



**A Report to the
Audit Committee**

Mayor
John Cooper

Nashville General Hospital
Chief Executive Officer
Dr. Joseph Webb

Audit Committee Members
Kevin Crumbo
Thom Druffel
Charles Frasier
Brackney Reed
Jim Shulman
Zulfat Suara

Metropolitan
Nashville
Office of
Internal Audit

Audit of Nashville General Hospital Pharmacy Operations

December 20, 2019

EXECUTIVE SUMMARY

December 20, 2019



Why We Did This Audit

The audit was initiated based on the amount of monetary transfers the Nashville General Hospital receives from the Metropolitan Nashville Government and due to the high physical and monetary risks surrounding pharmacy operations.

What We Recommend

- Develop an internal compliance monitoring program for the 340B Drug Discount Program.
- Improve internal controls for cash collections in the Community Pharmacy.
- Perform a cost-benefit analysis for the implementation of a drug inventory management system.
- Ensure possible drug diversion events are investigated and the results are reported.

Audit of Nashville General Hospital Pharmacy Operations

BACKGROUND

The Nashville General Hospital contains an inpatient hospital pharmacy and a retail outpatient pharmacy referred to as the Community Pharmacy. The inpatient pharmacy procures medications, manages the drug inventory supply, and dispenses medication to hospitalized patients. The inpatient pharmacy is staffed by approximately eight pharmacists and seven pharmacy technicians. The Community Pharmacy provides a prescription service to the public and is staffed by one pharmacist and one pharmacy technician.

The mission of the Nashville General Hospital Pharmacy Services is to provide pharmaceutical care to all patients through the responsible provision of drug therapy and to achieve positive patient outcomes that improve the quality of life for the Nashville General Hospital's patients.

OBJECTIVES AND SCOPE

The objectives of this audit are to determine if:

- Controls are in place to manage the procurement, receipt, and storage of drugs.
- Controls are in place for drug tracking and inventory management.
- Controls are in place to ensure cash receipts from the Community Pharmacy are complete, accurate, and deposited timely.
- Controls are in place to ensure compliance with the 340B Drug Discount Program.

The scope of this audit included the operations of the inpatient pharmacy and Community Pharmacy between May 1, 2017, and April 30, 2019.

WHAT WE FOUND

The Nashville General Pharmacy is managing the pharmacy with available resources to ensure that patients are receiving pharmaceutical care. While policies are in place for the majority of operational areas within the pharmacy, policies for drug diversion, cash collections in the Community Pharmacy, and the 340B Drug Discount Program should be drafted.

Drug orders are being placed by authorized individuals and records are being maintained for the procurement of controlled substances. However, a compliance program for the 340B Drug Discount Program should be established, and the inpatient pharmacy could benefit from an inventory management system.

GOVERNANCE

The Hospital Authority Board of Trustees consists of eleven members and is the governing body of the Nashville General Hospital. The Board of Trustees appoints the Chief Executive Officer of the Nashville General Hospital. The Chief Executive Officer has the authority and control to operate the Nashville General Hospital, subject only to policies adopted or orders issued by the Board of Trustees. The Director of Pharmaceutical Services is responsible for developing policies and procedures related to the pharmacy operations and reports directly to the Chief Operating Officer whom reports directly to the Chief Executive Officer.

The Pharmacy and Therapeutics Committee is composed of physicians, pharmacists, and hospital administrators and is responsible for overseeing the operation of the formulary system. The formulary system is the ongoing process through which the hospital establishes policies regarding the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the Nashville General Hospital patient population.

DRUG INVENTORY MANAGEMENT PROCESS

The drug inventory process within the Nashville General Hospital inpatient pharmacy is largely manual as the pharmacy lacks an electronic perpetual inventory management system. Daily drug orders are made through the pharmacy's drug vendor, McKesson. When a pharmacist or technician notices a drug supply is getting low, a notation is made in a notebook. The pharmacy buyer will use the notebook and perform a walkthrough of the pharmacy to identify any drug needs before placing an order using McKesson's online portal. The drug order will be delivered the next day where it will be verified by the pharmacy buyer and one other pharmacy employee.

AcuDose-Rx automated dispensing cabinets are located throughout the hospital. The cabinets interface with the computerized physician order entry within Paragon, the administration and hospital financial application used by Nashville General Hospital. A physician will input the order in Paragon, and the order will be displayed in a queue for the pharmacist to approve. Once approved, the nurse is able to withdraw medication from the AcuDose-Rx cabinet. To dispense and charge the medication to a patient, the nurse will scan the patient's wristband before administering the medication.

