Board of Pharmacy

INSPECTION GUIDE

Terminal Distributor of Dangerous Drugs

Animal Shelter

Updated 8/13/2024

To review updates, please see the update history section at the end of this document.

This document is reference material for licensees and applicants. The document does not bind the Ohio Board of Pharmacy, and does not confer any rights, privileges, benefits, or immunities for or on any person, applicant or licensee.

Applicability

This guide applies only to locations licensed as terminal distributor of dangerous drugs that meet the following definition of a "animal shelter" in rule 4729:5-15-01 of the Ohio Administrative Code:

> *"Animal shelter" means a facility licensed as terminal distributor of dangerous drugs in accordance with section 4729.531 of the Revised Code or section 4729.54 of the Revised Code. An animal shelter shall be operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code.*

NOTE: An animal shelter that does not have a licensed veterinarian serving as the responsible person shall obtain a limited license as terminal distributor of dangerous drugs in accordance with section 4729.531 of the Revised Code.

REMINDER: This inspection guide **does not apply** to pharmacies, institutional facilities, or any of the following license types that have their own corresponding chapter of the Ohio Administrative Code:

- Pain Management Clinics – 4729:5-11
- First Aid Departments – 4729:5-13
- Laboratories – 4729:5-16
- Office-Based Opioid Treatment Facilities – 4729:5-18
- Clinics and Prescriber Offices – 4729:5-19
- Veterinary Clinics – 4729:5-20
- Opioid Treatment Programs – 4729:5-21
- Non-limited Facilities – 4729:5-22
- Limited Facilities – 4729:5-23

Licensure Requirements – Animal Sanctuaries

The definition of animal shelter **DOES NOT** include an animal sanctuary or other facility that may care for animals (ex. zoo), unless that facility is either:

- Operated by a humane society or any society organized under Chapter 1717. of the Revised Code; or
- A dog pound operated pursuant to Chapter 955. of the Revised Code.

A facility where dangerous drugs are maintained for the treatment of animals that does not meet the definition of an animal shelter, must apply for a veterinary clinic license under Chapter 4729:5-20 of the Ohio Administrative Code. A veterinary clinic must have a veterinarian listed as the responsible person for the license. For more information on veterinary clinic licensure visit: www.pharmacy.ohio.gov/VetInspect.

Alternatively, animal sanctuaries that contract with a veterinarian to provide medical services may also opt to utilize a provision of rule 4729:5-3-13 of the Administrative Code whereby a veterinarian

may remove drugs from a veterinary clinic to treat animals at an off-site location. This permits a veterinarian to treat animals at a sanctuary or other location but not require the sanctuary to obtain a terminal distributor license. If a veterinarian opts to maintain a non-patient specific drug supply at another location (instead of returning those drugs to a licensed veterinary clinic location), the veterinarian must meet the security and recordkeeping requirements set forth in the rule. This also subjects the off-site location where the drugs are stored to inspection by the Board.

Inspection Authority

Pursuant to section 3719.13 of the Revised Code and rule 4729:5-3-03 of the Administrative Code, a location licensed by the State Board of Pharmacy as a terminal distributor of dangerous drugs is subject to an on-site inspection by the Board. An authorized Board agent may, without notice, carry out an on-site inspection or investigation of an entity licensed by the Board.

Upon verification of the Board agent's credentials, the agent shall be permitted to enter the licensed entity.

Submission of an application for a license as a terminal distributor of dangerous drugs with the State Board of Pharmacy constitutes permission for entry and on-site inspection by an authorized Board agent.

After the completion of the inspection, the authorized Board agent will provide an inspection report for review and any corrective actions required. If the inspection report requires a written response, responses must be e-mailed within 30 days of the inspection to writtenresponse@pharmacy.ohio.gov.

Applicable Rules

The following provides a general list of rule chapters that apply to animal shelters licensed as terminal distributor of dangerous drugs:

- **4729:5-1 – Definitions**
- **4729:5-2 – Licensing**
- **4729:5-3 – General Terminal Distributor Provisions**
- **4729:5-4 – Disciplinary Actions**
- **4729:5-15 – Animal Shelters**
    - 4729:5-15-01 – Animal Shelters - Definitions.
    - 4729:5-15-02 – Security and control of dangerous drugs.
    - 4729:5-15-03 – Record keeping.
    - 4729:5-15-04 – Drugs approved for euthanasia.
    - 4729:5-15-05 – Chemical capture classification.
    - 4729:5-20-02 (required by 4729:5-15-01) – Personally furnishing dangerous drugs.

Positive Identification Guidance

"Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

(1) A manual signature on a hard copy record;

(2) A magnetic card reader;

(3) A bar code reader;

(4) A biometric method;

(5) A proximity badge reader;

(6) A board approved system of randomly generated personal questions;

(7) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(8) Other effective methods for identifying individuals that have been approved by the board.

NOTE: A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

REMINDER: Positive identification should be at the conclusion of a drug transaction. For electronic systems, positive identification required at log-in does not document the specific drug transaction and causes other security problems. For example, a nurse does not document the administration of a medication when they log in to an electronic drug record keeping system.

Required Notifications or Document Submissions

Links to instructions and forms can be found in the table below and can also be accessed on the Board's terminal distributor licensing page: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx

Ohio Board of Pharmacy rules require the following notifications to the Board:

Notification/Submission Requirement	How to Submit
Change in Business Description *OAC 4729:5-2-03* Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted **within thirty days** of any change in the ownership, business or trade name, category, or address.	A change of business description must be completed online using Ohio's **eLicense** system. Instructions on submitting this information can be accessed **here**.
Discontinuation of Business *OAC 4729:5-2-04* A terminal distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the Board of Pharmacy. The notice shall be submitted, in a manner determined by the Board, **at least thirty days in advance** of the proposed date of discontinuing business, unless waived by the Board's Executive Director or the Director's Designee due to extraordinary circumstances beyond the licensee's control.	Requires submission of a **Written Notice of Discontinuing Business Form**.
Change of Responsible Person *OAC 4729:5-2-01* A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times. When there is a change of responsible person, the Board must be notified **within ten days** of the effective date of the appointment of the new responsible person.	Requires submission of a **Change of Responsible Person Form**.
Notification of Off-Site Records Storage *OAC 4729:5-15-03*	Requires submission of an **Off-Site Records Notification Form**.

