*An Audit Report on*

# Controlled Substances Management at Texas A&M University

- VMTH did not comply with certain federal and internal requirements for disposing of controlled substances.
- VMTH did not have accurate and complete disposal records.
- While VMTH documented most required information on product waste, it did not ensure that product waste was discarded in appropriate disposal containers.
- VMTH appropriately procured and securely stored controlled substances, but should strengthen its inventory management.

*Lisa R. Collier,* CPA, CFE, CIDA
State Auditor

The Veterinary Medical Teaching Hospital (VMTH) at Texas A&M University (University) did not have adequate processes and controls to ensure that it disposed of controlled substances, such as expired products and prescriptions that were no longer needed by animal owners, in accordance with applicable federal and internal requirements. VMTH also did not have accurate and complete records of the controlled substances transferred for off-site destruction. Additionally, while VMTH documented most required information on product waste, it should ensure that appropriate disposal containers for product waste are available and used by its personnel.



*This audit was conducted in accordance with Texas Government Code, Sections 321.013 and 321.0132.*

VMTH did have effective physical security controls in place to safeguard controlled substances. However, opportunities exist for VMTH to improve its inventory management processes.

**HIGH**

**DISPOSAL OF INVENTORY AND OTHER CONTROLLED SUBSTANCES**

VMTH did not comply with certain federal and internal disposal requirements and did not have adequate disposal records.

*Chapter 1-A | p. 8*

**MEDIUM**

**DISPOSAL OF PRODUCT WASTE**

Two VMTH personnel witnessed the disposal of most product waste. However, VMTH should ensure that product waste is discarded in appropriate disposal containers.

*Chapter 1-B | p. 16*

**MEDIUM**

**SAFEGUARDING**

VMTH securely stored controlled substances and restricted physical access to storage locations; however, certain aspects of its inventory management processes should be strengthened.

*Chapter 2 | p. 19*

**LOW**

**PROCUREMENT AND DISPENSING**

VMTH ensured that controlled substances were procured in accordance with applicable requirements and that two personnel witnessed most dispensing of controlled substances.

*Chapter 3 | p. 23*

*For more information about this audit, contact Audit Manager Willie Hicks or State Auditor Lisa Collier at 512-936-9500.*

*August 2023* | Report No. **23-040**

## Note on Confidential Findings

To minimize security risks, auditors communicated details about audit findings related to certain security weaknesses in a separate report to the University.


Those findings were rated Medium, indicating moderate risk. Action is needed to address the noted concerns and reduce risks to a more desirable level.

Auditors made recommendations in the confidential report to address the findings. The University agreed with the recommendations.

That separate report references confidential information. Pursuant to Standard 9.61 of the U.S. Government Accountability Office's *Government Auditing Standards*, certain information was omitted from this report because that information was deemed to present potential risks related to public safety, security, or the disclosure of private or confidential data. Under the provisions of Texas Government Code, Section 552.139, the omitted information is also exempt from the requirements of the Texas Public Information Act.

## Summary of Management's Response

Auditors made recommendations to address the issues identified during this audit. Those recommendations are provided at the end of each chapter in this report. The University agreed with the recommendations.

# Ratings Definitions

Auditors used professional judgment and rated the audit findings identified in this report. The issue ratings identified for each chapter were determined based on the degree of risk or effect of the findings in relation to the audit objective(s).

**PRIORITY:** Issues identified present risks or effects that if not addressed could ***critically affect*** the audited entity's ability to effectively administer the program(s)/function(s) audited. Immediate action is required to address the noted concern(s) and reduce risks to the audited entity.

**HIGH:** Issues identified present risks or effects that if not addressed could ***substantially affect*** the audited entity's ability to effectively administer the program(s)/function(s) audited. Prompt action is essential to address the noted concern(s) and reduce risks to the audited entity.

**MEDIUM:** Issues identified present risks or effects that if not addressed could ***moderately affect*** the audited entity's ability to effectively administer the program(s)/function(s) audited. Action is needed to address the noted concern(s) and reduce risks to a more desirable level.

**LOW:** The audit identified strengths that support the audited entity's ability to administer the program(s)/function(s) audited or the issues identified do not present significant risks ***or*** effects that would negatively affect the audited entity's ability to effectively administer the program(s)/function(s) audited.

For more on the methodology for issue ratings, see Report Ratings in Appendix 1.

# Background Information

## Schedules of Controlled Substances

The Controlled Substances Act (CSA) is the common name for Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, codified at United States Code, Title 21, Chapter 13, Subchapter I. The CSA placed each federally regulated controlled substance into one of five categories, referred to as schedules, based upon medical use, potential for abuse, and safety or likelihood of causing dependence when abused (see Figure 1).

The United States Department of Justice's Drug Enforcement Administration (DEA) is responsible for enforcing the CSA. The DEA produces a comprehensive list of the controlled substances in each schedule, which is published in the Code of Federal Regulations (CFR), Title 21, Part 1308.

Figure 1

### Overview of Schedules

| Schedule | Abuse Potential | Medical Use | Safety or Dependence | Examples |
|---|---|---|---|---|
| I | HIGH | None currently recognized | Lack of accepted safety for use under medical supervision. | *ecstasy, heroin, lysergic acid diethylamide (LSD)* |
| II | HIGH | Currently accepted | Abuse may lead to severe psychological or physical dependence. | *narcotics such as hydrocodone, methadone, oxycodone, fentanyl, and stimulants such as methamphetamine* |
| III | LESS than substances in Schedules I and II | Currently accepted | Abuse may lead to moderate or low physical dependence or high psychological dependence. | *anabolic steroids, ketamine, and narcotics such as buprenorphine and codeine products with acetaminophen* |
| IV | LOW relative to substances in Schedule III | Currently accepted | Abuse may lead to limited physical or psychological dependence relative to substances in Schedule III. | *narcotics such as tramadol, and depressants such as alprazolam, midazolam, and phenobarbital* |
| V | LOW relative to substances in Schedule IV | Currently accepted | Abuse may lead to limited physical or psychological dependence relative to substances in Schedule IV. | *cough medicines with codeine, and depressants such as pregabalin* |

Sources: United States Code, Title 21, Section 812; CFR, Title 21, Part 1308; and DEA.

# Closed Distribution System

The DEA's regulations establish a closed system of distribution so that controlled substances are at all times accounted for and under the legal control of registrants (see text box for more information) as they move through the chain of distribution—from their creation to their ultimate use (e.g., dispensed to a patient or used in research) or disposal.

Figure 2 shows the distribution cycle for a registrant that dispenses controlled substances to patients.