Each morning and afternoon, the AcuDose-Rx system will generate a refill report to the inpatient pharmacy. Pharmacy technicians will refill the cabinets which transfers the medication from the central inpatient inventory supply to the cabinets. This ensures medication is available for nurses throughout the day.

The process differs for controlled substances as these medications can only be ordered by authorized pharmacists using the Drug Enforcement Agency's Controlled Substance Ordering System. Controlled substances are maintained in a room secured by badge access only granted by the director of pharmaceutical services. A perpetual inventory system called NarcStation is in place for controlled substances. Inventory is checked for discrepancies each time a controlled substance is received.

The Community Pharmacy uses the WinRx Pharmacy Management System to monitor prescriptions and track inventory. WinRx is interfaced with the McKesson Connect online portal, which allows the on-hand quantity to be updated automatically when a drug order is received in the Community Pharmacy. The

on-hand quantity is then decreased when a prescription is filled. WinRx also serves as the point-of-sale system in the Community Pharmacy.

Drug costs for both the inpatient and outpatient pharmacies can be seen below in Exhibit A.

Exhibit A – Drug Costs for Nashville General Hospital

| Drug Expense Category | FY2017 | FY2018 | FY2019 |
|---------------------------------|--------------------|--------------------|--------------------|
| Hospital Pharmacy – Inpatient | \$3,947,045 | \$2,529,354 | \$2,089,195 |
| Hospital Pharmacy – Outpatient | 2,011,270 | 2,112,988 | 1,947,776 |
| Community Pharmacy – Inpatient | 15,251* | 107* | 0 |
| Community Pharmacy – Outpatient | 498,911 | 668,221 | 594,660 |
| Total Drug Costs | \$6,472,477 | \$5,310,670 | \$4,631,631 |

Source: Nashville General Hospital Finance Department

* The Community Pharmacy is a retail outpatient pharmacy. These amounts were posted in error at year end and subsequently corrected during the following year.

340B DRUG DISCOUNT PROGRAM

The 340B Drug Discount Program was created in 1992 and requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. The program is administered by the Office of Pharmacy Affairs, located within the Health Resources and Services Administration of the Department of Health and Human Services.

The Nashville General Hospital participates in the 340B Drug Discount Program as a Disproportionate Share Hospital. Disproportionate Share Hospitals are defined as hospitals that serve a significantly disproportionate number of low-income patients and receive payments from the Centers of Medicare and Medicaid Services to cover the costs of providing care to uninsured patients.

Ongoing requirements of the 340B Drug Discount Program include the following:

- Recertifying eligibility every year.
- Preventing diversion to ineligible patients.
- Prohibiting duplicate discounts (i.e., obtaining 340B price and a Medicaid drug rebate).
- Preparing for program audits (maintaining auditable records, having a self-audit program in place, etc.).
- Refraining from participating in a group purchasing organization for covered outpatient drugs.

There are no requirements of how the covered entity should use savings from the 340B Drug Discount Program. However, the implication is that the savings will be used for providing healthcare to the low-income and underinsured population.

Exhibit B displays the top drugs purchased with the 340B Drug Discount Program during the audit period and an example of the savings for each drug.

Exhibit B – Top Drugs Purchased with 340B Discount between May 1, 2017 and April 30, 2019

| Drug | Quantity Purchased | Wholesale Acquisition Cost | 340B Cost | 340B Savings | Total 340B Savings |
|---------------------------------|---------------------------|-----------------------------------|------------------|---------------------|---------------------------|
| Remicade | 579 | \$ 1,167.82 | \$ 482.66 | \$ 685.16 | \$396,707.64 |
| Ventolin HFA | 554 | \$ 22.06 | \$ 3.21 | \$ 18.85 | \$10,442.90 |
| Lexiscan | 509 | \$ 242.96 | \$ 147.27 | \$ 95.69 | \$48,706.21 |
| Irinotecan | 418 | \$ 30.66 | \$ 9.52 | \$ 21.14 | \$8,836.52 |
| Herceptin | 303 | \$ 1,558.42 | \$ 708.34 | \$ 850.08 | \$257,574.24 |
| Ipratropium / Albuterol Sulfate | 282 | \$ 15.00 | \$ 7.19 | \$ 7.81 | \$2,202.42 |
| Prednisolone Acetate | 265 | \$ 44.25 | \$ 13.20 | \$ 31.05 | \$8,228.25 |
| Leucovorin | 263 | \$ 18.95 | \$ 11.92 | \$ 7.03 | \$1,848.89 |
| Ofloxacin | 262 | \$ 16.75 | \$ 2.22 | \$ 14.53 | \$3,806.86 |
| Emend | 205 | \$ 320.22 | \$ 202.12 | \$ 118.10 | \$24,210.50 |

Source: McKesson Connect Online Portal

OBJECTIVES AND CONCLUSIONS

1. *Does the Nashville General Hospital Pharmacy have controls in place for the procurement, receipt, and storage of drugs?*

Generally, yes. A review of 47 drug invoices, which included 23 invoices for controlled drugs and 24 invoices for non-controlled drugs, was conducted. All 47 invoices were for orders placed by an authorized pharmacist or pharmacy technician. Electronic Drug Enforcement Agency information was available for review for all controlled substance orders. However, sales tax is being paid for medical supplies and over-the-counter medication. Additionally, the documentation of order receipt should be improved. (See Observation G.)