A terminal distributor intending to maintain records at a location other than the location licensed by the State Board of Pharmacy must notify the Board.	
Theft or Significant Loss of Dangerous Drugs and Drug Documents *OAC 4729:5-3-02* Licensees are required to report the theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) and drug documents.	For more information on this requirement, the Board developed this **guidance** document.
Drug List Modifications – Limited Licenses ONLY OAC *4729:5-15-03* An animal shelter licensed as a limited category II or limited category III terminal distributor of dangerous drugs may only possess dangerous drugs that are on the drug list submitted to the Board pursuant to section 4729.54 of Revised Code and only at locations licensed by the State Board of Pharmacy. The responsible person may modify the drugs that may be possessed and administered by the limited facility by submitting a new drug list to the State Board of Pharmacy in a manner determined by the Board. **IMPORTANT:** When uploading a drug list, it will replace the current drug list on file. The list should include all drugs (not just updates) that may be purchased and possessed by the licensee. Click here to review a licensee's current drug list.	Requires electronic submission of a signed drug list. A sample drug list along with instructions for submission can be accessed **here**. A licensee may submit drug list using a different format but it must include all of the components of the **sample drug list** provided by the Board.
Chemical Capture Classification *OAC 4729:5-15-05* Section 4729.542 of the Ohio Revised Code and rule 4729:5-15-05 of the Ohio Administrative Code allow an animal shelter or county dog warden that holds a limited terminal distributor of dangerous drugs license to apply for a chemical capture classification. This classification permits the holder to purchase, possess, and administer a combination of drugs for chemical capture.	To apply for a chemical capture classification, the certified officer must submit a Chemical Capture Attestation Form. This form, including submission instructions, can be accessed here: www.pharmacy.ohio.gov/CCform.

Use of Drugs as Part of the Euthanasia Process

Pursuant to section 4729.532 of the Revised Code and rule 4729:5-15-04, the Ohio Board of Pharmacy and the Ohio Veterinary Medical Licensing Board have approved the administration of the following additional dangerous drugs to be used by euthanasia technicians as part of the euthanasia process:

- Tiletamine and zolazepam for injection for anesthetizing an animal;
- Ketamine hydrochloride for anesthetizing an animal; and
- Xylazine for sedating an animal.

Important Terms

- **"Dangerous drug"** means any of the following:

  (1) Any drug to which either of the following applies:

  (a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription;

  (b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

  (2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

  (3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body;

  (4) Any drug that is a biological product, as defined in section 3715.01 of the Revised Code.

  IMPORTANT: Animal vaccines are NOT considered a dangerous drug.

- **"Distributor of dangerous drugs"** or "drug distributor " means the following persons licensed in accordance with section 4729.52 of the Revised Code:

  (1) Wholesale distributors of dangerous drugs, including:

  (a) Brokers; and

  (b) Virtual wholesalers.

  (2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(4) Third-party logistics providers.

(5) Repackagers of dangerous drugs.

- **"Euthanasia"** means the causing of humane death, through the rapid loss of consciousness followed by cardiac and respiratory arrest and the ultimate loss of brain function.

- **"Readily retrievable"** means that records maintained in accordance with this division shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the Board.

- **"Personal supervision"** means the person specified in rule shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs.

- **"Personally furnish"** or "personally furnishing" means the distribution of dangerous drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting. For the purposes of this chapter, the prescriber shall be a veterinarian.

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Animal Shelter - Inspection Guide

OAC = Ohio Administrative Code / ORC = Ohio Revised Code / CFR = Code of Federal Regulations

Licensing and Responsible Person

Question	Description / Guidance	Law/Rule
Have there been any changes in the facility's ownership, business name or trade name, category, or address without submitting a new application to the Board?	Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address.	OAC 4729:5-2-03
Does the responsible person match what is indicated in eLicense?	A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times. When there is a change of responsible person, the Board must be notified within ten days of the effective date of the appointment of the new responsible person. A change of responsible person form is available on the Board's website https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx.	OAC 4729:5-2-01

Personnel

Question	Guidance	Law/Rule
Have any licensed/registered employees at the facility with access to drug stock ever been disciplined by an Ohio licensing agency?	"Access to drug stock" includes not only physical access, but also any influence over the handling of dangerous drugs such as purchases, inventories, issuance of medical orders, etc. It does not include employees or contractors such as maintenance, janitorial, IT or other staff that may need limited supervised access to areas where dangerous drugs or D.E.A. controlled substance order forms are kept. Disciplinary action means any of the following, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement: (1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration, or certification; (2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action; (3) An administrative fine or money penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, censure, reprimand, or probation; (4) An action to reprimand or place the license, registration, or certification holder on probation; (5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, reprimand, probation, or surrender;	OAC 4729:5-1-01 OAC 4729:5-4-01

	(6) The withdrawal of a renewal application for licensure, registration or certification while under investigation; (7) The non-renewal of a license, registration or certification while under investigation or to avoid an investigation; (8) The surrender or other relinquishment of a license, registration or certification in lieu of a formal sanction against a person's license, registration or certificate, whether permanent or temporary; (9) In lieu of an adverse licensure, registration or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license, registration, or certification in the future; (10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation. **NOTE:** Licensee will be asked to provide the names of Ohio licensed/registered employees with access to drug stock to assist Board staff with verification.	
Have all agents and employees who perform euthanasia completed a euthanasia technician certification course?	An animal shelter shall ensure that all agents and employees who perform euthanasia, other than registered veterinary technicians or licensed veterinarians, shall successfully complete a euthanasia technician certification course described in section 4729.532 of the Revised Code. **NOTE:** Licensee must have documentation on-site for review by Board staff. This requirement does not apply to veterinarians and veterinary technicians.	OAC 4729:5-15-01

	A list of approved courses approved by the Ohio Veterinary Medical Licensing Board can be **accessed here**.	

Drug List

Question	Guidance	Law/Rule
Does the licensee's drug list match the list on-file with the Board?	A limited facility may only possess those controlled substances and dangerous drugs that are on the drug list submitted to the Board. The drug list on-file can be accessed here: www.pharmacy.ohio.gov/DL	OAC 4729:5-15-03
****FOR LIMITED LICENSES ONLY: Does the licensee possess any dangerous drugs that are not on the drug list on-file with the Board?**	An animal shelter licensed as a limited category II or limited category III terminal distributor of dangerous drugs may only possess dangerous drugs that are on the drug list submitted to the Board pursuant to section 4729.54 of Revised Code and only at locations licensed by the State Board of Pharmacy. The responsible person may modify the drugs that may be possessed and administered by the limited facility by submitting a new drug list to the State Board of Pharmacy in a manner determined by the Board. The drug list on-file can be accessed here: www.pharmacy.ohio.gov/DL Board staff will check the drug list with the drugs that are on hand to confirm.	OAC 4729:5-15-03

