Tempe
Internal Audit

Memorandum

TO: Greg Ruiz, Chief, Fire Medical Rescue

THRU: Bill Greene, City Auditor (X8982)

FROM: Keith Smith, Sr. Auditor (X8416)

CC: Andrew Ching, City Manager
Keith Burke, Deputy City Manager
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Lisette Camacho, Director, Financial Services

DATE: September 27, 2022

SUBJECT: FINAL REPORT: Management of Controlled Substances Audit

Attached is our final report on the subject audit. Copies of this report will be distributed to the mayor and council, the audit committee, and posted to the Internal Audit Office website.

Thank you and your staff for your cooperation during this project.

Management of Controlled Substances Audit

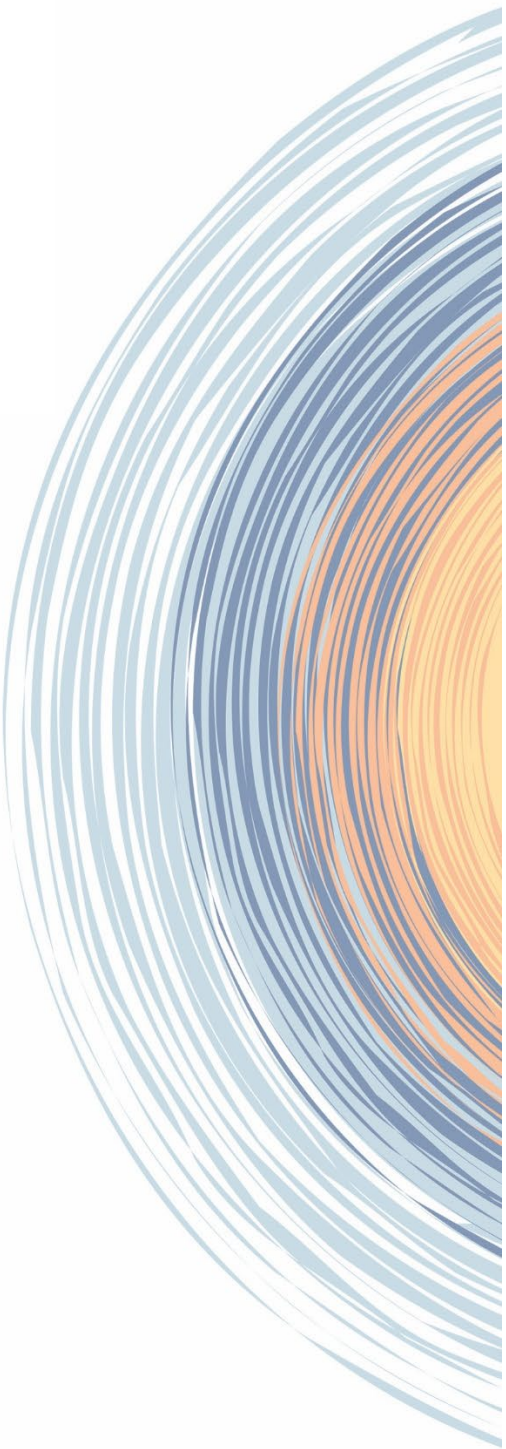
September 27, 2022

Project Team:

Bill Greene, City Auditor
Keith Smith, Sr. Auditor

Mission Statement

To enhance and protect organizational value by providing high-quality, objective, risk-based audit and consulting services to assist the City in accomplishing strategic priorities, goals, and objectives.



Tempe
Internal Audit

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Executive Summary

Purpose

We evaluated the adequacy of management controls over the payment, physical security, custody, refill, dispensing, and disposal of controlled substances used by the Tempe Fire and Medical Rescue Department (TFMRD).

Background

Some drugs administered by TFMRD are listed on the United States Drug Enforcement Administration's (DEA) Schedules of Controlled Substances. The DEA places substances in respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Title 21 Chapter 13 Subchapter I Part C §823(j) of the U.S. Code allows distribution of these substances by emergency medical service providers.