A process is in place for adding new drugs to the Nashville General Hospital formulary, and the drugs are being approved by the Pharmacy and Therapeutics Committee. However, the formulary should be updated in a timelier manner. (See Observation F.)

The pharmacy is secured by badge access and camera coverage is in place, but the access to the pharmacy should be reviewed periodically by the director of pharmaceutical services. Management should also ensure all cameras are operating. (See Observation D.)

2. *Does the Nashville General Hospital have controls in place for drug tracking and inventory management?*

Generally, yes. The Nashville General Hospital is managing inventory with the resources available. However, the inpatient pharmacy could benefit from an inventory management system. There is not an independent inventory record maintained for non-controlled drugs within the inpatient pharmacy. (See Observation C.)

A data analytics company is used to identify the possible diversion of controlled substances. The process for investigating the possible drug diversion events and reporting the results of the investigations could be improved. (See Observation E.)

3. *Are controls in place to ensure cash receipts from the Community Pharmacy are complete, accurate, and deposited timely?*

Generally, no. Controls over cash collections in the Community Pharmacy are lacking. There are currently no policies and procedures in place for the collection of cash receipts. Segregation of duties is not always possible because the Community Pharmacy is operated by one pharmacist and one pharmacy technician. However, no compensating controls were in place for the lack of segregation of duties.

The Community Pharmacy makes a cash deposit twice a week which represents approximately 209 cash deposits during the audit period. A review was performed for 21 (10 percent of population) cash deposits made by the Community Pharmacy during the audit period to ensure that the deposit reconciled to the WinRx point-of-sale close out report. No documentation was available for two sampled deposits because deposit slips and the WinRx point-of-sale close out reports were not maintained prior to July 2017. Additionally, the reconciliation could not be completed for 10 out of

21 deposits (48 percent) because, while the deposit slip was maintained for the deposit, the WinRx point-of-sale close out report was not maintained and available for review.

Additionally, there is no reconciliation process in place to ensure that third party reimbursement checks obtained from insurance carriers are complete and accurate. The lack of a reconciliation process increases the risk that the Community Pharmacy may not be receiving all entitled funds from insurance carriers or that a misappropriated check would not be discovered. (See Observation B.)

4. *Does the Nashville General Hospital have controls in place to ensure compliance with the 340B Drug Discount Program?*

Generally, no. The Nashville General Hospital utilizes Macro Helix, 340B program software, to accumulate eligible 340B purchases and help maximize participation in the program. However, no formal policies and procedures have been adopted, and there is no compliance monitoring or self-audit program in place within the Nashville General Hospital. Ensuring compliance with the 340B program requirements is vitally important as the Nashville General Hospital is subject to audit by manufacturers as well as the federal government. Failure to comply with program requirements could result in being liable for refunds of the discounts obtained or removal from the drug discount program. (See Observation A.)

AUDIT OBSERVATIONS

Internal control helps entities achieve important objectives to sustain and improve performance. The Committee of Sponsoring Organizations of the Treadway Commission (COSO), Internal Control – Integrated Framework, enables organizations to effectively and efficiently develop systems of internal control that adapt to changing business and operating environment, mitigate risks to acceptable levels, and support sound decision-making and governance of the organization. See **Appendix B** for a description of the observation *Assessed Risk Rating*.

Observation A – 340B Compliance Program

The Nashville General Hospital does not have a 340B compliance monitoring program in place and does not have policies and procedures for the 340B Drug Discount Program. There are requirements for participation in the 340B Drug Discount Program including preventing diversion to ineligible patients, preventing duplicate discounts with both the 340B discount price and Medicare drug rebate for the same drug, refraining from participating in a group purchasing organization for covered inpatient drugs, and maintaining auditable records. The Nashville General Hospital has begun the process for researching and drafting policies and procedures for the 340B Drug Discount Program but does not have any approved and in place. The purpose of the policies and procedures would be to provide guidelines for decisions and actions within the hospital by promoting compliance with the 340B statute, guidance, and policy requirements while also standardizing practices within the hospital.