Patient Records and Drug Administration

Question	Guidance	Law/Rule
Does this site use a manual, computerized or combination of both to maintain drug records?	Describe what type of system (manual, electronic or both).	
If using a computerized record keeping system, does the system have effective security controls to prevent unauthorized access?	All computerized systems must contain security features to prevent unauthorized access. Such features may include unique user names and passwords, biometrics (i.e. fingerprint), or any other method that ensures only authorized users may obtain access. All methods for accessing electronic records must be user-specific (i.e. no shared user names or passwords).	OAC 4729:5-15-03
If using a computerized system, are records backed up daily to prevent against record loss?	Licensee should provide documentation demonstrating that computerized records are backed up daily.	OAC 4729:5-15-03
If using computerized record keeping system, is it stand-alone or able to be shared or accessed by another location?	If shared access, Board staff will confirm that security features are in place to prevent unauthorized access from other locations.	OAC 4729:5-15-03
Does the licensee maintain records of drug administration containing the required information?	Records of drug administration must be maintained for at least three years. Records of administration, including the administration of patient specific dangerous drugs, shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name or	OAC 4729:5-15-03

	identification of the animal to whom or for whose use the dangerous drugs were administered, and the date of administration. For controlled substance dangerous drugs, the administration record shall also include the positive identification of the person administering the drug. Records of dangerous drugs administered which become a permanent part of the patient's medical record meet the requirements of the rule. **REMINDER:** Administration of patient-specific medications are required to be captured as part of the drug administration record. **NOTE:** Board staff will review drug records to determine compliance.	
Are orders for the administration of controlled substances documented using positive identification?	Records of controlled substances administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber must include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. Orders for the administration of controlled substances shall be documented using positive identification. This requirement does not apply either of the following: ▪ Administration of controlled substances authorized in rule 4729:5-15-01 to perform euthanasia by a veterinarian, registered veterinary technician, or euthanasia technician. ▪ Administration of controlled substances that have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration to an animal [see paragraph (E) of OAC 4729:5-15-02].	OAC 4729:5-15-03

	An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of the rule. **NOTE:** Board staff will review drug records to determine compliance.	
Are protocols being used to administer dangerous drugs?	Protocols may only be used as follows: (1) The provision of medical services to individuals in an emergency situation when the services of a prescriber authorized by the revised code to prescribe dangerous drugs as part of their professional practice are not immediately available. An emergency situation may manifest itself by acute symptoms of sufficient severity that an authorized individual providing medical services under this paragraph could reasonably expect the absence of immediate medical attention to result in placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Examples of emergency situations includes cases such as heart attacks, severe burns, extravasation, overdoses, cyanide poisonings, electrocutions, or severe asthmatic attacks; (2) The administration of biologicals or vaccines to individuals for the purpose of preventing diseases; (3) The administration of vitamin K for prevention of vitamin K deficient bleeding in newborns; (4) The administration of erythromycin for prevention of ophthalmia neonatorum; and	OAC 4729:5-3-12

	(5) The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, as defined in agency 4729 of the Administrative Code, according to current guidance issued by the United States center for disease control and prevention. If yes, Board staff will review protocols to ensure they meet the allowed uses and comply with the following: (1) Includes a description of the intended recipients to whom the drugs are to be administered; drug name and strength; instructions of how to administer the drug, dosage, and frequency; signature of a prescriber or some other form of positive identification; and date of signature. (2) Are maintained by the terminal distributor of dangerous drugs for a period of three years from the date of authorization or reauthorization following any modification or amendment.	
Are pre-printed orders used for the administration of dangerous drugs?	A "pre-printed order" means a patient specific and dose specific order for the administration of a specific drug or drugs prescribed by a licensed health care professional authorized to prescribe drugs. If yes, Board staff will confirm the following: (1) A prescriber completes an assessment and make a diagnosis prior to initiating a pre-printed order in accordance with the prescriber's scope of practice. (2) The order contains the following information: the name of the patient; drug name and strength; specific instructions of how to administer the drug, dosage, and frequency; instructions of any patient specified dosage range based on objective measures such as	OAC 4729:5-3-12

	calculations and patient physiologic data; signature of the prescriber or some other form of positive identification of the prescriber; and date of signature.	

Drug and Hypodermic Security

Question	Guidance	Law/Rule
Are controlled substances used to perform euthanasia stored in a securely locked, substantially constructed cabinet or safe?	The cabinet or safe containing controlled substances used to perform euthanasia must meet the following requirements: (1) The cabinet or safe shall be placed in an area that is not readily accessible to the public (ex. waiting areas or areas where the public are allowed without supervision by staff). The public does not include volunteers of the animal shelter. (2) When not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility. (3) The cabinet or safe is locked and secured when not in use. (4) In the case of a combination lock or access code, the combination or access code is changed upon termination of employment of an employee having knowledge of the combination or access code. **REMINDER:** The following controlled substances are approved for use as part of the euthanasia process: ▪ Combination drugs that contain pentobarbital and at least one noncontrolled substance active ingredient, in a manufactured dosage form, whose only indication is for euthanizing animals; and ▪ The following substances only for the purpose of anesthetizing an animal as part of the euthanasia process: o Tiletamine and zolazepam for injection;	OAC 4729:5-15-02

	○ Xylazine; and ○ Ketamine hydrochloride. (See OAC 4729:5-15-04)	
Do the methods utilized for accessing the cabinet or safe containing controlled substances used to perform euthanasia prevent unauthorized access?	Access to the cabinet or safe containing controlled substances used to perform euthanasia must comply with the following: In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian, registered veterinary technician, responsible person, euthanasia technician, or executive director of the shelter. All locks shall be kept in good working order with keys removed therefrom. **REMINDER:** Only a veterinarian, registered veterinary technician, euthanasia technician, executive director of the shelter, or the shelter's responsible person shall be able to access the cabinet or safe containing controlled substances used to perform euthanasia.	OAC 4729:5-15-02
Are controlled substances not used as part of the euthanasia process stored in a securely locked, substantially constructed cabinet or safe?	The cabinet or safe for storing controlled substances that are not used as part of the euthanasia process must meet the following requirements: (1) The cabinet or safe shall be placed in an area that is not readily accessible to the public (ex. waiting areas or areas where the public are allowed without supervision by staff). The public does not include volunteers of the animal shelter. (2) When not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility. (3) The cabinet or safe is locked and secured when not in use.	OAC 4729:5-15-02

	(4) In the case of a combination lock or access code, the combination or access code is changed upon termination of employment of an employee having knowledge of the combination or access code. **IMPORTANT:** Controlled substances that are not used as part of the euthanasia process must be stored in a separate cabinet or safe from the cabinet or safe utilized to store controlled substances used as part of the euthanasia process.	
Do the methods utilized for accessing the cabinet or safe containing controlled substances prevent unauthorized access?	Access to the cabinet or safe containing controlled substances that are not used to perform euthanasia must comply with the following: (1) In the case of a key lock, all locks are kept in good working order with keys removed therefrom. All keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian if not being used by a veterinarian (or by a veterinary technician - see #2 and #3 below). (2) A veterinarian may provide a veterinary technician with a temporary key for the purposes of accessing the cabinet or safe. A veterinary technician must return the key to the veterinarian or to a secured location with restricted access (such as a lockbox) no later than the end of the veterinary technician's shift or if there is no longer a veterinarian available to provide personal supervision. (3) A veterinarian may provide a veterinary technician with a key, combination or access code for the purposes of accessing the cabinet or safe, if all the following conditions apply: (a) The cabinet or safe is maintained in a room secured by a physical barrier with suitable locks that can only be unlocked by a veterinarian; and	OAC 4729:5-15-02