TFMRD maintains supplies of controlled substances in combination with other medications for use during emergency medical service calls. Drugs are typically stored in ambulances and other fire apparatus. Because of the high-risk nature of these drugs, acquisition, record-keeping, custody and inventory controls are vital.

Results in Brief

Overall, controls related to the payments for medications are appropriate. Regular reports detailing drug usage would be helpful to compare quantities billed to amounts used before payments are authorized.

We reviewed invoices and payments for controlled substances for the audit period (FY 2021-22). Payments totaled just under $19,000 and matched invoices without exception. There are currently no reports readily available to compare billed quantities to amounts used. Given the low expenditure amounts, a time-consuming reconciliation process is not warranted. However, a high-level usage report based on data recorded in TMFRD systems could aid in the review of invoices for reasonableness.

TFMRD implemented controls over the security and inventory of controlled substances to protect from theft or loss of medication. Medication inventory contained in the Special Event bags should be accounted for using Target Solutions to ensure a consistent process.

Controlled substances and other medications are stored in large orange boxes secured with combination locks. Within fire vehicles, boxes are located in locked cabinets and secured with an additional combination lock. Inside each orange box, controlled substances are kept in a separate drug box and sealed with a numbered red tag that is recorded in TFMRD's inventory system (Target Solutions). While in fire stations, access to vehicle bays is restricted to TFRMD personnel. Station doors are generally locked

and secured via key card access. Emergency Medical Services (EMS) staff perform daily physical inventories of all drug boxes before each shift. Any discrepancies are followed-up through the chain of command.

Medical supply bags used to support EMS personnel deployed during special events are stocked with medications and secured at a fire station. For these drugs, we noted that an Excel spreadsheet was used to track inventory and expiration dates rather than Target Solutions which TFMRD uses for all other medications. Use of Target Solutions would offer more control and consistency than a standalone spreadsheet.

TFMRD has well-developed policies, procedures and processes in place to help ensure the accurate recording of controlled substances dispensed in the conduct of work. TFMRD and hospitals have formal policies and controls in place to ensure appropriate drugs are refilled as necessary.

TFMRD uses the Target Solutions system to track controlled substance and other medication inventory. A separate system (Image Trend) is used to record patient care information (including medications that are dispensed). TFMRD procedures include controls such as the required input of data into Image Trend (dosages administered, seal numbers, and waste amounts) and crew member signoffs. Without signatures, patient care forms cannot be electronically submitted in Image Trend.

Drugs used during EMS calls are replenished by TFMRD medical staff at area hospital pharmacies as they are used (primarily Tempe St. Luke's Hospital (TSL). Other hospitals used less frequently include Banner Desert and Banner University Medical Centers. We reviewed TSL written policies governing the refill of controlled substances and conducted a site visit to interview TSL staff and review procedures. According to TSL policies, their Pharmacy Department restocks and maintains the Paramedic Drug Dispensing device and Drug Boxes as its part of the Base Hospital responsibility for the State EMS Paramedic Program. If a controlled substance is used, the pharmacy dispenses enough to replace that which was used. The paramedic accepting the controlled substance signs their name and medic number for the medication and is required to provide TSL staff an electronic patient care record with the documented medication and waste usages.

Controls over the disposal and exchange of expired drugs are adequate to ensure expired medications are replaced when needed.

On the first of each month, paramedics are required to check the expiration dates of each drug in the box. As needed, expired drugs are replaced at area hospital pharmacies (primarily TSL) the next time an EMS call results in a trip to a hospital.

Recommendations

Our detailed report contains a few recommendations to further strengthen the controls over controlled substances.