A self-audit or compliance monitoring program would include periodically reviewing 340B policies and procedures and reviewing a sample of 340B drug transactions. Transactions should then be reviewed to ensure the individual receiving the drug was a patient of Nashville General Hospital, the drug was for an outpatient visit, the prescribing physician was an employee or under contract with the hospital, the 340B drug was not purchased with a group purchasing organization, and a Medicaid drug rebate was not received for the 340B drug.

The Nashville General Hospital is subject to audit by drug manufacturers and the federal government, and failure to comply with program requirements could result in being liable for refunds of the discounts obtained or removal from the 340B Drug Discount Program. Removal from 340B Drug Discount Program would substantially increase the cost of outpatient drugs purchased by the Nashville General Hospital which could place a significant financial burden on the hospital and/or its patients.

Criteria:

- COSO, Control Activities—Principle 10—The organization selects and develops control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels.
- Section 340B Public Health Service Act

Assessed Risk Rating:

High

Recommendations for management of the Nashville General Hospital to:

1. Develop policies and procedures for the 340B Drug Discount Program within the Nashville General Hospital.
2. Develop an internal compliance monitoring program for the 340B Drug Discount Program. The program should include periodically reviewing policies and procedures, reviewing 340B drug transactions for compliance, and maintaining auditable records.

Observation B – Community Pharmacy Cash Controls

Controls over cash collections in the Community Pharmacy should be improved. Cash collections in the Community Pharmacy totaled \$1,665,813 between May 1, 2017 and April 30, 2019. The Community Pharmacy collects cash and checks for outpatient prescriptions and third-party reimbursement checks for insurance carriers. The pharmacist collects both cash receipts and checks and prepares the deposit. The Community Pharmacy is only staffed with one pharmacist and one pharmacy technician, so segregation of duties is not always possible. However, no compensating controls such as requiring both employees to verify the deposit or having a third independent employee reconcile the cash deposits to the WinRx point-of-sale close out reports were being performed.

Cash collections for the Community Pharmacy are only deposited in the bank twice a week. Cash receipts are transferred to the bank using the hospital's courier. The Nashville General Hospital does not have a policy and procedure in place that specifies how often deposits should be made. However, the Metropolitan Nashville Government's Cash Deposits policy states that cash receipts should be deposited within one business day of collection. Improvements around documenting the cash custody transfers could also be made. There is currently not a process in place in which the courier will sign for the prepared deposit when picking it up from the Community Pharmacy.

The maintenance of deposit documentation should be improved. A review was performed for 21 cash deposits made by the Community Pharmacy during the audit period to ensure that the deposit reconciled to the WinRx point-of-sale close out report. No documentation was available for two sampled deposits because deposit slips and the WinRx point-of-sale close out reports were not maintained prior to July 2017. The reconciliation could not be completed for 10 out of 21 deposits (48 percent) because the WinRx point-of-sale close out report was not maintained.

Additionally, there is no reconciliation process in place to ensure that third party reimbursement checks obtained by insurance carriers are complete and accurate. Checks from insurance carriers can range from a few dollars to a few thousand. The checks are stamped "For Deposit Only" upon receipt, but not deposited daily. The pharmacist will maintain the checks in a drawer and deposit them in bulk a few times a week. The checks should be reconciled to claims processed to ensure the Community Pharmacy is receiving all entitled funds. The lack of a reconciliation process increases the risk that the Community Pharmacy may not be receiving all entitled funds from insurance carriers or that a misappropriated check would not be discovered.

Criteria:

COSO, Control Activities—Principle 10—The organization selects and develops control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels.

Metropolitan Nashville Government Finance Department Treasury Policy #9 – Cash Deposits

Assessed Risk Rating:

High

Recommendations for management of the Nashville General Hospital to:

1. Develop policies and procedures for the collection of cash receipts in the Community Pharmacy.
2. Develop a retention policy for deposit documentation in the Community Pharmacy and maintain the documentation in the Community Pharmacy for the specified time frame.
3. Require both the pharmacist and the pharmacy technician to sign off on the accuracy of the Community Pharmacy cash deposit.
4. Develop a process in which an employee outside of the Community Pharmacy reconciles the Community Pharmacy cash deposits to the WinRx point-of-sale close out reports.
5. Maintain a log in Community Pharmacy to document the transfer of cash from the Community Pharmacy to the courier. Require the courier to sign for the deposit before transferring it to the bank. An employee outside of the Community Pharmacy should periodically reconcile the log to bank account to ensure all cash receipts were properly deposited.
6. Ensure that cash receipts are deposited in the bank within one business day of receipt.
7. Develop a methodology for reconciling the third-party reimbursement checks from insurance carriers to claims processed in the WinRx Pharmacy Management Software to ensure accuracy and completeness.