**Registration with the DEA**

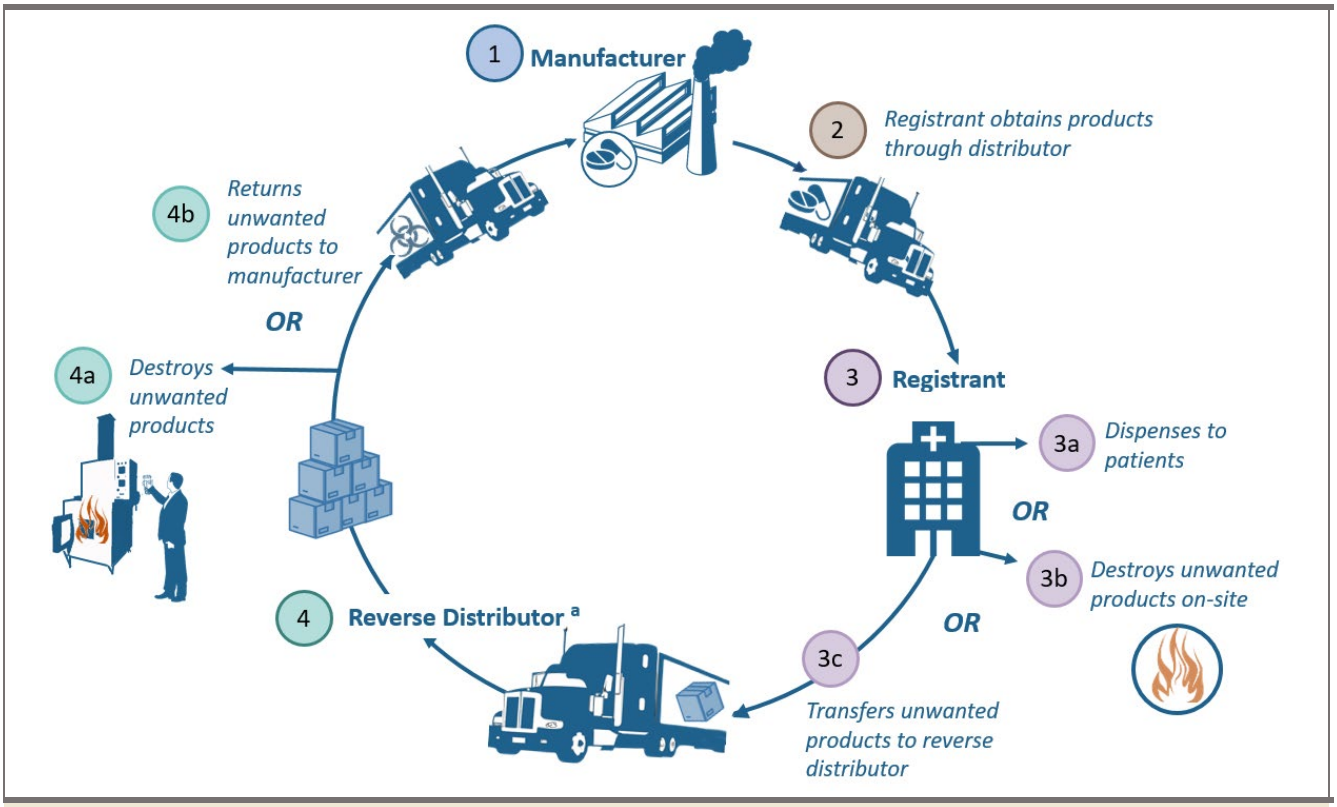
Those who engage or propose to engage in the manufacture, distribution, or dispensing of controlled substances must register with the DEA, unless an exemption applies.

Registrants may engage only in the specific activities covered by their registration(s), such as manufacturing, distributing, reverse distributing, research, dispensing, importing, or exporting.

Source: CFR, Title 21, Part 1301.

Figure 2

## Closed System for Distributing Controlled Substances




[a] A reverse distributor may determine whether expired or damaged controlled substances received from a registrant are eligible for manufacturer credits and, if applicable, share the credits received with the registrant.

Sources: CFR, Title 21, Sections 1301.13 and 1317.05; DEA; and VMTH's policies.

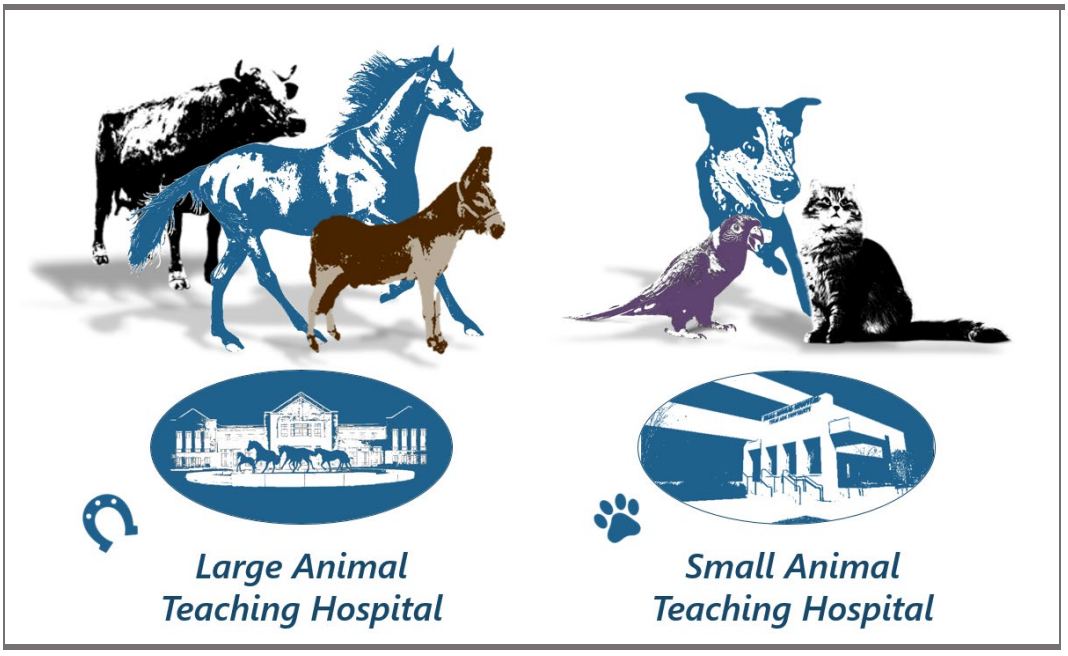
# Texas A&M University's Veterinary Medical Teaching Hospital

Texas A&M University's Veterinary Medical Teaching Hospital (VMTH) is registered as a Teaching Institution[1] with the DEA. VMTH's registration covers the use of controlled substances in Schedules II through V in dispensing and instructional activities.