Department Responses to Recommendations

Rec. 1.1: TFMRD data analyst work with EMS Coordinator to develop a high-level controlled substance usage report (including drugs administered and expired) that can be used to compare to monthly hospital invoices for reasonableness of billing quantities.	
***Response*:** The TFMR Data Analyst will create a monthly report using data in ImageTrend to track drug administration on incidents that can be used to compare to monthly hospital invoices for reasonableness of billing quantities by the EMS Coordinator.	***Target Date*:** Complete
***Explanation, Target Date > 90 Days:* N/A**	
Rec. 1.2: Procurement Division develop and maintain written justification and approval for the "not practical to quote" exception to the pricing requirements contained in City Code for controlled substances and other medications purchased from hospital pharmacies.	
***Response*:** Concur. The written justification and approval for the "not practical to quote" exception to the pricing requirements contained in City Code for controlled substances and other medications purchased from hospital pharmacies were completed on 9-14-22.	***Target Date*:** Complete
***Explanation, Target Date > 90 Days:* N/A**	
Rec. 2.1: TFMRD management revise policy 2-210.11 to reflect a current daily controlled substance inventory count process by one staff member versus two or change the current process to match existing policy requirements.	
***Response*:** Policy 210.11 will be updated by the Medical Services Division at TFMR to reflect that one staff member will conduct the daily controlled substance inventory count process for each apparatus.	***Target Date*:** 11/1/22
***Explanation, Target Date > 90 Days:* N/A**	
Rec. 2.2: Replace the Special Events bag tracking spreadsheet with the new Check It system (some modifications may be needed).	
***Response*:** The Medical Services Deputy Chief will coordinate the creation and implementation of a new monthly drug bag check off process for the special event drug bags that will be documented in VectorSolutions.	***Target Date*:** 11/1/22

Explanation, Target Date > 90 Days: **N/A**	
Rec. 3.1: TFMRD consider the development of a routine report or dashboard to display usage of drugs and a process to identify and follow-up on unusual trends.	
Response**:** The TFMR EMS Coordinator will coordinate with the department's data analyst to create a monthly routine report of drug administration that can be used to identify and follow-up on unusual trends. The same report for recommendation 1.1 should suffice for this purpose.	***Target Date*****:** Complete
Explanation, Target Date > 90 Days: **N/A**	
Rec. 3.2: Explore options to provide advance notice of large refill orders to the TSL pharmacy to reduce wait times and lessen demand on TSL staff.	
Response**:** The TFMR EMS Coordinator explored and verified that the VectorSolutions Check-It program cannot generate a report based on drug expiration dates that can be forwarded to the TSL pharmacy. Additionally, the TSL pharmacy's request to fax over the names and quantities of medications ahead of time is not feasible because only 2 fire stations have access to office equipment with a fax capability.	***Target Date*****:** Complete
Explanation, Target Date > 90 Days: **N/A**	

1 – Purchase Process Controls

Background

Per TFMRD Policy 2-210.11, four controlled substances are stocked on all response vehicles:

- Ketamine
- Fentanyl
- Midazolam (Versed)
- Morphine

Once these drugs (controlled substances and other medications) are administered to patients treated on scene, supplies are replenished at local hospital pharmacies (primarily Tempe St. Luke Hospital (TSL)). Hospital pharmacies subsequently invoice TFMRD for amounts suppled.

Approach

The IAO conducted the following steps to evaluate controls over the purchase of controlled substances:

- Obtained and reviewed Tempe St. Luke Hospital (TSL) Pharmacy dispensing policies;
- Interviewed TSL staff and conducted a site visit to document the pharmacy billing process;
- Interviewed City staff that receive and process invoices for the purchase of pharmaceuticals and reviewed the approval process and other payment controls;
- Retrieved City financial records documenting payment from for FY 2021-22 to date and reconciled to invoices;
- Determined if prices are governed by a purchasing contract.

Results

Drugs are obtained at hospital pharmacies (primarily TSL) and monthly billings are prepared by the hospitals' accounting departments based on the type and quantity of drugs provided to TFMRD staff.