	(b) The room is locked during non-business hours or when there is no longer a veterinarian available to provide personal supervision. **NOTE:** If a licensee proposes an alternate security plan for accessing the controlled substance safe or cabinet, that plan must be submitted and approved by the Director of Compliance and Enforcement [see OAC 4729:5-15-02 (C)(6)(c)]. **REMINDER:** A veterinary technician may have access to controlled substances that are not used to perform euthanasia only under the personal supervision of a veterinarian.	
Does the licensee comply with the security requirements for storing thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine?	Thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a separate safe or steel cabinet equivalent to a U.S. Government Class V security container from all other controlled substances. See OAC 4729:5-15-02 (I) for additional information on the storage of thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine.	OAC 4729:5-15-02
Does the licensee maintain patient-specific controlled substances for on-site administration in a substantially constructed cabinet, safe, or room?	An animal shelter shall comply with all the following for storage and use of patient-specific controlled substances: (1) The drugs must have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration to an animal. (2) The drugs must be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, safe, or room. Access to the cabinet, safe, or room shall be limited to designated staff. (3) If using a cabinet or safe, it must be separate from those required for non-patient specific controlled substances.	OAC 4729:5-15-02

	(4) If using a cabinet or safe, it must be placed in an area that is not readily accessible to the public. The public does not include volunteers of the animal shelter. (5) The cabinet, safe, or room shall remain locked and secured when not in use. (6) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than designated staff. All locks shall be kept in good working order with keys removed therefrom. (7) If using a cabinet or safe and when not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility. **REMINDER:** The responsible person or shelter's executive director shall maintain a current list of all designated employees or volunteers that may have access to patient-specific controlled substances for on-site administration for immediate inspection by an agent, officer or inspector of the Board.	
Are non-controlled dangerous drugs maintained under appropriate supervision and control?	When not staffed by shelter personnel, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours (i.e. when staffed by shelter personnel), non-controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs. Members of the public do not include volunteers of the animal shelter.	OAC 4729:5-15-02

	NOTE: Generally, non-controlled dangerous drugs must be maintained under the supervision of shelter staff. When not staffed by shelter personnel, the goal is to ensure the facility can be secured to prevent unauthorized access (i.e. individuals who are not employed by or volunteering at the shelter). **REMINDER:** Non-controlled dangerous drugs that have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration may be administered by an animal shelter employee or volunteer.	
Are hypodermics maintained under appropriate supervision and control?	When not staffed by shelter personnel, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours (i.e. when staffed by shelter personnel), hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections. Members of the public do not include volunteers of the animal shelter. **NOTE:** Generally, hypodermics must be maintained under the supervision of shelter staff and volunteers. When not staffed by shelter personnel, the goal is to ensure the facility can be secured to prevent unauthorized access (i.e. individuals who are not employed by or volunteering at the shelter). **REMINDER:** Ohio law (ORC 3719.172) requires reasonable precautions to prevent any hypodermic in the person's possession from theft or acquisition by any unauthorized person.	OAC 4729:5-15-02 ORC 3719.172

Drug Storage and Temperature Control

Question	Guidance	Law/Rule
Are areas where dangerous drugs are stored dry, well-lit, well-ventilated, and maintained in a clean and orderly condition?	All areas where dangerous drugs are stored must be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition.	OAC 4729:5-15-02
Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?	Storage areas must be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. There is not a requirement for monitoring room temperature, however, Board staff may document temperature readings if storage areas are excessively hot or cold.	OAC 4729:5-15-02
Are refrigerators and/or freezers used for the storage of drugs maintained at the proper temperature?	The facility must maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained: (1) Temperature logs with, at a minimum, daily observations; or (2) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion. Records of temperature control monitoring for refrigerators and freezers used for the storage of drugs must include any of the following: (1) For temperature logs, either:	OAC 4729:5-15-02 OAC 4729:5-15-03

	(a) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or (b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded. (2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion. **NOTE:** A licensee may select the appropriate method for monitoring temperature (i.e. electronic, manual, etc.). Temperature readings should be available for review by Board staff.	
Does the licensee have a policy to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs?	A licensee is required to develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs. The policy should be made available for review upon inspection and should describe, at a minimum, all the following: ▪ The actions to be taken in the event of temperature excursions outside the labelled storage conditions. ▪ The process for appropriately investigating, documenting, and assessing temperature excursions outside the labelled storage conditions to ensure the integrity of the drug stock (for example, stability data or technical justification).	OAC 4729:5-15-02

Are refrigerators and/or freezers use for the storage of drugs free of food or beverage products?	A licensee is required to develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs. The policy should be made available for review upon inspection and all refrigerators and freezers used for drug storage will be examined to ensure compliance. **NOTE:** Facilities may keep unopened bottled water in the refrigerator doors to help maintain consistent temperatures. Shelters are also permitted to keep animal food necessary to administer dangerous drugs in refrigerators and/or freezers used to store dangerous drugs.	OAC 4729:5-15-02

Theft or Significant Loss of Drugs and Drug Documents

Question	Guidance	Law/Rule
Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?	A licensee is required to notify the Board of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to a prescriber, terminal distributor, or drug distributor. ***This includes the theft or significant loss of any patient-specific dangerous drugs maintained for on-site administration.*** In addition to the initial notification requirements, a licensee is required to submit a detailed report of the theft or significant loss to the Board using the online portal within thirty days following the discovery of such theft or significant loss. **REMINDER:** For more information on reporting theft or loss, visit: www.pharmacy.ohio.gov/theft	OAC 4729:5-3-02 OAC 4729:5-15-02
Has the licensee experienced any theft or loss of uncompleted prescription blank(s), written prescription order(s) not yet dispensed, or D.E.A. controlled substance order forms in the past twenty-four months?	A licensee is required to report, immediately upon discovery, to the Board any theft or loss of uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms (Form 222), written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed. In addition to the initial notification requirements, a licensee is required to submit a detailed report of the theft or loss to the Board using the online portal within thirty days following the discovery of such theft or loss.	OAC 4729:5-3-02

	NOTE: Unlike dangerous drugs, drug documents do not have a significant loss threshold. Therefore, all losses (in addition to thefts) must be reported to the Board. **REMINDER:** For more information on reporting theft or loss, visit: www.pharmacy.ohio.gov/theft	

Orders for Schedule II Controlled Substances

Question	Guidance	Law/Rule
Are all executed DEA Forms 222 retained for at least three years?	21 CFR 1305.17 requires executed DEA Forms 222 must be maintained separately from all other records of the registrant. Ohio regulations require these records to be retained for at least three years.	OAC 4729:5-15-02
Are DEA Forms 222 secured when not in use?	For an animal shelter that is licensed in accordance with section 4729.54 of the Revised Code: personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of a veterinarian. D.E.A. controlled substance order forms shall be secured when not in use. For an animal shelter that is licensed in accordance with section 4729.531 of the Revised Code: personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of the responsible person. D.E.A. controlled substance order forms shall be secured when not in use. D.E.A. controlled substance order forms (DEA Form 222) must be secured when not in use. This may include the following: a locked drawer, filing cabinet, safe, lock box, lockable bag, or any other method that can be locked to prevent unauthorized access. **NOTE:** Individuals granted power of attorney to sign DEA 222 Forms may have unsupervised access to DEA 222 Forms if a terminal distributor of dangerous drugs complies with the requirements of 21 CFR 1305.05. Licensees should have the required power of attorney forms available for inspection.	OAC 4729:5-15-02