VMTH personnel[2] use controlled substances in research, teaching, and clinical services provided to the public at VMTH's two veterinary hospitals. The large and small animal hospitals offer veterinary services for all species, such as the animals shown in Figure 3.

Figure 3

**Types of Animal Patients Treated at VMTH**




Source: VMTH.

[1] The DEA defines a "Teaching Institution" as a physical location where inpatient, outpatient, or emergency medical services are not provided to human patients, but where medicine is taught under the authority of a State-accredited college or university.

[2] VMTH personnel may include clinical faculty, staff, visiting scholars, and students.

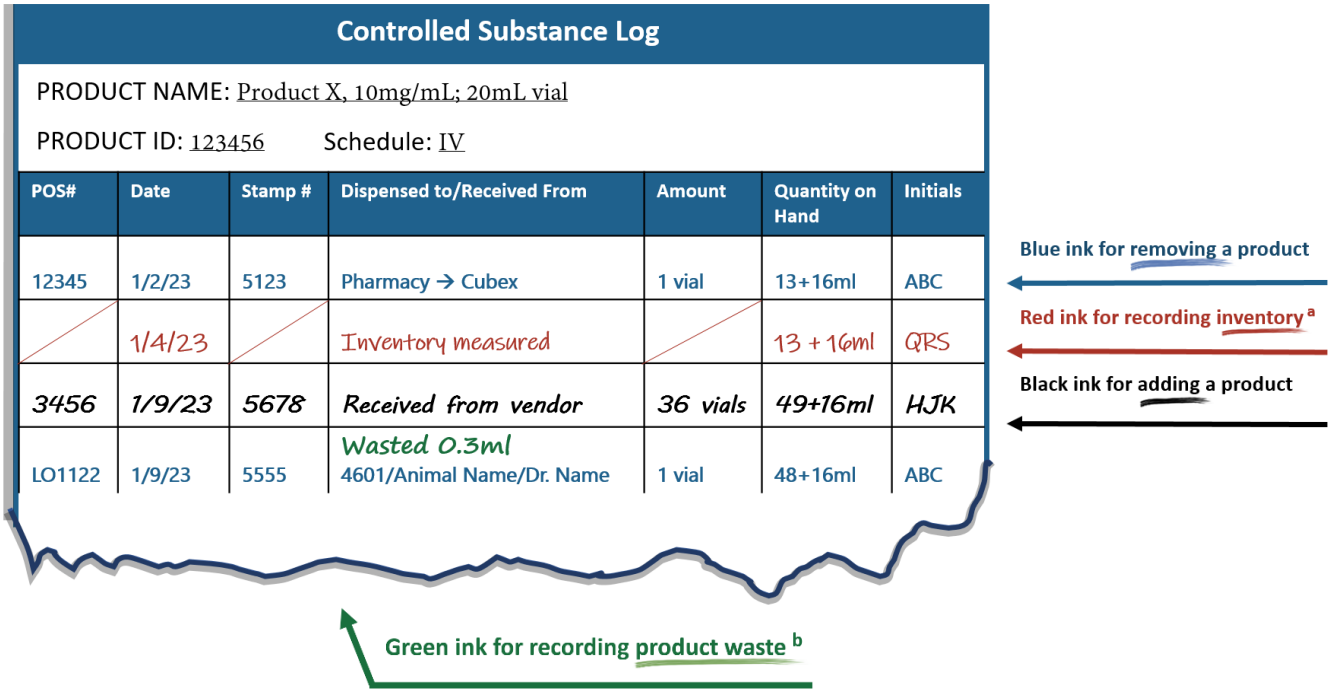
## Management of Controlled Substances

VMTH's two on-site pharmacies[3] are responsible for ordering and managing the inventory of controlled substances used at VMTH. VMTH uses its Veterinary Medical Information System, Cubex automated dispensing machines[4] (Cubex), and handwritten logbooks to track and manage controlled substances stored in and dispensed from 24 locations throughout its 2 hospitals, which include lockboxes, Cubex, and 5 field service trucks.

Figure 4 provides an example of VMTH's handwritten logbook, in which VMTH uses a color-coded system for tracking controlled substances in its lockboxes.

Figure 4

### Example of Handwritten Logbook Records for VMTH's Lockboxes




[a] See Chapter 2 for more information on VMTH's inventory processes.

[b] See Chapter 1-B for more information on product waste.

Source: VMTH.

[3] VMTH has a pharmacy located in each animal hospital; the pharmacies are open seven days a week.

[4] Cubex consists of computerized cabinets located throughout the animal hospitals that allow VMTH to electronically record and monitor the storage and dispensing of controlled substances used to treat animals.

Chapter 1-A

HIGH

# Disposal of Inventory and Other Controlled Substances

Texas A&M University's Veterinary Medical Teaching Hospital (VMTH) is registered with the Drug Enforcement Administration (DEA) to handle controlled substances in Schedules II through V. (See Background Information for examples of controlled substances in those schedules.)

VMTH may dispose of damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances from its inventory by either (1) using an on-site method of destruction sufficient to render a controlled substance non-retrievable[5], such as incineration or chemical digestion, or (2) transferring a controlled substance to a reverse distributor (a disposal vendor registered with the DEA) for off-site destruction.

## VMTH did not comply with federal and internal requirements for destroying controlled substances on-site.

**Authority to Destroy Controlled Substances Received From Others.** During the audit scope (September 2021 through April 2023), VMTH inappropriately disposed of controlled substances that were not a part of its inventory. According to its records, it disposed of 25 controlled substances that were either abandoned or no longer needed by (1) owners of animals and (2) other registrants, such as non-VMTH personnel. However, as a Teaching Institution, VMTH is not eligible to register with the DEA as a collector[6], which authorizes a registrant to collect and dispose of controlled substances for others.

[5] The Code of Federal Regulations (CFR), Title 21, Section 1300.05, defines "non-retrievable" as the condition or state to which a controlled substance shall be rendered following a process that permanently alters its physical or chemical condition or state through irreversible means that render it unavailable and unusable for all practical purposes.

[6] The term "collector" means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized to receive a controlled substance for the purpose of destruction (CFR, Title 21, Section 1300.01(b)).

In addition, although VMTH had a process for transferring controlled substances from other registrants to its inventory, it did not follow that process before it accepted controlled substances that belonged to non-VMTH personnel for purposes of disposal.

The DEA recognizes that entities sometimes may lack authority to dispose of controlled substances, and it recommends that in those instances, the entity should contact local law enforcement or the nearest DEA office for guidance on proper disposal procedures.