While at the hospital, TFMRD EMS staff complete and sign an order form for drugs that have been used on scene or during transport. The form is then turned into the pharmacy and the pharmacist provides replacements. Order forms are collected by the pharmacy and totals are calculated at the end of each month. The TSL pharmacist send the totals to the hospital's corporate accounting department who then processes and sends invoices to TFMRD. (Note: Controls over the drug refill process are discussed in Section 3 of this report).

Payment controls for pharmacy invoices are limited but appropriate given the low risk associated with the relatively minimal dollar amounts. Additional reports may be created to facilitate a high-level review to verify the reasonableness of quantities billed.

We reviewed invoices and payments for controlled substances for FY 2021-22 to date. Payments totaled just under $19,000 for the period reviewed. The Fire Services Inventory Technician receives invoices from the hospital pharmacies. Upon review and approval by the Deputy Chief and Emergency Medical Services Coordinator, the Inventory Technician initiates payment in PeopleSoft. The Deputy Chief and EMS Coordinator review invoices for reasonableness, but there is currently no report readily available from TFMR systems (Image Trend or Target Solutions) to compare billed quantities to amounts used.

Given the low expenditure amounts, a time-consuming reconciliation process is not warranted. However, based on our discussions with the TFMRD Data Analyst, it may be possible to produce a high-level usage report (using Imagine Trend data for drugs administered and Target Solutions for expired drug data) that could aid in the review of invoices for reasonableness.

The Finance Department, Procurement Division should document a written exception to memorialize compliance with City Code purchasing requirements for drugs procured from area hospitals.

There is no contract or other purchasing document in place with area hospitals governing the purchase of controlled substances and other medications and establishing prices. According to City Code 26A-11, purchases between $5,000 and $99,999 require three quotes. However, in our discussion with the City's Procurement Administrator, he believes that because of their unique nature, these purchases fall under an exception in the code, "not practical to quote." This section states:

> *The procurement officer with the approval of the Procurement Administrator may determine in writing that a purchase under the formal solicitation threshold is not practical to quote. The written determination will document why this determination is made and what circumstances limits the item from being competed.*

The formal, written documentation of this exception has not yet been completed by Procurement staff.

Recommendations

1.1. TFMRD data analyst work with EMS Coordinator to develop a high-level controlled substance usage report (including drugs administered and expired) that can be used to compare to monthly hospital invoices for reasonableness of billing quantities.

1.2 Procurement Division develop and maintain written justification and approval for the “not practical to quote” exception to the pricing requirements contained in City Code for controlled substances and other medications purchased from hospital pharmacies.

2 – Custody and Inventory Controls

Background

Some drugs administered by TFMRD are listed on the United States Drug Enforcement Administration's (DEA) Schedules of Controlled Substances. The DEA places substances in respective schedules (Schedule 1 – 5) based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Title 21 Chapter 13 Subchapter I Part C §823(j) of the U.S. Code allows distribution of these substances by emergency medical service providers.

TFMRD maintains supplies of controlled substances in combination with other medications for use during emergency medical service calls. Drugs are typically stored in ambulances and other fire apparatus. Because of the high-risk nature of these drugs, custody and inventory controls are vital.

Approach

We conducted the following audit tests to verify if TFMRD procedures ensured the physical security and proper custody of controlled substances. We also evaluated inventory management controls:

Custody/Security:

- Conducted physical observations of fire apparatus to determine where and how drugs are stored and secured;
- Determined how access to controlled substances is restricted to appropriate staff;
- Observed the storage location and written procedures for controlled substances located in special events bags.

Inventory Controls:

- Identified criteria used by TFRMD to determine the type and quantities of drugs maintained on each fire apparatus;
- Interviewed TFMRD management currently piloting an upgraded inventory software application interface (Check-It);
- Observed daily physical inventories conducted by TFMRD staff to evaluate procedures and verify if drugs were secured and maintained at required quantities;
- Reviewed the TFMRD system (Target Solutions) used to record drug inventory and use of the new "Check-It" application.

Results

Controlled substances are adequately secured by restricting access to vehicles while at the stations and using multi-level locking and tagging systems on vehicles and containers.