Controlled Substance Inventory

IMPORTANT: *Inventory requirements only apply to non-patient specific medications. While licensees are encouraged to closely monitor the use of patient-specific drugs, an inventory of those drugs is not required.*

Question	Guidance	Law/Rule
Does the licensee conduct an annual inventory of controlled substances?	All Category III licensees must complete an annual inventory **even if drugs are not on-site** (zero balance). Records of inventories must be maintained for at least three years. Inventories must follow the process for conducting a DEA controlled substance inventory. Each inventory must contain a complete and accurate record of all controlled substances on hand the date the inventory is conducted. The inventory must have the names of the controlled substances, each finished form, the number of units, and/or the number of commercial containers of each finished form. If listed in Schedules I or II, make an exact count or measure of the contents. If listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case the licensee must make an exact count of the contents. **NOTE:** The annual inventory may be taken on any date which is within thirteen months of the previous inventory date. Board staff will review records to determine compliance.	OAC 4729:5-3-07

Does the licensee conduct monthly inventories of controlled substances used to anesthetize an animal as part of the euthanasia process?	This only applies to the following controlled substances authorized in OAC 4729:5-15-04 to be used as part of the euthanasia process: tiletamine and zolazepam for injection, xylazine, and ketamine hydrochloride. In addition to the inventory requirements set forth in rule 4729:5-3-07 of the Administrative Code, the responsible person for an animal shelter that maintains controlled substance dangerous drugs used to perform euthanasia shall be responsible for completing a monthly inventory, in accordance with rule 4729:5-3-07 of the Administrative Code, of those drugs to deter and detect diversion. Board staff will review records to determine compliance.	OAC 4729:5-15-03
How does the licensee monitor its inventory of controlled substances?	Board staff will review and document how the licensee monitors its inventory of controlled substances (e.g. daily count, perpetual inventory, etc.).	

Drug Purchases

Question	Guidance	Law/Rule
Does the licensee maintain complete and accurate records of drugs purchased?	Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement. Records must be maintained for a period of three years. Board staff will review records of receipt to determine compliance.	OAC 4729:5-15-03
Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?	Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale (including samples), the terminal distributor shall query the Board's online roster to confirm any of the following: (1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code (i.e. wholesaler, manufacturer, repackager, outsourcing facility or 3PL); or (2) The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code (i.e. pharmacies or other terminal distributors). If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated section 4729.51 of the Revised Code in making the purchase.	OAC 4729:5-3-04

	NOTE: Except for veterinary drugs (OAC 4729:7-2-05), compounded drugs used for office-stock can no longer be ordered from compounding pharmacies. Documented queries must be maintained for three years. Board staff will review drug invoices and compare to documented queries of eLicense.	

Drug Disposal

Question	Guidance	Rule/Law
Does the licensee dispose of controlled substances on-site using a method that renders the drug non-retrievable?	Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances shall dispose of such drugs in accordance with 21 C.F.R. 1317 (1/1/2016). The method of destruction must render the dangerous drugs which are controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (1/1/2016) shall be maintained for a minimum of three years and made available to the board of pharmacy upon request. "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes. **NOTE:** Per the Drug Enforcement Administration, flushing (i.e. drain or toilet) does not meet the definition of non-retrievable. A licensee is responsible for maintaining documentation demonstrating that the method of disposal meets the requirement to render controlled substances non-retrievable.	OAC 4729:5-3-01

Does the licensee use a reverse distributor for the disposal of controlled substances?	If yes, Board staff will document the name of the reverse distributor.	
Does the licensee maintain complete and accurate records of the disposal of controlled substances?	A licensee must use a DEA Form 41 to document the disposal of controlled substances. **NOTE:** Use of the DEA Form 41 does not apply to the disposal of an unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply. If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification on the DEA Form 41 of two persons conducting and witnessing the disposal, one of whom shall be the responsible person or a veterinarian, registered veterinary technician, or certified euthanasia technician. All records must be maintained for a period of three years. Board staff will review records of disposal to determine compliance. **REMINDER:** Documentation also is required for the disposal of any patient-specific controlled substances maintained for on-site administration.	OAC 4729:5-3-01 OAC 4729:5-15-02
Does the licensee maintain complete and accurate records of the disposal of unused portions of controlled substances	Records must include the name of the drug, the quantity disposed, the date and manner of disposal, and the positive identification of two persons conducting and witnessing the disposal, one of whom shall be the responsible person or a veterinarian, registered veterinary technician, or certified euthanasia technician.	OAC 4729:5-3-01 OAC 4729:5-15-03

resulting from patient administration?	Documentation may be maintained in the patient record (i.e. with administration record). The disposal method does not have to render the unused portion of the drug non-retrievable. All records must be maintained for a period of three years. Board staff will review records of disposal to determine compliance. **REMINDER:** Documentation also is required for the disposal of any patient-specific controlled substances maintained for on-site administration.	
Does the licensee dispose of non-controlled drugs using a method that prevents the possession or use of the drugs by unauthorized persons?	Methods of disposal of non-controlled dangerous drugs must prevent the possession or use of the drugs by unauthorized persons.	OAC 4729:5-3-06
Does the licensee maintain complete and accurate records of the disposal of non-controlled dangerous drugs?	Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the person that performed the disposal. NOTE: This does not apply to wastage from administration. For non-controlled drugs, such documentation is not required. All records must be maintained for a period of three years. Board staff will review records of disposal to determine compliance.	OAC 4729:5-15-03

	REMINDER: Documentation is required for the disposal of any patient-specific dangerous drugs maintained for on-site administration.	

Personally Furnishing

REMINDER: *This section does not apply to the transfer of patient-specific dangerous drugs from an animal shelter to a new owner or caregiver per paragraph (L) of OAC 4729:5-15-02 (see next section for requirements).*

Question	Guidance	Rule/Law
Does the licensee personally furnish any dangerous drugs to patients/caregivers?	Are dangerous drugs, including any drug samples, personally furnished to patients? Board staff will document the types of drugs personally furnished by the licensee.	
If personally furnishing controlled substances, list the controlled substances the licensee has in stock with dosage forms.	If yes, Board staff will document the controlled substances that the licensee has on hand with dosage forms.	
Are non-sample drugs that are personally furnished to patients properly labeled?	Drugs personally furnished to a patient must be labelled and packaged in accordance with state and federal drug laws and rules and regulations adopted pursuant to those laws. A veterinarian who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, must affix to the container a label showing: (1) The name and address of the veterinarian; (2) The name of the patient for whom the drug is intended, which shall include the name of the owner and identification of the animal or animals; (3) Name and strength of the drug; (4) Directions for use; (5) Date furnished; and	OAC 4729:5-20-02 [as required by OAC 4729:5-15-01 (H)]