**On-site Disposal Method and Records.** From February through October of 2022, VMTH disposed of 12 controlled substances on-site; however, it did not use a method of on-site destruction sufficient to render them non-retrievable, as required by CFR, Title 21, Section 1317.90. Instead, VMTH mixed those controlled substances with kitty litter. While that method is appropriate for the on-site disposal of product waste—i.e., the amount of a product remaining in a container after the prescribed dosage has been dispensed (see Chapter 1-B for more information)—it is not a federally accepted method for the on-site destruction of controlled substances taken from a registrant's inventory.

VMTH also did not complete the *Registrant Record of Controlled Substances Destroyed* (Form DEA-41) to record the on-site destruction of those controlled substances, as required by CFR, Title 21, Section 1304.21. By not using that form, VMTH did not document all required information about the controlled substances it destroyed, such as the method of destruction and signatures of the two personnel who witnessed destruction. To help prevent diversion (see text box for more information), CFR, Title 21, Section 1317.95(d) requires that two employees witness the destruction of a controlled substance until it is rendered non-retrievable.

**Diversion**

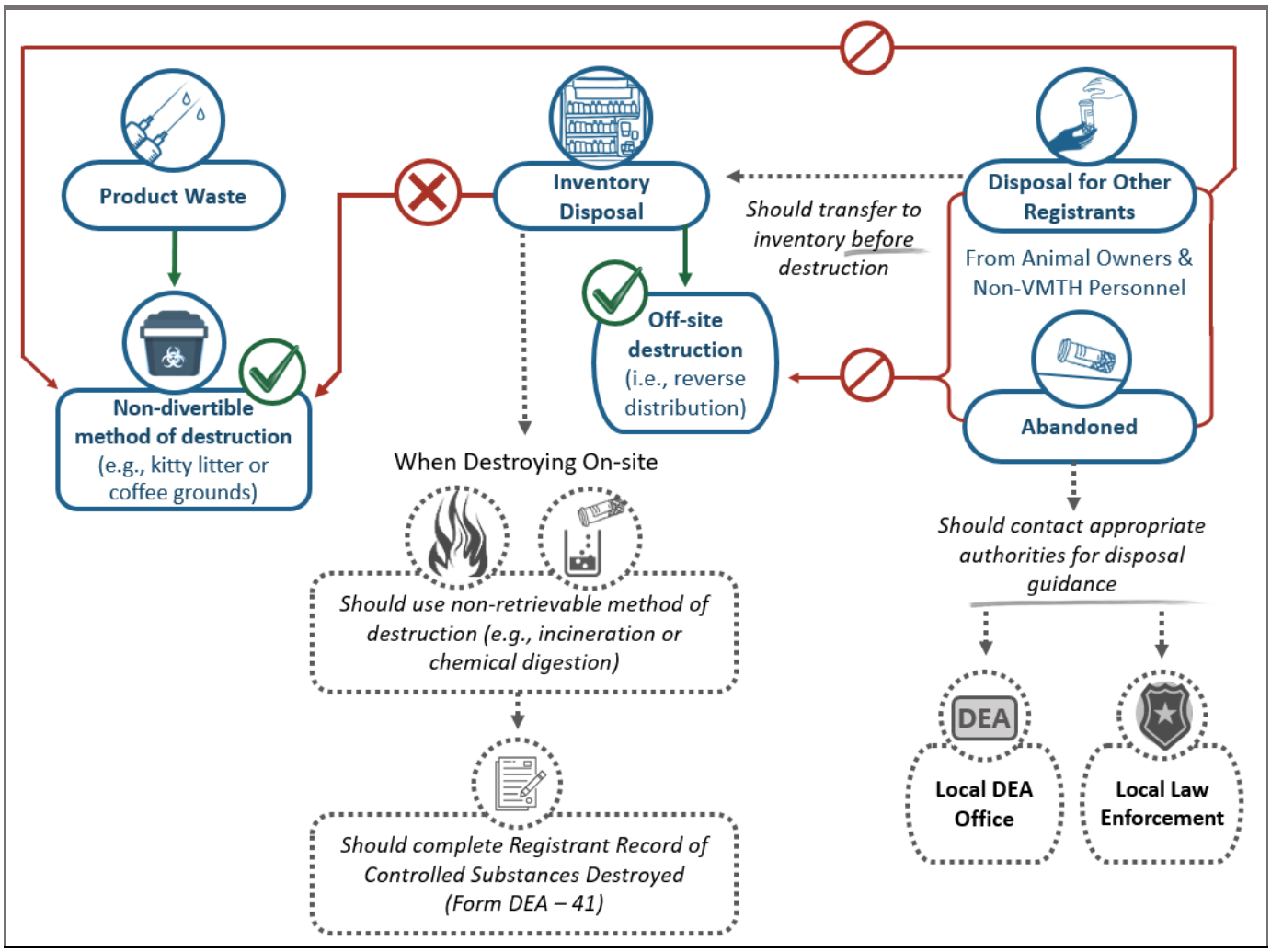
Diversion is the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.

Source: Based on guidance provided by CFR, Title 21, Parts 1300-1317.

Figure 5 on the next page shows a summary of the methods that VMTH used to dispose of the controlled substances discussed above.

Figure 5

## VMTH Methods for Disposal of Controlled Substances




Sources: CFR, Title 21, Parts 1317 and 1304; DEA; Environmental Protection Agency; and VMTH's records.

## VMTH did not have accurate or complete records for controlled substances that were disposed of off-site.

There were significant differences between (1) VMTH's disposal ledger for the controlled substances transferred to its reverse distributor (see text box for definition) and (2) its reverse distributor's manifests listing the controlled substances received from VMTH between October 2021 and March 2023. Those discrepancies create opportunities for someone to divert controlled substances awaiting transfer for disposal.