Controlled substances are kept on the following types of fire apparatus:

- Engines
- Ladder Trucks
- Ladder Tenders
- Ambulances
- One Specialty vehicle

Controlled substances and other medications are stored in large orange boxes secured with combination locks. Within fire vehicles, boxes are located in locked cabinets and secured with an additional combination lock. Inside each orange box, controlled substances are kept in a separate drug box and sealed with a numbered red tag that is recorded in TFMRD's inventory system (Target Solutions). While in fire stations, access to vehicle bays is restricted to TFRMD personnel. Station doors are generally locked and secured via key card access.

There is a different code for the box on each truck. Combinations to the locks are known to all medical staff and the mechanics who need access to work on trucks. TFMRD does not change combinations due to habit and ease of use.

TFMRD also keeps a supply of controlled substances in Special Event drug bags for use by EMS staff during large events (e.g., downtown concerts, festivals, etc.). We viewed the storage area of these bags at Fire Station #6 on June 1, 2022 and observed that Special Event drug bags were contained in a locked storage room and further secured in a locked cage. Each bag was also sealed with a plastic red numbered tag.

The new Check It application currently being tested by TFMRD should facilitate greater ease of use during daily and monthly inventory verifications and also provides additional controls.

We interviewed TFMRD management staff responsible for piloting the Check It application. Check It is an upgrade of the existing Target Solutions system used for drug and supply inventory developed by the existing vendor. We also observed a demonstration of the Check It application and noted the following enhancements:

- Auto notifications are sent if the daily inventory check is not complete:
  - Noon – notifies EMS Coordinator and EMS Captain
  - 4PM – notifies the Deputy Chief
- If a discrepancy in the inventory is found, the box is confiscated by the EMS Coordinator and the screens are locked so no edits can be made. A Deputy Chief then investigates.
- Drug expiration notifications are shown visually using red/green/yellow to designate status.

- The CS Tag number is displayed so that it can be verified during the daily inventory process.
- Future enhancements will include the ability to scan in vials (lot # and expiration date) which will help eliminate entry errors.

Daily and monthly inventory checks include effective controls to ensure the proper type and quantity of drugs are maintained, expiration dates are monitored, and any variances are flagged for follow-up and resolution by the chain of command. Policies and procedures should be adjusted to reflect a current count process by one staff member versus two.

The Arizona Department of Health Services has established minimum supply levels for the controlled substances carried by TFMR under Arizona Administrative Code Title 9, Chapter 25, Article 5 (R-25-502 Table 1). According to TFMRD polices, the amount and types of drugs kept on each apparatus are based on ADHS minimum supply recommendations.

We observed daily inventory checks at two stations in May 2022:

- Station #1 (Target Solutions and Check It used)
- Station #2 (Target solutions only)

During our observations, we noted the following steps taken:

Station Using Check It

- System log-in credentials are assigned to each individual.
- Staff performing inventory use an iPad or cell phones to access the application. Using the application, they select station #, apparatus #, and drug box check off option. Check It displays all drugs with a green, orange or red indicator designating expiration dates.
- Staff view expiration dates on bottles and the tag number to compare to tag in system. They ensure all controlled substances are accounted or according to minimum inventory list in policy (a laminated print-out is included in drug box)
- If a red tag seal is broken, staff record the old tag and new tag numbers in Check it. Check It displays the previous tag number when they log in so they know if it is different.
- Daily inventories are conducted every morning at the start if their shift (about 8am/365 days per year).

Stations Using Target Solutions

- This system does not visually display drug expiration dates (e.g. red/orange/green indicators) like the Check It application.
- Target Solutions has a similar check-off form link in the application.
- Staff enter apparatus number and shift.
- System control prevents staff from saving and closing out of forms without entering all required fields.
- Staff enters the tag number on the CS box (Target Solutions doesn't display or compare to previous tag number entered like Check It).

- Staff checks off minimum amounts accounted for.
- Staff enter initials and medic ID number.