	(6) If a compounded drug, the statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.	
Are sample drugs that are personally furnished to patients properly labeled?	A veterinarian who personally furnishes a dangerous drug labeled as a sample and where the directions for use are different from the directions on or in the sample container must affix a label to the sample container or provide written documentation accompanying the sample that includes the following: (1) The name of the veterinarian; (2) The name of the patient for whom the drug is intended, which shall include the name of the owner and identification of the animal or animals; (3) Directions for use. Board staff will review labels to confirm compliance. "Sample" means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer. Except as provided in paragraph (E) of this rule, samples may only be provided to and furnished by a licensed prescriber as defined in rule 4729:5-1-02 of the Administrative Code in accordance with paragraph (B) of this rule.	OAC 4729:5-20-02 [as required by OAC 4729:5-15-01 (H)]
Are animal aides preparing and packaging drugs to be personally furnished?	A veterinarian may delegate to a registered veterinary technician or animal aide, acting within the scope of the professional's practice, the act of preparing and packaging a dangerous drug that will be personally furnished.	OAC 4729:5-20-02 [as required by OAC 4729:5-15-01 (H)]

	Unless otherwise authorized under Chapter 4741. of the Revised Code and the rules adopted thereunder, animal aides shall not prepare and package dangerous drugs that are anesthetic agents or controlled substances.	
Does the licensee maintain complete and accurate records of drugs personally furnished?	Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name or identification of the animal or animals, name and address of the animal's or animals' owner or caregiver, the date the drug is personally furnished and, if applicable, the date the drug is received by the animal's or animals' owner or caregiver. A veterinarian shall be required to document the final association of a controlled substance dangerous drug with a patient using positive identification. Records of personally furnishing must be maintained for at least three years. Board staff will review records to determine compliance.	OAC 4729:5-15-03
Is counseling offered to owners/caregivers when drugs are personally furnished?	A veterinarian must personally offer to provide, or may provide in writing, the service of counseling to an owner or caregiver whenever any dangerous drug is personally furnished. A veterinarian shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.	OAC 4729:5-20-02 [as required by OAC 4729:5-15-01 (H)]
Are drugs that are personally furnished distributed under appropriate supervision and control?	A veterinarian may delegate an individual or individuals to distribute dangerous drugs that are personally furnished if all the following apply:	OAC 4729:5-20-02 [as required by OAC 4729:5-15-01 (H)]

	(1) A veterinarian provides personal supervision (i.e. is on-site). Personal supervision is not required for non-controlled drugs if the drugs are provided by a by a registered veterinary technician or animal aide and a veterinarian is available for counseling by means of electronic communication during normal hours of operation. -AND- (2) Counseling is offered.	
Does the licensee personally furnish compounded drugs that were initially prepared by a pharmacy for in-office use?	A veterinarian may personally furnish up to a seven-day supply of a compounded drug to a patient when, in their professional judgment, failure to provide the drug would result in potential harm to the patient. Board staff will review records to determine compliance.	OAC 4729:7-2-05

Patient-Specific Drug Transfers

Question	Guidance	Rule/Law
Does the licensee engage in the transfer of patient-specific drugs to the animal's new owner or caregiver that have been personally furnished by a veterinarian or dispensed by a pharmacy?	In the event of a change of ownership of an animal, a shelter employee or volunteer may transfer dangerous drugs that have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration to an animal to the animal's new owner or caregiver.	OAC 4729:5-15-02
Does the licensee maintain records of controlled substances transferred to a new owner or caregiver?	Records of controlled substances transferred in accordance with paragraph (L) of rule 4729:5-15-02 of the Administrative Code shall contain the name, strength, dosage form, and quantity of the dangerous drugs transferred, the name or identification of the animal, name and address of the animal's owner or caregiver if the owner or caregiver is not the animal shelter, the positive identification of the animal shelter employee or volunteer transferring the drug, the date the drug is transferred, and the date the drug is received by the animal's owner or caregiver. Board staff will review records to determine compliance.	OAC 4729:5-15-02

Drug Samples

Question	Guidance	Rule/Law
Does the licensee distribute samples to patients?	Board staff will document the types of drugs received as samples.	
Does the licensee receive samples at the request of a prescriber?	Prescribers must request samples. Samples cannot be dropped off at a facility without permission. No drug distributor or distributor's representative, including sales representatives, may sell or distribute a sample of a drug to a licensed prescriber unless requested by the prescriber.	OAC 4729:6-3-08
Are sample drugs personally furnished free of charge, in the original container, and prior to the drug's expiration date?	Licensees cannot open sample packages and distribute them in alternate containers or partial quantities. Samples must be provided free of charge. Expired samples must be disposed of in the same manner as all other drug inventory and may not be dispensed or donated, unless they are donated to a pharmacy school under ORC 3715.89.	ORC 3719.81

OARRS

Question	Guidance	Rule/Law
Are any of the prescribers using delegates to request OARRS reports?	Delegates are required to have their own OARRS accounts. A delegate is not permitted to use the username and login for a prescriber or another delegate.	4729.80

Drug Compounding

Question	Guidance	Rule/Law
Is the licensee engaged in hazardous drug compounding?	If engaged in hazardous drug compounding, an animal shelter may be subject to an additional inspection by a Board Specialist (i.e. pharmacist). "Hazardous drug" means any drug listed in table one on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. A separate compounding guide will be made available for licensees engaged in drug compounding, including the preparation of hazardous drugs.	

Prescriptions

For more information on the Board's requirements for issuing a valid prescription, visit: www.pharmacy.ohio.gov/Rx.

Question	Guidance	Rule/Law
Does the facility use pre-printed prescriptions?	Board staff will review prescription blanks to ensure that any pre-printed prescriptions with multiple drug names or strength combinations do not contain any controlled substances among the choices.	OAC 4729:5-5-05
How does the licensee issue prescription?	Board staff will document the methods used for transmitting prescriptions (written, oral, fax, or electronic transmission). If the licensee faxes hard copy prescriptions, Board staff will confirm the original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the location where it was issued for three years from the date of issuance. Following the successful transmission of the prescription, the word "VOID" or "FAXED" shall be written or stamped on the face of the original prescription in a manner that does not destroy any of the original information contained on the prescription.	OAC 4729:5-3-11
Are uncompleted prescription blanks secured when not in use?	Only a veterinarian shall have access to uncompleted prescription blanks used for writing a prescription. Uncompleted prescription blanks shall be secured when not in use. Prescription blanks must be secured when not on the veterinarian's person. This may include the following: a locked drawer, filing cabinet, safe, lock box, lockable bag, or any other method that can be locked to prevent unauthorized access.	OAC 4729:5-15-02

