffed with 134 personnel, composed of staff pharmacists, pharmacy technicians (PT), administrative support, per diem pharmacists, and residents. The two main units in Pharamcy Services are inpatient (IP) and outpatient (OP). Each are separately responsible for the procurement, storage, control, distribution, and monitoring of controlled substance through out the medical center.

III.   PURPOSE, SCOPE AND OBJECTIVES

The primary purpose of the audit was to perform a general review of Pharamcy Services business operations to assess business risk, internal controls and compliance with University policies and procedures. The scope focused on operational and financial activities during the FY 2014-2015.

Based on the assesed risks, the audit included the following objectives.

1. Determine if adequate controls exist over controlled and non-controlled substances purchasing and receiving processes.

2. Determine if there were adequate controls over automated dispensing machines.

3. Determine if controls over cash handling operations were adequate.

4. Determine if controls over investigational drugs billings and collections are proper and timely.

5. Determine if adeuqate controls exist over overtime hours.

6. Review and evaluate certain informational technology (IT) general controls.

IV.   CONCLUSION

Based on the review, certain internal controls and processes could be strenghthened and improved. Business risks, internal control, and compliance concerns were identified in the area of controlled substance medications purchasing and receiving processes, automated dispense machine access, non-controlled substances inventory, cash handling, investigational drug billing and collections, and overtime hours not authorized.

Observation details and recommendations were discussed with management, who formulated action plans to address the issues. These details are presented below.

V.   OBSERVATIONS AND MANAGEMENT ACTION PLANS

1. Controlled Substances Procurement Processes

Background

Controlled substances are medications that have potential for abuse or dependence. Controlled substances located at the IP are secured and tracked in the Pyxis systems, CII Safe, and Med-station, which support decentralized medication management. Controlled substances received from vendors are stored in the CII safe located in the IP, which is used to restock Pyxis machines throughout the hospital and clinics. Once controlled substances are stocked in the systems, the CII safe and Med-stations communicate with each other to automatically track and monitor perpetual inventory for IP personnel to review, monitor, and control.

Observation

A lack of seperation of duties exist between purchasing, recording, and receiving controlled substances located within the IP. IAS observed that only one individual was responsible for purchasing and receiving all controlled substances, which increases the risk of drug diversion that may go undetected. In addition, there were no internal written procedures in place regarding purchasing, recording, and receiving of controlled substances, to clearly define roles and responsibilities and processes over key procurement functions.

Management Action Plan

Written procedures regarding internal controls over purchasing, recording, and receiving of controlled substances will be implemented and communicated to all personnel. In addition, Pharmacy Services will assign one individual for purchasing/recording of controlled substances and a separate individual for receiving medications, which will minimize the risk of drug diversion. IAS will follow up on this action plan by February 29, 2016.

2. **Automated Dispense Machine Access**

   a. Pyxis Access

   Background

   Pyxis is a dispensing and drug storage system machine that electronically distributes medications in a controlled manner and tracks medication usage. Pharmacy Services has documented various policies to manage privileges to the Pyxis MedStation system including the following.

   - Ensure adequate security for medications, including controlled substances.

   - Provide for proper documentation of medication use.

   - Assure confidentially of patient data.

Oversight of these dispensing systems is the responsibility of the Director of Pharmacy with the assistance of the Pharmacy Pyxis System Administrator.

Observation

Employee's access to Pyxis machines did not have adequate supporting documentation to determine if access was proper. IAS sampled 25 employees and noted that 23 did not have confidentiality agreements on file, which require supervisor approval signatures before access is granted.

To ensure critical operations and data can only be accessed by proper personnel, processes must be in place to limit access based only on the least amount of privileges needed to perform a job and be approved by authorized personnel.

b. Box Picker Access

Background

Box Picker is an automated pharmacy storage system used to dispense non-controlled substances, and is password protected. The system also ensures inventory control and audit capabilities, specifically, loading and dispensing controls.

Observation

Access controls need to be strengthened over the Box Picker. Access was not limited based on the least amount of data and privileges needed to perform a job. There were 99 users with access to the system. Based on discussions with key personnel, not all of the users had appropriate privileges or required access to the system. The following is a summary of the observations.

Based on accounts provided, 37 users have administrative privileges, of which nine have elevated privileges (powers users)

- Nine terminated Pharmacy Services employees still have active accounts.

- Generic identifications were used to create administrative accounts, of which some had elevated privileges (37 users have administrative privileges, of which nine have elevated privileges).

- There was no evidence to verify if user access was authorized in advance by the appropriate supervisor for all the active employees.

Management Action Plan

Pharmacy Services management will discuss expectations regarding receipt of completed security request forms for the Pyxis and Box Picker systems. These forms will be properly completed and staff will be trained prior to granting access to these systems. The new procedures will be implemented immediately after staff education is completed.

In addition, Pharmacy Services management will implement a process that ensures that access is appropriate e.g. (1) granting access, (2) periodic reviews to make sure ongoing appropriate access, and (3) procedures that ensure access is revoked timely when employees separate or their job responsibilities no longer require the access. IAS will follow-up on the action plan by February 29, 2016.