Observation C – Leveraging of Technology for Inventory Management

The accountability of non-controlled medications is lacking due to the absence of an inventory management system within the inpatient pharmacy. When medications are received in the inpatient pharmacy the medications are placed on the shelves without updating any other record. In order to get an on-hand count, a physical count must be made and added to the total count of medication in AcuDose-Rx cabinets located throughout the hospital. Additionally, there are no physical inventories that take place for the purpose of detecting discrepancies between the expected count of medications and the actual on-hand count of medications. This increases the risk of any misappropriated medications not being detected. An inventory is conducted at the end of the fiscal year, but only for the purpose of obtaining an inventory valuation for the Nashville General Hospital financial statements. No analysis is conducted to determine inventory shrinkage since the last physical inventory.

An inventory was conducted for seven expensive and frequently purchased drugs by taking the on-hand count from the previous inventory, adding the purchased amount, subtracting the amount dispensed, expired, or discarded and comparing that figure to the current on-hand count. Three out of seven (43 percent) had a discrepancy. One drug had a higher than expected on-hand count leading to an under reported \$4,861.10 in inventory. Two drugs had a less than expected on-hand count and resulted in an over reporting of \$6,174.96 in inventory.

Benefits of an inventory management system include the following:

- Ensuring traceability of inventory from purchase through administration to the patient or disposal.
- Allowing the pharmacy to accurately record inventory components such as medication expiration dates and physical quantities.
- Providing real-time inventory quantities to assist in maintaining the balance between stocking appropriate quantities to satisfy patient requirements and minimizing excess inventory.
- Setting par levels for automated medication ordering.
- Enhanced security to restrict adding, updating, and removing inventory to approved employees.
- Easily conduct cycle counts to determine if discrepancies in inventory levels exist.

Criteria:

COSO, Control Activities—Principle 10—The organization selects and develops control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels.

Evaluating Hospital Pharmacy Inventory Management and Revenue Cycle Processes – Deloitte / Association of Healthcare Internal Auditors

Assessed Risk Rating:

High

Recommendations for management of the Nashville General Hospital to:

1. Perform a cost-benefit analysis for the implementation of a drug inventory management system in the inpatient pharmacy.
2. Establish a physical inventory methodology as part of the inventory management process within the Nashville General Hospital inpatient and Community Pharmacy. Inventory shrinkage over a specified percentage should be investigated. For example, cycle counting could be used for medications with a high cost.

Observation D – Physical Security of the Pharmacy

Physical security monitoring controls could be improved. Both the outpatient and inpatient pharmacies are controlled with badge access. Badge access is controlled by the Nashville General Hospital Human Resources Department. A Badge Access Report was provided to the Office of Internal Audit for review. The report was found to have terminated employees and three employees from the Human Resources

Department. It was explained that the Human Resources employees need access for employee relations issues and recruitment activities. Before inquiries were made for this audit, a Badge Access Report had never been pulled or reviewed by the Director of Pharmaceutical Services for accuracy.

The only camera in the outpatient pharmacy is not currently operational. The outpatient pharmacy accepts cash payments and manages both non-controlled and controlled drug inventory. Having operational cameras is an important monitoring internal control and supports the safety of both Nashville General Hospital employees and the general public. In addition, not all cameras are currently operational in the inpatient pharmacy. Cameras in the inpatient pharmacy can help prevent and detect the misappropriation of drug inventory.

Criteria:

COSO, Control Activities—Principle 10—The organization selects and develops control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels.

Assessed Risk Rating:

High

Recommendations for management of the Nashville General Hospital to:

1. Ensure pharmacy badge access is removed for terminated employees in a timely manner and employees that do not have pharmacy related job duties. The director of pharmaceutical services should be periodically provided with the listing to ensure that only authorized employees can enter the pharmacies.
2. Ensure all cameras in the inpatient pharmacy and Community Pharmacy are operational and that footage is periodically reviewed.

Observation E – Controlled Substance Monitoring

The monitoring of controlled substances could be improved. Each month, the pharmacy submits data from AcuDose-Rx automated dispensing cabinets to Medacist, a drug diversion analytics company. Medacist will perform analytics on the submitted data and submit an RxAuditor report back to the pharmacy. The RxAuditor report will detail abnormalities in the data. For example, employees that have a higher than average number of transactions for the hours worked or have a higher than average number of transactions for a given controlled substance compared with the population. Pharmacy staff will save the RxAuditor report on a shared network drive and notify members of management in nursing, risk, and compliance that the report is ready for review. Nursing management is then responsible for researching the identified employees in the report to either confirm or negate potential drug diversion events.