**Reverse Distributor**

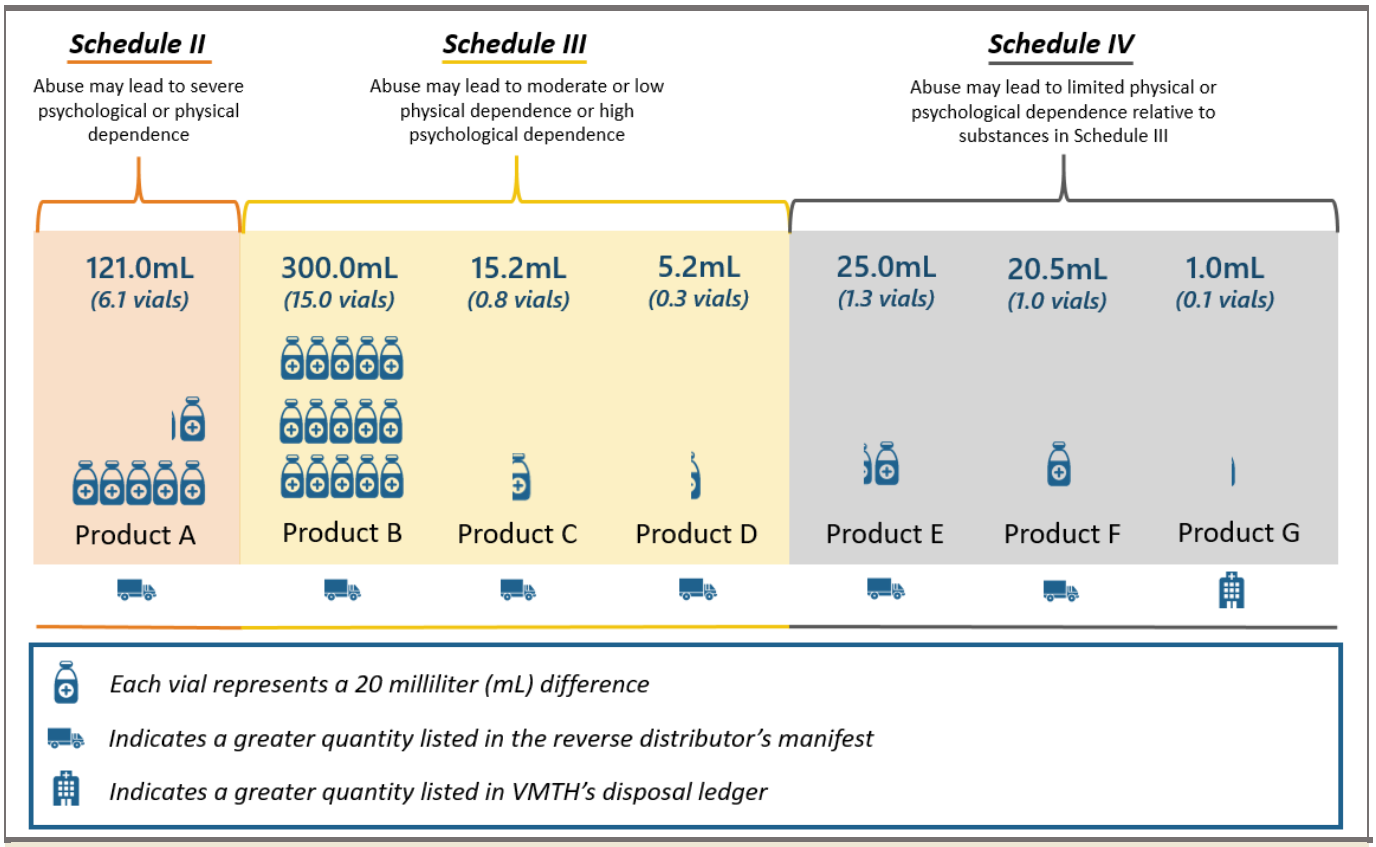
A reverse distributor is a vendor authorized by the DEA to collect controlled substances from other DEA registrants (such as pharmacies and hospitals) and either return the controlled substances to the manufacturer or arrange for their destruction.

Source: CFR, Title 21, Part 1300.

Figure 6 on the next page shows the net volume differences that auditors identified between those two sets of records for seven controlled substances.

Figure 6

## Volume Differences Between Disposal Ledger and Manifests [a]




[a] VMTH's disposal ledger and the reverse distributor's manifests collectively included 26 unique products, consisting of controlled substances in liquid, powder, tablet, capsule, and patch form. Of those 26 products, 7 were controlled substances in liquid form that had net quantity differences of at least 1.0 milliliter (mL).

Sources: VMTH's disposal ledger and its reverse distributor's manifests.

The differences identified resulted from several causes, including ineffective recordkeeping and review processes. Specifically:

- **Inaccurate Disposal Ledger.** VMTH had a process for identifying expired products in its inventory and moving them to a designated storage location until they could be transferred to its reverse distributor. However, VMTH did not always accurately or completely record the transfer of those products in its disposal ledger. For example, the 300-mL difference between VMTH's disposal ledger and the reverse distributor's manifest in Figure 6 above arose because VMTH did not record Product B in its disposal ledger for transfer to the reverse distributor.

If VMTH does not accurately and completely record in its disposal ledger the products physically awaiting transfer, there is an increased risk of those products being diverted instead of transferred.

- **Inadequate Oversight.** VMTH's process for reviewing and approving the reverse distributor's manifests was not sufficient to identify and address differences between the controlled substances intended for transfer, the controlled substances awaiting transfer, and the controlled substances that were actually transferred. For example, the following discrepancies were identified:
    - For the March 2023 transfer observed by auditors, the reverse distributor included one controlled substance in its manifest that was not physically present. However, VMTH did not identify that error when it reconciled the manifest to its disposal ledger and approved the manifest.
    - The reverse distributor had no record of receiving one controlled substance that was shown in VMTH's disposal ledger as being transferred.
    - The quantity of one controlled substance was originally recorded in VMTH's disposal ledger at 40 mL but was reduced to 35 mL at the time of transfer.

    While the latter two differences could have been due to errors, such as incorrectly measuring or recording the quantities for disposal, there is also the risk that the controlled substances were diverted while awaiting transfer.

It is important for VMTH to maintain accurate and complete disposal records so that it can identify and investigate differences that could be indications of diversion.

## Recommendations

VMTH should:

- Seek guidance from the DEA and local law enforcement on the proper disposal of controlled substances that are not a part of its inventory.

- Consider implementing an on-site method of destruction sufficient to render controlled substances non-retrievable. If an on-site method is established, implement policies and procedures to ensure that personnel complete the required DEA forms when destroying controlled substances.
- Strengthen its policies and procedures to ensure that personnel document the controlled substances transferred to its inventory in accordance with all applicable requirements.
- Implement policies for and train personnel on accurately documenting the quantities of controlled substances to be disposed.
- Implement a process to reconcile the physical count of its controlled substances awaiting transfer to (1) its disposal ledger and (2) the reverse distributor's manifests to identify and, if applicable, address any discrepancies.

## Management's Response

> The Veterinary Medical Teaching Hospital (VMTH) takes disposal of controlled substances very seriously. We agree there have been some issues in this area, particularly around non-inventory controlled substances and we have worked to correct this deficiency. Our primary goal was to remove controlled substances from those who no longer need them and destroy them appropriately.
>
> Historically, the VMTH was limited by the inability to remove surrendered controlled substances from the premises via a reverse distributor (RD). In November of 2022, this inability was lifted from the RD; and, since that time, all surrendered medications have been documented and returned with the RD services. As the audit reveals, while allowed by the RD, this is not an acceptable method for disposal of non-inventory items. After contacting the University Police Department (UPD) on August 9, 2023, our policy moving forward will be to document these surrendered medications and phone UPD for pickup. We will continue to document in our ledger and note that it was surrendered to UPD rather than the RD. This documentation will ensure safeguarding of the substance until UPD arrives.