Expired/Adulterated Drugs

Question	Guidance	Rule/Law
Are multi-dose vials properly labeled?	Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a date opened.	OAC 4729:5-15-02
Do multi-dose vials exhibit any characteristics indicating adulteration?	Multiple-dose vials shall be examined prior to use for evidence of physical or chemical contamination. Vials that have any of the following characteristics shall be deemed adulterated: (1) Contain particulate matter, precipitates, turbidity, or discoloration; (2) Mislabeled; or (3) Noticeable coring (damage to the rubber stopper).	OAC 4729:5-15-02
Are there expired/adulterated drugs present in the licensee's active drug stock?	Board staff will conduct a check for expired drugs/adulterated drugs, including, but not limited to, the following: ▪ Expired drugs in common stock areas. ▪ Multidose vials that have been opened/punctured and exhibit any characteristics of adulteration (contain particulate matter, precipitates, turbidity, or discoloration; are mislabeled; or noticeable coring).	OAC 4729:5-3-06
Are expired/adulterated drugs appropriately segregated from the licensee's active drug stock?	Expired/adulterated drugs must be stored separately from active drug stock in a manner that prohibits access by unauthorized persons. Expired/adulterated controlled substances that are segregated must be secured in the same manner as active controlled substance stock. This can be a bin/bag clearly marked “outdated/do not use” or a similar statement that is stored where active controlled substance	OAC 4729:5-3-06

	stock is maintained but segregated in a manner that is clear to all who see it that the drugs may not be used. Expired/adulterated non-controlled substance drugs must be segregated from the active drug stock. This can be a bin/bag clearly marked "outdated/do not use" or a similar statement that is stored in common stock areas but segregated in a manner that is clear to all who see it that the drugs may not be used. Expired/adulterated non-controlled substance drugs must be maintained under the same supervision requirements as active non-controlled substance drug stock.	
Are expired/adulterated drugs stored no longer than one year from the date of expiration/adulteration?	Expired/adulterated drugs shall be stored no longer than one year from the date of expiration/adulteration by those holding a terminal distributor of dangerous drugs license. Board staff will review expired/adulterated drugs to confirm.	OAC 4729:5-3-06

General Record Keeping

Question	Guidance	Rule/Law
Does the licensee maintain all required records on-site for a period of three years in a readily retrievable manner?	All records maintained in accordance with this rule shall be readily retrievable and shall be kept on-site for a period of three years. If stored off-site, Board staff will document the off-site location and confirm the licensee submitted proper notification to the Board.	OAC 4729:5-15-03
Are records maintained under appropriate supervision and control to restrict unauthorized access?	All records relating to the receipt, administration, distribution, personally furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access. Generally, a licensee should avoid having any patient records easily accessible to the general public (i.e. waiting rooms, unsecured storage facilities, or any other place where the public could easily access drug records). The public does not include volunteers of the animal shelter.	OAC 4729:5-15-02
Are records electronically created and maintained?	Such records may be electronically created and maintained in accordance with the following: (1) Complies with the requirements of the record keeping rule (including positive identification requirements); (2) All paper records shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user; (3) Contains security features to prevent unauthorized access; and (4) Contains daily back-up functionality to protect against record loss.	OAC 4729:5-15-03

	Board staff will ask the licensee to provide documentation demonstrating daily back-up functionality to protect against record loss.	
Does the licensee engage in the transfer or sale of dangerous drugs?	If yes, records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code must contain the name, strength, dosage form, national drug code, expiration date and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale. **NOTE:** This includes intracompany transfers/sales and occasional sales. It does not apply to the transfer of patient-specific drugs to new owners/caregivers. Occasional sales by non-pharmacies (i.e. sales outside of a commonly owned company) are limited to naloxone and drugs that are in shortage. "Drug shortage," with respect to an occasional sale, means a drug on the United States Food and Drug Administration's drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler. Board staff will review records to determine compliance.	OAC 4729:5-15-03 OAC 4729:5-3-09

Temporary Removal of Drugs

Question	Description / Guidance	Law/Rule
Does the licensee engage in the temporary off-site storage of dangerous drugs?	A veterinarian licensed pursuant to Chapter 4741. of the Revised Code may maintain a supply of dangerous drugs obtained from a licensed terminal distributor of dangerous drugs at another location in order to treat current or prospective patients.	OAC 4729:5-3-13
Does the licensee maintain records of all controlled substances stored off-site for more than twenty-four hours?	The terminal distributor of dangerous drugs shall also maintain the following records for controlled substance dangerous drugs removed from the terminal distributor of dangerous drugs that are stored off-site for more than twenty-four hours: name, strength, dosage form, and quantity of the controlled substance dangerous drugs, the positive identification of the veterinarian who removed the drugs, and the address of the location where the drugs are maintained. Corresponding records shall also be maintained for any controlled substances returned to the terminal distributor's inventory of dangerous drugs from the off-site location. All records required in accordance with this paragraph shall be readily retrievable and maintained for at least three years from the date of removal or return.	OAC 4729:5-3-13
Does a veterinarian temporarily removing drugs from a licensed location maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the licensed location?	The veterinarian temporarily removing drugs from a licensed location shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. "Direct supervision" means an individual authorized pursuant to this rule is in the immediate area and within visual range of dangerous drugs and/or hypodermics to deter and detect diversion.	OAC 4729:5-3-13
If direct supervision is not provided, are the drugs that are temporarily removed	If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and all reasonable efforts shall be made to store	OAC 4729:5-3-13

securely stored at temperatures and conditions which will ensure the integrity of the drugs?	the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Securely stored means that the drugs are secured in a manner that prevents unauthorized access. This may include the following: a locked drawer, filing cabinet, locked room, safe, lock box, or any other method that can be locked to prevent unauthorized access.	

Chemical Capture

This section applies to animal shelters and dog wardens who obtain a chemical capture classification. For more information about this classification, visit: www.pharmacy.ohio.gov/ChemCapture

Question	Description / Guidance	Law/Rule
Does the licensee employ a certified officer?	To qualify for a chemical capture classification, a licensee shall appoint or employ a certified officer. An individual is considered a certified officer if the individual does one of the following: (1) Successfully completes a chemical capture course that has a curriculum approved by the Ohio Veterinary Medical Licensing Board (OVMLB); (2) Successfully completes training acceptable to the Ohio Veterinary Medical Licensing Board from the National Animal Control Association or Safe Capture International, Inc*. *Safe Capture International, Inc is now the San Diego Zoo Wildlife Alliance Safe Capture. A listing of OVMLB approved chemical capture courses can be accessed here: www.pharmacy.ohio.gov/coursesCC (scroll to the bottom of the page). Board staff will review training records to determine compliance.	OAC 4729:5-15-05
Is the facility utilizing drugs for chemical capture that have been approved by the Board?	A certified officer may use any of the following drugs for chemical capture: 1. Ketamine; 2. Xylazine; 3. Tiletamine and zolazepam; 4. Yohimbine;	OAC 4729:5-15-05