The Office of Internal Audit conducted a review of RxAuditor reports for February 2019 through April 2019 and made a listing of six employees that were listed on two or more of the reports. Inquiries were made as to whether the instances identified were investigated. Nursing management conducted a review and were able to determine that there were no suspected diversions for four of the employees. Due to management changes, a review of the other two employees is still ongoing.

While a process was in place for conducting reviews of possible drug diversion events identified in RxAuditor reports and reporting the conclusions of those reviews, the process was not consistently followed or documented in a formal policy and procedure.

A Diversion Policy is currently being drafted by the Nashville General Hospital Compliance Officer. Moving forward, all investigations will be reviewed by the Medication Diversion Prevention Committee as a sub-committee of the Compliance Committee. The findings from the Medication Diversion Prevention Committee will be reported to the Compliance Committee and the Pharmacy and Therapeutics Committee.

Criteria:

COSO, Control Activities—Principle 10—The organization selects and develops control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels.

Assessed Risk Rating:

High

Recommendation for management of the Nashville General Hospital to:

Formally document the process for investigating possible drug diversion events identified in RxAuditor reports and reporting the conclusions of the investigations in a formal policy and procedure.

Observation F – Formulary Management

The Nashville General Hospital formulary should be updated in more timely manner. A formulary is a list of medications that the hospital has stocked in the pharmacy and allows the hospital's physicians to know what medications are available to treat a given symptom or condition. The Pharmacy and Therapeutics Committee ultimately decides which drugs will appear on the hospital formulary. A physician may request a medication be added to the hospital formulary by filling out a formulary drug request form. The request will go through a review process within the pharmacy before being presented to the Pharmacy and Therapeutics Committee for discussion and approval.

A selection of four new drugs approved by the Pharmacy and Therapeutics Committee were reviewed. Three out of four (75 percent) drugs were not added to the formulary. Additionally, the auditor reviewed 47 invoices for purchased medications during the audit period. One out of 47 (2 percent) included a purchased drug that had previously been removed from the Nashville General Hospital formulary.

Criteria:

COSO, Control Activities—Principle 10—The organization selects and develops control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels.

Nashville General Hospital Medication Selection and Procurement Policy

Assessed Risk Rating:

Medium

Recommendation for management of the Nashville General Hospital to:

Ensure the Nashville General Hospital Formulary is updated after each Pharmacy and Therapeutics Committee meeting.

Observation G – Drug Procurement and Receipt

The Nashville General Hospital is paying sales tax for over-the-counter medications and medical supplies purchased from McKesson, the hospital's drug supplier. Additionally, receipt verification was not always documented by pharmacy staff when receiving drug orders.

Nine out of 24 invoices (38 percent) included sales tax for over-the-counter medications and medical supplies. The Nashville General Hospital is exempt from sales tax under Tennessee Code Annotated § 67-6-322. The exemption should be communicated to McKesson to prevent sales tax from being paid going forward.

Drug orders are received daily in the pharmacy. The orders will be either verified by an employee different from the pharmacy buyer or by two employees if the pharmacy buyer is involved in the verification. This verification is documented by initialing the invoice. Verification was not documented for 7 out of 24 reviewed drug orders (29 percent), and segregation of duties between placing the order and receiving the order could not be determined.

Criteria:

COSO, Control Activities—Principle 11—The organization selects and develops general control activities over technology to support the achievement of objectives.

Tennessee Code Annotated §67-6-322 “There shall be exempt from this chapter any sales or use tax upon tangible personal property, computer software, or taxable services sold, given, or donated to any... (8) Hospital”

Assessed Risk Rating:

Medium

Recommendation for management of the Nashville General Hospital to:

1. Ensure that the Tennessee sales tax exemption is communicated to McKesson to prevent sales tax from being paid on over-the count medication and medical supplies.
2. Ensure that drug orders are placed and received by different employees or the drug orders are received using two-person verification. Receipt verification should be documented and maintained in the pharmacy.

GOVERNMENT AUDITING STANDARDS COMPLIANCE

We conducted this performance audit in accordance with generally accepted government auditing standards. 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 observations and conclusions based on our audit objectives.

METHODOLOGY

To accomplish our audit objectives, we performed the following steps:

- Interviewed key personnel within the Nashville General Hospital.
- Reviewed and analyzed documentation for compliance with the Tennessee Code Annotated, Metropolitan Nashville Code of Laws, and other applicable laws, regulations, and policies.
- Evaluated internal controls currently in place.
- Reviewed sample selections to determine the effectiveness of internal controls.
- Considered risk of fraud, waste, and abuse.