For researchers using the VMTH to remove expired controlled substances from their possession, appropriate transfer paperwork is required to transfer them to the VMTH DEA and a RD will be utilized for disposal.

VMTH considered the recommendation to implement an on-site method of disposal but considering the hazards of incinerating on campus we are not planning to move forward with this process at this time.

VMTH has a new policy to standardize the way drugs are moved from the pharmacy/ Cubex locations to the expired box for pick-up and entered into the ledger. Before a medication is removed from inventory, the product will be measured/ counted, and the quantity changed on-hand either in the Cubex "log" or the book log. The bottle will be sealed (with tape or something similar) and date and amount written on with Sharpie. The measured quantity will then be removed from the pharmacy/ Cubex and that quantity will be written in the ledger. Prior to now, the volumes in the vials were estimated based on what Cubex reported. This should remove incompatibility between the ledger and RD. This policy has been updated.

In March of 2023, VMTH personnel started auditing the reverse distributor's manifest with our ledger book before the company leaves. Prior to the RD's visit, VMTH personnel are verifying the ledger against the controlled substances awaiting pick up.

Our Chief Pharmacist was responsible for implementation and training of these changes.

Implementation Date: August 9, 2023

MEDIUM

# Chapter 1-B
# Disposal of Product Waste

## Two personnel were involved in the disposal of most product waste.

VMTH has implemented manual processes and automated controls that require two personnel to witness and record the destruction of product waste (see text box for more information). At VMTH, product waste is created when its on-site pharmacies fill prescriptions for controlled substances and when personnel administer controlled substances to the animals in its care.

**Product Waste**

Product waste, commonly referred to as "drug wastage" or "pharmaceutical wastage," occurs when dosages of controlled substances are not fully exhausted (e.g., some of the product remains in a vial, tube, or syringe) but cannot or may not be used any further.

For example, if VMTH needs to dispense only half of a pre-filled syringe to a patient, the product remaining in the syringe is unusable and must be disposed.

Sources: DEA and VMTH.

As shown in Figure 7, two personnel were involved in VMTH's disposal of most product waste, according to records tested from its Cubex automated dispensing machines (Cubex), on-site pharmacies, and General Surgery Department. Although there is not a federal requirement for two personnel to witness the destruction of product waste (as there is for the destruction of unwanted controlled substances, as discussed in Chapter 1-A), the practice is strongly encouraged by the DEA.

Figure 7

### Product Waste Records Tested

| Types of Records Tested | Number of Records Tested | Number and Percentage of Records with Two Personnel |
|---|---|---|
| Cubex | 5,359 | 5,169 (96.4%) |
| On-site Pharmacies and General Surgery | 214[a] | 198 (92.5%) |

[a] The 214 records tested included 190 pharmacy and 24 General Surgery logbook entries and prescriptions forms. Two personnel were involved in disposal for 175 (92.1 percent) of the pharmacy records and 23 (95.8 percent) of the General Surgery records.

Source: VMTH's records.

## VMTH captured most required information in its product waste records.

VMTH's product waste records contained most of the information required by CFR, Title 21, Section 1304.22, which included:

- Name of Controlled Substance
- Form (e.g., tablet, liquid, powder, patch, etc.)
- Quantity

VMTH also documented the date of disposal for most controlled substance records tested. However, VMTH did not have procedures for documenting the manner in which product waste was disposed (i.e., using kitty litter). VMTH did not document that information in either Cubex or the records maintained by its on-site pharmacies and General Surgery. Those records provide accountability for controlled substances from the time VMTH orders them through dispensing to animals or disposal.

## VMTH should ensure that appropriate disposal containers are always available and properly used by personnel.

VMTH's expectation is for its personnel to (1) discard product waste into a disposal container filled with kitty litter and then, if applicable, (2) safely discard the needle or syringe in a separate sharps container (see text box for more information).

During a walkthrough of VMTH's facilities in March 2023, auditors observed that both types of disposal containers were available and appropriately used at 8 (57 percent) of 14 disposal areas visited. The other six disposal areas either (1) did not have both containers or (2) had both containers, but personnel did not properly dispose of product waste and syringes separately.

**Discarding Product Waste**

Common practices for discarding product waste include:

(1) Expelling product waste into a **sequestration device**, which is a container designed to collect product waste in a way that is highly resistant to diversion. For example, mixing product waste with an undesirable material, such as kitty litter or coffee grounds, is a common way to ensure product waste is unusable.

(2) Then, if applicable, discard the needle or syringe into a **sharps container**—a puncture- and leak-resistant container with an opening that allows personnel to deposit objects with sharp points or edges, but is not large enough for a hand to enter.

Sources: DEA, Environmental Protection Agency, Food and Drug Administration, and VMTH policies.

Consistently having both types of containers available can help ensure that product waste from controlled substances is not diverted and reduce the risk of injury and infections from sharp objects.

## Recommendations

VMTH should:

- Implement policies and procedures to document the method used to dispose of product waste.
- Train its personnel on those policies and procedures.
- Train personnel and monitor disposal areas to ensure that appropriate disposal containers are available and being used correctly.

## Management's Response

> The VMTH has previously established policies and procedures to document the method used to dispose of patient waste; however, the manner of disposal is not adequately captured in the waste records because we currently only have one method of disposal. Moving forward, VMTH will include manner of disposal in the logbook. Additionally, Cubex requires a reason for disposal with a comments section and VMTH will train personnel to include manner of disposal in this comments section. All new individuals are trained on controlled substance dispensing and wasting during Cubex orientation. Hospital wide re-training sessions started in May 2023, by the chief pharmacist, and will occur annually for all users including appropriate documentation.
>
> The VMTH pharmacy personnel will continue to improve training on how to properly waste and document medications.
>
> Implementation Date: September 1, 2023

MEDIUM

# Chapter 2
# Safeguarding

## VMTH appropriately secured and restricted physical access to controlled substances.

VMTH had effective physical security controls in place to guard against the diversion of controlled substances. For example, VMTH:

- Used badge readers to limit entry to the hospital buildings and the areas within the hospital where controlled substances are stored.
- Securely stored controlled substances in lockboxes that require access by either keys, which themselves require a combination code to retrieve, or electronic badges to open.

In addition, VMTH ensured that access to those lockboxes was restricted to appropriate personnel.