Policy Deviation
During our observations at two stations, one paramedic inspected the contents of each CS box and signed the check off in Target Solutions/Check It. However, the TFMRD Paramedic Drug Box policy (2-210.11) states the following:

"Each shift, two on-coming paramedics should inspect the controlled substances and RSI Kit boxes to ensure they are either still locked from the previous shift, or use has been documented and the medication restocked, with the new lock securely placed per this policy. The oncoming paramedics should then electronically sign the controlled substances check-off to assume control over the drug box."

TFMRD should decide whether to change to process or update the policy to reflect current practice.

Use of the Target Solutions/Check-It process to inventory drugs in the Special Events bags would provide greater control and consistency with other drug inventory processes.

While at the Station #6, we observed the storage of the special event drug bags in a locked storage room. Per Special Event procedures, special event bags are to be checked on the first of the month for expired medications. However, since it was the start of summer and there are no special events planned, staff do not replace expired drugs to avoid waste. The Fire Captain for Emergency Services provided an Excel spreadsheet where drugs are listed with expiration dates and bag tag numbers are recorded. The only CS listed on the spreadsheet was Versed. Use of Check-It (Target Solutions) would offer more control and consistency than a separate spreadsheet tracking process.

Recommendations

2.1 TFMRD management revise policy 2-210.11 to reflect a current daily controlled substance inventory count process by one staff member versus two or change the current process to match existing policy requirements.

2.2 Replace the Special Events bag tracking spreadsheet with the new Check It system (some modifications may be needed).

3 – Record-Keeping, Refill and Disposal

Background

Drugs used during EMS calls and expired drugs are replenished by TFMRD medical staff at area hospital pharmacies as they are used or expiration dates dictate (primarily Tempe St. Luke's Hospital). Other hospitals used less frequently include Banner Desert and Banner University Medical Centers. At TSL, procedures to replenish drug supplies differ depending on the time of day. Supplies are either replenished by the pharmacy or through a locked drug cabinet system called "Pyxis,"

Approach

We conducted the following tests to evaluate management controls over TFMRD's controlled substance record-keeping, refill and disposal process.

For Record-Keeping/Refill controls:

- Identified the IT system used by TFMRD to record use of drugs;
- Observed a demonstration of Image Trend and tested critical system controls;
- Reviewed hospital pharmacy procedures and conducted a site visit to observe processes;
- Reviewed available system activity reports;
- Identified and tested controls over recording the usage of drugs in the system.
- Checked system access profiles and determined if all users were active TFMRD employees.

For controls over the Disposal of expired drugs:

- Observed the monthly inventory process to review for expired drugs;
- Review pharmacy policies and procedures regarding disposal and interviewed TFMRD and hospital staff;
- Determined if data is available to track amounts of drugs disposed.

Results

TFMRD has well-developed policies, procedures and processes in place to help ensure the accurate recording of controlled substances dispensed in the conduct of work. TFMRD and hospitals have formal policies and controls in place to ensure appropriate drugs are refilled as necessary.

Recordkeeping

As discussed in Section 2, TFMRD uses the Target Solutions system to track controlled substance and other medication inventory. A separate system (Image Trend) is used to

record patient care data (including medications that are dispensed) and support subsequent ambulance billings, if necessary

We noted the following control procedures governing the recording of controlled substance usage in Image Trend:

- Once used, EMS staff record the dosage administered in Image Trend. Information recorded includes seal #, usage amount, waste amount.
- A crew member signs off on the Image Trend entry. A second signature is only required is there is "waste" to account for (i.e. drugs opened but not administered).
- Without signatures, the form cannot be electronically submitted in Image Trend.
- A new tag number on drug box is entered into Target Solutions.

We observed test entries in the systems to ensure that forms could not be submitted without signature and also viewed tag number change screens.