	5. Tolazoline; and 6. Atipamezole.	
Are areas where drugs and devices used for chemical capture at the licensee's facility stored in accordance with rule 4729:5-15-02 of the Administrative Code?	Drugs used for chemical capture that are stored at the licensee's location must meet the following security requirements: Controlled substance dangerous drugs used to perform euthanasia **or chemical capture** shall be stored in a securely locked, substantially constructed cabinet or safe. (1) The cabinet or safe shall be placed in an area that is not readily accessible to the public. The public does not include volunteers of the animal shelter. (2) The cabinet or safe shall remain locked and secured when not in use. (3) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code. (4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian, registered veterinary technician, responsible person, euthanasia technician, certified officer, dog warden, or executive director of the shelter. All locks shall be kept in good working order with keys removed therefrom. (5) When not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.	OAC 4729:5-15-05 → OAC 4729:5-15-02

	(6) Only a veterinarian, registered veterinary technician, euthanasia technician, executive director of the shelter, certified officer, dog warden, or the licensee's responsible person shall be able to access the cabinet or safe.	
Are areas where drugs and devices used for chemical capture at the licensee's facility stored in accordance with rule 4729:5-3-13 of the Administrative Code?	A certified officer may maintain a supply of dangerous drugs, as authorized in rule 4729:5-15-05 of the Administrative Code, obtained from a licensed terminal distributor of dangerous drugs with a chemical capture classification at another location in order to engage in chemical capture. A certified officer shall maintain direct supervision and control over the dangerous drugs, equipment, and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs, equipment, and any hypodermics shall be physically secured in a manner to prevent unauthorized access and all reasonable efforts shall be made to store the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. A certified officer maintaining dangerous drugs off-site shall only obtain the drugs from single terminal distributor and shall not co-mingle drug stock from another terminal distributor of dangerous drugs. The terminal distributor of dangerous drugs shall also maintain the following records for controlled substance dangerous drugs removed from the terminal distributor of dangerous drugs that are stored off-site: name, strength, dosage form, and quantity of the controlled substance dangerous drugs, the positive identification of the certified	OAC 4729:5-3-13

	officer who removed the drugs, and the address of the location where the drugs are maintained. Corresponding records shall also be maintained for any controlled substances returned to the terminal distributor's inventory of dangerous drugs from the off-site location. All records required for off-site use shall be readily retrievable and maintained for at least three years from the date of removal or return.	
Does the licensee have a drug dosing protocol that complies with the requirements of OAC 4729:5-15-05?	The animal shelter or dog warden shall develop and implement a drug dosing protocol for all drugs and equipment used in chemical capture. (1) The protocol shall be reviewed and signed by a veterinarian licensed under Chapter 4741. of the Revised Code. (2) The protocol shall include the following: drug, dose, concentration, approved uses for drug delivery, approved equipment for use, circumstances for use, contraindications, any known common complications/side effects, and weight ranges with corresponding volume of drug to be administered. (3) A documented review of the protocol shall be conducted by a veterinarian licensed under Chapter 4741. of the Revised Code at least once every five years. Board staff will review protocol to determine compliance.	OAC 4729:5-15-05
Is equipment used in chemical capture secured to prevent unauthorized access?	All equipment used in chemical capture shall be secured to prevent unauthorized access by individuals who are not certified officers.	OAC 4729:5-15-05

Does the licensee have policies and procedures that determine when chemical capture is appropriate?	An animal shelter or dog warden with a chemical capture classification shall develop and implement policies and procedures that incorporate the following based upon nationally recognized standards for chemical capture: Determining when chemical capture is appropriate. Such policies and procedures shall make all reasonable efforts to ensure animal safety, certified officer safety, and the safety of the public. Board staff will review policies and procedures to determine compliance.	OAC 4729:5-15-05
Does the licensee have policies and procedures that provide for the care of a companion animal upon capture?	An animal shelter or dog warden with a chemical capture classification shall develop and implement policies and procedures that incorporate the following based upon nationally recognized standards for chemical capture: The care of a companion animal immediately upon capture. Certified officers engaged in chemical capture must have a written animal handling and post capture protocol which includes: (a) The procedure for removing the dart from a captured animal; (b) First aid for the animal, with particular reference to the dart wound and potential emergencies (including: hyperthermia, hypothermia, shock, bloat, respiratory distress, and cardiac arrest); and (c) Appropriate location and handling for the animal during recovery from the capture event. Board staff will review policies and procedures to determine compliance.	OAC 4729:5-15-05

Recall Procedures

These rules are effective on November 11, 2024. For more information on this rule, see our Recall Procedures for Terminal Distributors document: www.pharmacy.ohio.gov/recalls

Question	Description / Guidance	Law/Rule
Does the facility have a written procedure in place to manage recalls for the dangerous drugs stocked, dispensed, or personally furnished by the licensee?	A terminal distributor of dangerous drugs is required to develop and implement a written procedure to manage recalls for the dangerous drugs stocked, dispensed, or personally furnished by the licensee. Such procedures must be regularly updated as necessary and must be readily retrievable (e.g., produced within three business days) upon request.	OAC 4729:5-3-18
Do the facility's written recall procedures include all the requirements established in rule?	The written recall procedures must include all of the following: 1. The terminal distributor must, where appropriate, contact patients to whom the recalled drug products have been dispensed or personally furnished. 2. The terminal distributor must make a reasonable attempt to ensure that a recalled drug has been removed from inventory no later than the next business day after receipt of the recall notice by the terminal distributor's responsible person or the responsible person's designee, and quarantined until proper disposal, destruction, or return of the drug. **IMPORTANT:** If a drug that is subject to a recall is maintained by the terminal distributor in a container without a lot number, the terminal distributor shall consider this drug included in the recall. 3. Maintaining all required documentation and records for activities taken by the terminal distributor in relation to a drug recall. **NOTE:** All records documenting recall activities shall be maintained for three years and shall be made readily retrievable.	OAC 4729:5-3-18

Does the facility maintain records documenting recall activities in a readily retrievable manner?	All records documenting recall activities shall be maintained for three years and shall be made readily retrievable (e.g., produced within three business days).	OAC 4729:5-3-18

Update History

Update Date	Section Update	Update
2/14/2020	Drug Storage and Temperature Control	Clarifies shelters are also permitted to keep animal food necessary to administer dangerous drugs in refrigerators and/or freezers used to store dangerous drugs.
6/8/2020	Orders for Schedule II Controlled Substances	Authorizes individuals granted power of attorney to sign DEA 222 Forms to have unsupervised access to DEA 222 Forms if a terminal distributor of dangerous drugs complies with the requirements of 21 CFR 1305.05. **NOTE: This provision was added via Board resolution but will be incorporated in a subsequent rule amendment.**
1/21/2022	Chemical Capture	Adds chemical capture section of the guide to comply with the requirements of ORC 4729.533. For more information about this classification, visit: www.pharmacy.ohio.gov/ChemCapture.
3/10/2022	Prescriptions	Updated rule reference for the Board's prescription formatting rule.
1/13/2023	Chemical Capture	Updated the list of drugs that can be utilized for chemical capture.
8/13/2024	Recall Procedures	Adds a recall procedure section of the guide to comply with the requirements of OAC 4729:5-3-18.

		For more information, see our Recall Procedures for Terminal Distributors document: www.pharmacy.ohio.gov/recalls