## VMTH should strengthen its inventory processes.

**Inventory Management.** VMTH has established and implemented processes for monitoring its inventory of controlled substances annually, monthly, and daily. Specifically, between September 2021 and February 2023, VMTH performed:

- Annual and monthly inventories of its products, which were more frequent than the biennial inventory required by the United States Code, Title 21, Section 827. VMTH conducted annual inventories in November 2021 and November 2022. Auditors also verified that it conducted most monthly inventories for (1) lockboxes and (2) Cubex for the three months selected for testing.
- Daily reviews of the products that were sold, transferred, or used to make other in-house products. VMTH personnel accurately and consistently performed those reviews for the 25 days selected for testing.

In addition, VMTH had adequate controls in place to ensure the appropriateness of users' access to the Veterinary Medical Information System, which it uses for managing its inventory.

However, certain aspects of VMTH's annual and monthly inventory processes should be improved:

- **Completeness.** VMTH should ensure that monthly inventories are performed for all controlled substances at all storage locations. Its personnel did not consistently capture the quantities of controlled substances physically on-hand for 3 lockbox and 11 Cubex locations that auditors tested. Specifically:
  - Fifteen percent of monthly lockbox inventories were not performed during three months reviewed (October 2021, November 2021, and July 2022).
  - Twelve percent of monthly Cubex inventories were not performed between September 2021 and February 2023.

  Performing consistent and complete inventories can help VMTH ensure that it has an adequate supply of products on-hand and can promptly address discrepancies. For example, during one monthly inventory, VMTH discovered a discrepancy in the quantity of a product transferred between its on-site pharmacies. VMTH investigated the difference, determined that a significant product loss had occurred, and completed the reporting form required by the DEA as specified by CFR, Title 21, Part 1301. VMTH indicated that it submitted that form to the DEA through the DEA's online Theft Loss Reporting system.

- **Methodology.** VMTH personnel did not always document whether the inventory of a product was based on an estimate or an exact count or measurement of the product on-hand. For example, instead of indicating that the liquid volume of a product was estimated or measured, personnel recorded that the volume was "checked" or "counted." It is important for VMTH to know which methodology is used because that information can help explain differences between the actual and recorded quantities on-hand that can arise due to product loss (see text box for additional information).

**Product Loss**

Examples of the types of product loss that VMTH indicated it experiences during an inventory of controlled substances included:

- **"Draw" loss.** This occurs when some of the liquid drawn up in a syringe is trapped between the needle and barrel of the syringe, known as the hub, and cannot be plunged out.
- **"Pour" loss.** This occurs when powders are poured out of their containers to be weighed and some of the fine granules are lost in the transition between the containers and the scale.

Source: VMTH.

- **Monitoring Discrepancies.** VMTH should strengthen its processes for monitoring differences between actual and recorded quantities on-hand so that it can investigate unexplained differences (e.g., differences that could not be fully explained by product loss), which could be indications of diversion.

  While VMTH's physical inventory reasonably matched its inventory records for most controlled substances examined[7] after accounting for product loss, there were differences between the actual and recorded quantities on-hand for 3 (8 percent) of 37 controlled substances tested that could not be fully explained.

## Recommendations

VMTH should:

- Implement processes to verify that a full and complete inventory of controlled substances is performed for all storage locations.
- Implement a policy and train personnel on how to clearly document the type of inventory methodology used.
- Strengthen its processes for monitoring, investigating, and documenting explanations for differences between actual and recorded inventory.

## Management's Response

> The VMTH does an outstanding job of maintaining inventory of their many locations of controlled substances. While the federal law mandates every other year inventory, the VMTH strives for monthly or weekly inventories whenever possible. VMTH has implemented better documentation guidelines, including methodology and expectations and will continue to improve training to ensure adherence to these higher standards.

[7] Auditors examined VMTH's product inventory during site visits on March 7, 2023, and March 22, 2023.

The VMTH continues to research better ways to monitor and explain when discrepancies arise. For example, we have security cameras on each Cubex and in the pharmacies. We are solidifying access to those cameras to review and explain discrepancies as soon as they become apparent. VMTH will continue to evaluate new technology with our IT security teams on a semi-annual basis to identify new options to further safeguard controlled substances (i.e., digital logs, biometric access verification, etc.).

Implementation Date: September 30, 2023

LOW

# Chapter 3
# Procurement and Dispensing

## VMTH had adequate processes and controls in place to ensure that controlled substances were procured in accordance with applicable requirements.

**Procurement.** For 18 purchases tested, VMTH complied with federal requirements and its own policies for purchasing controlled substances. Specifically, VMTH ensured that:

- Separation of duties was maintained between the personnel responsible for ordering, approving, and recording the receipt of controlled substances.
- Two personnel were involved in the physical receipt of controlled substances.
- The receipt of controlled substances was accurately recorded in its inventory records.
- The two personnel responsible for placing orders for Schedule II controlled substances were properly authorized by VMTH. CFR, Title 21, Part 1305, requires registrants to execute a power of attorney to authorize personnel to place orders for Schedule II controlled substances (see text box for more information).

**Orders for Controlled Substances**

For Schedule I and II controlled substances, a registrant may authorize one or more individuals to place orders on that registrant's behalf by executing a power of attorney for each such individual.

With a few exceptions, those orders may be made only (1) electronically through the DEA's Controlled Substance Ordering System or (2) on the DEA's official order form.

Sources: CFR, Title 21, Part 1305; and DEA.

## Two personnel were involved in dispensing most controlled substances, but adherence to that practice could be improved.

**Dispensing.** To help ensure accuracy of product names, quantities, strengths, and dosage forms and to reduce the risk of diversion, VMTH requires that two

personnel be involved in dispensing[8] controlled substances, whenever practical.

As shown in Figure 8, two personnel were involved in most instances of dispensing controlled substances from Cubex and the General Surgery lockbox. VMTH programmed Cubex to help enforce that expectation, resulting in the highest compliance rate for that method. However, the on-site pharmacies had a lower rate of compliance. The pharmacies are open seven days a week, and VMTH indicated that there are times, typically on weekends, where only one person is working.

Figure 8

### Dispensing Records Tested

| Types of Records Tested | Number of Records Tested | Number and Percentage of Records With Two Personnel |
|---|---|---|
| Cubex [a] | 51,314 | 51,225 (99.8%) |
| General Surgery | 23 | 21 (91.3%) |
| On-site Pharmacies [b] | 25 | 18 (72.0%) |

[a] The Cubex records tested did not include several products that are often needed in emergency situations where having two personnel involved in dispensing may not be possible.

[b] The records tested for the on-site pharmacies were prescriptions processed through VMTH's Veterinary Medical Information System.

Sources: VMTH's dispensing records for Cubex, General Surgery, and the on-site pharmacies.

## Recommendations

VMTH should:

- Ensure that the on-site pharmacies involve at least two personnel in dispensing controlled substances, whenever practical.
- Document explanations for instances when the on-site pharmacies are unable to have two personnel involved in dispensing.