AUDIT TEAM

Seth Hatfield, CPA, CIA, CFE, In-Charge Auditor

Lauren Riley, CPA, CIA, ACDA, Principal Auditor

Gina Pruitt, CPA, CITP, CISA, CHFP, CQA, CEMB, CGMA, CRISC, CCSFP, CHCO, Interim Metropolitan Auditor



December 5, 2019

Ms. Gina Pruitt
Mr. Seth Hatfield
Metropolitan Auditor
Office of Internal Audit
222 3rd Avenue N., Suite 401
Nashville, TN 37201

Der. Ms. Pruitt and Mr. Hatfield,

The Executive Leadership Team, Pharmacy Department Leadership and the Compliance Officer have reviewed the audit findings and recommendations from your Pharmacy Operations report dated November 18, 2019, and we accept your recommendations. Please see our attached responses to those findings and recommendations and our timeline for implementing corrective action.

We look forward to working with you to ensure responsible management of our resources and care for some of Nashville's most fragile residents.

Sincerely,

Joseph Webb, D.Sc., FACHE,
Chief Executive Officer

A handwritten signature in blue ink, appearing to read 'Mark Brown', written over a horizontal line.

Mark Brown
Chief Operations Officer

Julie Groves
Compliance Officer

Enc. A handwritten signature in blue ink, appearing to read 'Julie Groves', written over a horizontal line.

APPENDIX A – MANAGEMENT RESPONSE AND CORRECTIVE ACTION PLAN

We believe that operational management is in a unique position to best understand their operations and may be able to identify more innovative and effective approaches, and we encourage them to do so when providing their response to our recommendations.

| | Recommendation | Concurrence and Corrective Action Plan | Proposed Completion Date |
|-------------|--|---|--------------------------|
| <i>Risk</i> | <i>Recommendations for the management of the Nashville General Hospital to:</i> | | |
| H | A.1 – Develop policies and procedures for the 340B Drug Discount Program within the Nashville General Hospital. | Accept – The NGH Compliance Department in conjunction with the Pharmacy Department will establish policies and procedures to ensure appropriate oversight and compliance with the Department of Health and Human Services. | February 29, 2020 |
| H | A.2 – Develop an internal compliance program for the 340B Drug Discount Program. The compliance program should include periodically reviewing policies and procedures, reviewing 340B drug transactions for compliance, and maintaining auditable records. | Accept – The NGH Compliance Department in conjunction with the Pharmacy Department will establish a 340B compliance program to ensure compliance with federal requirements of the NGH 340B program. Self-auditing of the 340B program will be included in the Compliance Annual Workplan. | February 29, 2020 |
| H | B.1 – Develop policies and procedures for the collection of cash receipts in the Community Pharmacy. | Accept – The outpatient pharmacy department will create a policy and procedure on the collection of cash receipts. | December 31, 2019 |
| H | B.2 – Develop a retention policy for deposit documentation in the Community Pharmacy and maintain the documentation for the specified time frame. | Accept – A policy for retaining appropriate documentation for all cash deposits will be created. All cash deposits will be completed on a daily basis. | December 31, 2019 |
| H | B.3 – Require both the pharmacist and the pharmacy technician to sign off on the accuracy of the Community Pharmacy cash deposit. | Accept – The outpatient pharmacist as well as a secondary party either from Finance or Inpatient pharmacy will sign off on the accuracy of the cash deposit. | December 31, 2019 |
| H | B.4 – Develop a process in which an employee outside of the Community Pharmacy reconciles the Community Pharmacy cash deposits to the WinRx point-of-sale close out reports. | Accept – A process will be developed where an individual in the inpatient pharmacy will reconcile the cash deposits to the WinRx point of sale close out reports. | December 31, 2019 |
| H | B.5 – Maintain a log in the Community Pharmacy to document the transfer of cash from the Community Pharmacy to the courier. Require the courier to sign for the deposit before transferring it to the bank. | Accept – A log has been created to document the transfer of cash from the Community Pharmacy to the NGH courier. A process has already been put in place where the courier counter signs the deposit slip. | December 31, 2019 |