Controlled Substance Refill

TSL developed a policy (*AL 112-Paramedic Drug Dispensing and Drug Boxes*) regulating the restocking of drugs used by emergency response personnel. We reviewed the TSL policies governing the refill of controlled substances and conducted a site visit to interview TSL staff and review procedures. According to TSL policies, their Pharmacy Department restocks and maintains the Paramedic Drug Dispensing device and Drug Boxes as its part of the Base Hospital responsibility for the State EMS Paramedic Program. If a controlled substance is used, the pharmacy dispenses enough to replace that which was used. The paramedic accepting the controlled substance signs their name and includes their medic number for the medication. The paramedic is also required to provide an electronic patient care record with the documented medication and waste to hospital staff.

Drug Refill procedures at TSL vary depending on the time of day:

From 9PM to 6AM

The TSL pharmacy is closed during this time frame. EMTs present the report from Image Trend (using their portable device or the desktop in the ER) with medications needed based on usage and the form is signed by TFRMD staff and a nurse. The charge nurse logs into the Pyxis system and notes the medications needed and the cabinets where they are stored automatically unlocks. Medications are distributed to the EMT and the paperwork is locked in the cabinet.

From 6AM to 9PM

Medication are obtained directly from the hospital pharmacy during this time frame. A pharmacy order form is completed by the EMT. The form is initialed by the EMT and turned into the Pharmacy along with Image Trend report signed by the EMT and nurse. The Pharmacist distributes meds to EMT and they sign a record ("green sheet") as evidence the Pharmacy distributed the meds.

Image Trend contains data that provides an opportunity to create a data dashboard or series of reports to track the usage of drugs at the station, apparatus, area of call and/or employee levels. This information would help identify unusual trends for further research.

TFMRD does not currently track or report the usage of controlled substances or other medications on a department-wide basis. In our discussions with the TFMRD data analyst, he stated that data exists in the Image Trend system that could support the development of reports. These reports could be used to identify unusual trends in the amount of controlled substances or other medications administered for follow-up by management. Involvement of the EMS Coordinator is necessary to identify the data points that would be meaningful to management without creating an undue burden on staff time.

Controls over the disposal and exchange of expired drugs are adequate to ensure expired medications are replaced when needed. There may be an opportunity to reduce wait times at the hospital pharmacy.

On the first of each month, paramedics are required to check the expiration dates of each drug on the box. We observed the first of the month check for expired medications at Fire Station #6 without exception. The next time a call takes them to TSL, they replace expired drugs at the pharmacy.

During our visit to the TSL Pharmacy, TSL staff indicated there is an opportunity to improve the process for refilling expired drugs. Because expiration checks are conducted by TFMRD at the same time each month, it can result in relatively larger orders and demand for pharmacy staff. For example, when the special event bags need to be replenished after the off season, multiple orders need to be filled at once and the pharmacy can become a bit overwhelmed depending on other operational demands. If advance notice was provided, rather than an on-the-spot order at the pharmacy window, TSL pharmacy staff believe they could smooth out the processing of orders and reduce the wait time for TFMRD staff.

Recommendations

3.1 TFMRD consider the development of a routine report or dashboard to display usage of drugs and a process to identify and follow-up on unusual trends.

3.2 Explore options to provide advance notice of large refill orders to the TSL pharmacy to reduce wait times and lessen demand on TSL staff.

Scope and Methods

Scope

We audited management controls over the payment, physical security, custody, dispensing, and disposal of controlled substances used by the TFMRD in place at the time of this audit. Payments were reviewed for FY 21/22 to date.

Methods

We used the following methods to complete this audit:

- Reviewed applicable TFMRD and TSL policies and procedures;
- Performed on-site observations at fire stations;
- Evaluated systems and applications used to inventory and track usage of medications;
- Interviewed relevant TFMRD and TSL staff;
- Reviewed invoices, payment documents, and City financial report related to the purchase of drugs;
- Tested relevant management controls.

Unless otherwise stated in the report, all sampling in this audit was conducted using a judgmental methodology to maximize efficiency based on auditor knowledge of the population being tested. As such, sample results cannot be extrapolated to the entire population and are limited to a discussion of only those items reviewed.