[8] The term "dispense" means to deliver a controlled substance by or pursuant to the lawful order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare it for such delivery (United States Code, Title 21, Section 802).

## Management's Response

Due to the 24-hour nature of the VMTH, there are times outside of normal business hours that two individuals are not present while dispensing controlled substances. After-hours staff send pictures via text to verify the correct product and verify the amount for all controlled substance prescriptions. The VMTH will work to increase documentation when controlled substances are dispensed at nights and on weekends. Verifying the accuracy of the log further verifies accurate dispensing.

Implementation Date: August 9, 2023

# Appendix 1

# Objective, Scope, and Methodology

**The following members of the State Auditor's staff performed the audit:**

- Tessa Mlynar, CIA, CISA, CFE (Project Manager)
- Brady Bennett, MBA, CFE, CGAP (Assistant Project Manager)
- Evan Cresap, CPA
- Cheri Jones, MBA
- Alex Kipple
- Ava Shahparasti
- Michelle Ann Duncan Feller, CPA, CIA (Quality Control Reviewer)
- Willie Hicks, CIA, MBA, CGAP (Audit Manager)

## Objective

The objective of this audit was to determine whether Texas A&M University (University) has adequate processes and related controls to ensure that the institution procures, distributes, safeguards, and disposes of controlled substances in accordance with applicable requirements.

## Scope

The scope of this audit included processes and controls in use at the University's Veterinary Medical Teaching Hospital (VMTH) from September 1, 2021, through April 30, 2023.

The scope also included a review of significant internal control components related to VMTH's management of controlled substances.

# Methodology

We conducted this performance audit from November 2022 through August 2023 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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective. In addition, during the audit, matters not required to be reported in accordance with *Government Auditing Standards* were communicated to University management for consideration.

## Addressing the Audit Objective

During the audit, we performed the following:

- Interviewed VMTH management and staff to gain an understanding of processes and internal controls for managing controlled substances.
- Identified relevant criteria, including the following:
  - The Controlled Substances Act (United States Code, Title 21, Chapter 13, Subchapter I).
  - The Code of Federal Regulations, Title 21 Food and Drugs, Chapter II Drug Enforcement Administration, Department of Justice.
  - VMTH policies and procedures.
- Observed the physical security controls in place to safeguard controlled substances.
- Tested user access to VMTH's Veterinary Medical Information System (VMIS) and its Cubex automated dispensing machines (Cubex).
- Reviewed VMTH's processes and analyzed their records related to the disposal of controlled substances.
- Reviewed records from Cubex, the on-site pharmacies, and the General Surgery Department to determine whether two personnel were involved in the dispensing and disposal of controlled substances.

## Random Samples Tested

Auditors tested samples to determine whether VMTH complied with applicable federal requirements and its own policies for managing the purchase, inventory, and dispensing of controlled substances. The following tests were performed:

- Tested a sample of purchases made from March 29, 2022, through January 31, 2023, to determine whether (1) there was adequate separation of duties in the receiving process and (2) the receipt of controlled substances was accurately recorded.
- Tested samples of (1) monthly inventories for the 17 months between September 1, 2021, and January 31, 2023, and (2) daily reports of controlled substances sold, transferred, or used to make other in-house products from September 1, 2021, to February 28, 2023.
- Tested a sample of prescriptions filled between September 1, 2021, and January 31, 2023, to determine whether two personnel were involved in dispensing controlled substances from VMTH's on-site pharmacies.

Figure 9 provides details on the random samples used in the testing described above.

Figure 9

### Random Samples Selected

| Description | Population | Sample Size | Representative Determination |
|---|---|---|---|
| Controlled substances purchased | 174 | 18 | Not representative [a] |
| Daily reports of controlled substances sold, transferred, or used to make other in-house products | 1,092 | 25 | Representative [b] |
| Monthly inventories | 17 | 3 | Representative [b] |
| Pharmacy prescriptions | 2,007 | 25 | Representative [b] |

[a] Some purchases made during the time period reviewed were excluded from the population used for sampling and analyzed separately; therefore, it would not be appropriate to project the test results.

[b] The random sample methodology was chosen so samples would be representative and could be evaluated in the context of the population. Sample results may be projected to the population, but the accuracy of the projection cannot be measured.

## Risk-based Samples Tested

Auditors tested 37 controlled substances to determine whether the physical inventory of products accurately matched VMTH's inventory records. The following risk-based samples were selected to obtain coverage of various controlled substances from Schedules II through V, various forms (such as powder, liquid, and tablet) used by VMTH, and various storage locations:

- Sixteen controlled substances selected from the 158 controlled substances included in VMTH's electronic inventory records as of March 6, 2023.
- Twenty-one controlled substances selected from certain storage locations that auditors examined during site visits on March 7, 2023, and March 22, 2023. While VMTH maintains most of its inventory records electronically, several products are tracked manually. Therefore, the total population of controlled substances in inventory at the time of auditors' site visits was undetermined.

The samples selected were not necessarily representative of the population; therefore, it would not be appropriate to project test results to the population.

## Data Reliability and Completeness

Auditors determined that the following data was sufficiently reliable for the purposes of the audit:

- VMIS data on controlled substances (1) purchased from September 1, 2021, to February 1, 2023, and (2) dispensed from September 1, 2021, to January 31, 2023.
- Data on controlled substances stored in and dispensed from Cubex from September 1, 2021, through March 3, 2023.

To determine reliability of the datasets used, auditors (1) reviewed the parameters used to extract all three of the datasets and also observed VMTH extract data for the two VMIS datasets, and (2) analyzed the data for reasonableness and completeness.

## Report Ratings

In determining the ratings of audit findings, auditors considered factors such as financial impact; potential failure to meet program/function objectives; noncompliance with state statute(s), rules, regulations, and other requirements or criteria; and the inadequacy of the design and/or operating effectiveness of internal controls. In addition, evidence of potential fraud, waste, or abuse; significant control environment issues; and little to no corrective action for issues previously identified could increase the ratings for audit findings. Auditors also identified and considered other factors when appropriate.

Copies of this report have been distributed to the following:

## Legislative Audit Committee

The Honorable Dan Patrick, Lieutenant Governor, Joint Chair

The Honorable Dade Phelan, Speaker of the House, Joint Chair

The Honorable Joan Huffman, Senate Finance Committee

The Honorable Robert Nichols, Member, Texas Senate

The Honorable Greg Bonnen, House Appropriations Committee

The Honorable Morgan Meyer, House Ways and Means Committee

## Office of the Governor

The Honorable Greg Abbott, Governor

## Texas A&M University

Members of the Texas A&M System Board of Regents

Mr. John Sharp, Chancellor, Texas A&M University System

General (Ret.) Mark A. Welsh III, Interim President