3. Santa Ana Clinic Inventory

Observation

For the Santa Ana Family Clinic, no perpetual or periodic spot checks exist to ensure medications are adequately accounted for and that daily transactions such as transfers and deletions are properly tracked. In addition, when IAS conducted testing of inventory, some items did not trace to the inventory list. As of June 2015, total inventory value for the Santa Ana Clinic Pharmacy was $57,649. However, this amount does not take in to account all of the medication purchases and uses that flow through the inventory during the year. Also, inventory adjustments and/or write-offs cannot be properly performed and authorized under the current method, increasing the risk of medications to be lost, misplaced, or misused without detection.

Management Action Plan

Pharmacy Services will propose a purchase of inventory maintenance software for Santa Ana Clinic Pharmacy to keep track of inventory perpetually. This will be considered a capital purchase and will have to go through capital purchase approval process, which occurs annually in July 2016. In the meantime, Santa Ana Clinic Pharmacy will perform periodic audits of inventory to ensure all medications including expired medications are accounted for and tracked properly.   IAS will follow-up on the action plan regarding propose a perpetual inventory system by August 2016 and the action plan regarding periodic audits of non-control substance inventory by February 29, 2016.

4. Cash Handling

Background

Business and Finance Bulletin (BFB) BUS-49 establishes the University's policies related to handling and processing cash and cash equivalents, and defines roles and responsibilities related to the receipt, safeguarding, reporting and recordkeeping for all University cash and cash equivalents. Its purpose is to ensure that University assets are protected, accurately and timely processed, and properly reported. The bulletin also establishes basic internal control principles (accountability, separation of duties, security, and reconciliation) in regard to collecting and accounting for cash and cash equivalents.

a. Post Deposit Reconciliation

Observation

For OP, accountability and accuracy of general ledger records can be strengthened by performing post deposit reconciliations. Through discussion with Pharmacy Services personnel, they rely on the Main Cashiering Office to ensure the deposits are accurate and complete, and when there is a discrepancy, the Main Cashiering Office will follow-up with Pharmacy Services.

Failure to validate deposits weakens the control structure and made lead to loss or theft.

b. Separation of Duties

Observation

Control procedures that ensure no one person is responsible for collecting, handling, depositing, and accounting for cash in the OP should be strengthened. IAS determined through observations and discussions with personnel that there are multiple individuals in the OPs located at Santa Ana and the main hospital that accept payments from patients with one cash register. In addition, there are no cash counts when changing shifts between individuals. These incompatible duties do not provide an adequate separation of duties and an independent reconciliation of patient payments to actual payments received and recorded.

Management Action Plan

Effective immediately, reconciliation of cash in registers will occur twice daily. In addition, Pharmacy Services will reconcile cash receipts with the bank statements and records from the Main Cashiering Office every month to ensure payments were deposited appropriately. IAS will follow-up with this action plan on February 29, 2016.

5. Investigational Drugs

Background

Investigational drugs are defined as any research medications, which are administered per research protocol by authorized licensed staff under the control of Pharmacy Services.

Prior to administration of the investigational drugs, study approval must be submitted by the Human Subjects Review Committee (Institutional Review Board or IRB) and other regulatory bodies as appropriate such as Sponsored Projects Administration. Pharmacy Services is responsible for receiving, storing, dispensing, returning and destroying all research medications.

Observation

Pharmacy Services did not have adequate controls over investigational drugs billing (recharge) processes. Specifically, they did not have a process in place to identify, review, and approve fee rates for dispensing investigational drugs. In addition, testing revealed that the Cancer Center Pharmacy did not bill for 138 investigational drugs during FY 2015.

Management Action Plan

Fees for investigational drug maintenance and dispensing were updated to ensure competitive pricing as of October 2015. Investigational drug services charges for services provided from July 2014 through June 2015 by the Cancer Center Pharmacy were invoiced on August 17, 2015. In addition, as of October 2015, Pharmacy Services reviews investigational drugs maintenance and dispensing fees every month or as needed to ensure all fees are tracked and submitted for billing. IAS will follow-up on this action plan by February 29, 2016.

6. Overtime Hours

Background

Per University Compensation Policy – PPSM 30, overtime for staff members requires the department head to approve overtime for non-exempt employees to meet essential operating needs. The department is responsible for ensuring an employee requested advance approval for overtime work and properly report the overtime worked in a timely manner prior to compensation.

Observation

IAS reviewed the overtime paid amounts as well as the approval process. IAS noted that approvals for overtime along with the number of hours approved for overtime and the related justifications substantiating the necessity for overtime were not documented and obtained in advance as required by policy.

During FY 2015, over 400 hours of overtime was reported totaling $294,932 plus benefits. Based on the review, overtime was compensated, however, none of the hours were approved in advance as required by policy.

Compliance with the policies and procedures ensures that overtime compensation is not only properly approved in advance and justified, but also appropriate and accurate for compensation.

Management Action Plan

As of September 22, 2015, Pharmacy Services implemented a formalized approval process whereby all staff overtime is approved by the designated supervisor prior to the overtime being taken. Supervisor approval is documented, which allows the department director to view the overtime before timecards are approved for the pay period. IAS will follow-up on this action plan by February 29, 2016.