APPENDIX A – MANAGEMENT RESPONSE AND CORRECTIVE ACTION PLAN

| | Recommendation | Concurrence and Corrective Action Plan | Proposed Completion Date |
|---|--|---|--------------------------|
| H | B.6 – Ensure that cash receipts are deposited in the bank within one business day of collection. | Accept – This has already been put in place. All cash deposits from the Community Pharmacy are now done on a daily basis. | Completed |
| H | B.7 – Develop a methodology for reconciling the third-party reimbursement checks from insurance carriers to claims processed in the WinRx Pharmacy Management Software to ensure accuracy and completeness. | Accept – The Compliance Department is working with the Pharmacy Department to develop a method to reconcile third party reimbursement checks from third party payors. | January 31, 2020 |
| H | C.1 – Perform a cost-benefit analysis for the implementation of a drug inventory management system in the inpatient pharmacy. | Accept – The Pharmacy Department is collecting bids from three vendors to determine cost of a drug inventory management system. Once those bids are received, a cost benefit analysis will be completed. | January 31, 2020 |
| H | C.2 – Establish a physical inventory methodology as part of the inventory management process within the Nashville General Hospital inpatient and Community Pharmacy. Inventory shrinkage over a specified percentage should be investigated. For example, cycle counting could be used for medications with a high cost. | Accept – The Pharmacy Department will implement a methodology within the inpatient pharmacy department as well as the Community Pharmacy for a physical inventory process. | February 29, 2020 |
| H | D.1 – Ensure the pharmacy badge access is removed for terminated employees in a timely manner and employees that do not have pharmacy related job duties. The director of pharmaceutical services should be periodically provided with the listing to ensure that only authorized employees can enter the pharmacies. | Accept – This has already been completed. When any employee is terminated their badge access is immediately deactivated. The Pharmacy Director will review the badge access report on a monthly basis. All unauthorized/unnecessary access to the pharmacies at the time of this audit have been removed. | Completed |
| H | D.2 – Ensure that all cameras in the inpatient pharmacy and the Community Pharmacy are operational and that footage is periodically reviewed. | Accept – All cameras in the inpatient pharmacy as well as the Community Pharmacy have been confirmed to be working. All cameras in the inpatient pharmacy as well as the Community Pharmacy will be reviewed on a monthly basis by the Compliance Officer or Risk Manager. | Completed |

APPENDIX A – MANAGEMENT RESPONSE AND CORRECTIVE ACTION PLAN

| | Recommendation | Concurrence and Corrective Action Plan | Proposed Completion Date |
|----------|---|--|---|
| H | E.1 – Formally document the process for investigating possible drug diversion events identified in RxAuditor reports and reporting the conclusions of the investigations in a formal policy and procedure. | Accept – The Medication Diversion Prevention Committee has been created and will report up to the hospital Compliance Committee. The committee meets monthly where all drug diversion reports/investigations will be reviewed. | January 31, 2020 |
| M | F.1 – Ensure the Nashville General Hospital Formulary is updated after each Pharmacy and Therapeutics Committee meeting. | Accept – All formulary changes will be updated after each Pharmacy and Therapeutics Committee. | Completed |
| M | G.1 – Ensure that Tennessee sales tax exemption is communicated to McKesson to prevent sales tax from being paid on over-the-counter medication and medical supplies. | Accept – The sales tax exemption verification has been communicated to McKesson in order to prevent sales tax being paid on over the counter medication and medical supplies. | Completed |
| M | G.2 – Ensure that drug orders are placed and received by different employees or the drug orders are received using two-person verification. Receipt verification should be documented and maintained in the pharmacy. | Accept – A two-person verification is now being enforced. Compliance department has confirmed with the Pharmacy Director that the two party will not consist of two pharmacy staff, that a second non-pharmacy staff member will sign off. Policy for this is in process of being drafted. | Completed December 31, 2019 – for the policy |

APPENDIX B – MANAGEMENT RESPONSE AND CORRECTIVE ACTION PLAN

Observations identified during the course of the audit are assigned a risk rating, as outlined in the table below. The risk rating is based on the financial, operational, compliance or reputational impact the issue identified has on the Metropolitan Nashville Government. Items deemed “Low Risk” will be considered “Emerging Issues” in the final report and do not require a management response and corrective action plan.

| Rating | Financial | Internal Controls | Compliance | Public |
|---------------------------------|--|---|--|---|
| HIGH | Large financial impact >\$25,000 Remiss in responsibilities of being a custodian of the public trust | Missing, or inadequate key internal controls | Noncompliance with applicable Federal, state, and local laws, or Metro Nashville Government policies | High probability for negative public trust perception |
| MEDIUM | Moderate financial impact \$25,000 to \$10,000 | Partial controls Not adequate to identify noncompliance or misappropriation timely | Inconsistent compliance with Federal, state, and local laws, or Metro Nashville Government policies | The potential for negative public trust perception |
| LOW/ Emerging Issues | Low financial impact <\$10,000 | Internal controls in place but not consistently efficient or effective Implementing / enhancing controls could prevent future problems | Generally complies with Federal, state, and local laws, or Metro Nashville Government policies, but some minor discrepancies exist | Low probability for negative public trust perception |
| Efficiency Opportunity | An efficiency opportunity is where controls are functioning as intended; however, a modification would make the process more efficient | | | |