

INSPECTION GUIDE

Terminal Distributor of Dangerous Drugs Veterinary Clinic

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To review updates, please see the <u>update history</u> 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 a terminal distributor of dangerous drugs that meet the following definition of a "veterinary clinic" in rule 4729:5-20-01 of the Ohio Administrative Code:

"Veterinary clinic" or "clinic" means a facility licensed as a terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code where a licensed veterinarian serves as the responsible person on the license and drugs are possessed on-site for administration or to personally furnish.

REMINDER: This inspection guide <u>does not apply</u> 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
- Animal Shelters 4729:5-15
- Laboratories 4729:5-16
- Office-Based Opioid Treatment Facilities 4729:5-18
- Clinics and Prescriber Offices 4729:5-19
- Opioid Treatment Programs 4729:5-21
- Non-limited Facilities 4729:5-22
- Limited Facilities 4729:5-23

Inspection Authority

Pursuant to section <u>3719.13</u> of the Revised Code and rule <u>4729:5-3-03</u> 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 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 veterinary clinics 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
- 4729:5-20 Veterinary Clinics
 - o 4729:5-20-01 Veterinary Clinics Definitions.
 - o <u>4729:5-20-02</u> Personally furnishing dangerous drugs.
 - o <u>4729:5-20-03</u> Security and control of dangerous drugs.
 - o <u>4729:5-20-04</u> Record Keeping.

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.

Personally Furnishing Compounded Drugs Obtained from an Outsourcing Facility

An outsourcing facility is permitted to provide non-patient specific compounded sterile drug products to healthcare professionals. These products are compounded under current good manufacturing practice (CGMP) requirements and the facilities are inspected by the FDA on a risk-based schedule. For more information on outsourcing facilities, including how to find those licensed by the Board of Pharmacy, visit: www.pharmacy.ohio.gov/outsourcing

The Board has confirmed with the FDA that non-patient specific drugs purchased directly from an outsourcing facility may be further prescribed and personally furnished to a patient. Please be advised that the 7-day supply limitation that applies to personally furnishing compounded drugs provided by a pharmacy (see 4729:7-2-05 (E)) does not apply to compounded drugs purchased from an outsourcing facility.

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	A change of business
OAC 4729:5-2-03	description must be
	completed online using
Any change in the ownership, business or trade name, category, or	Ohio's <u>eLicense</u> system.
address of a terminal distributor of dangerous drugs requires a new	
application, required fee, and license. The new application and	Instructions on submitting
required fee shall be submitted within thirty days of any change in	this information can be
the ownership, business or trade name, category, or address.	accessed <u>here</u> .
<u>Discontinuation of Business</u>	Requires submission of a
OAC <u>4729:5-2-04</u>	Written Notice of
	Discontinuing Business
A terminal distributor of dangerous drugs who plans to discontinue	Form.
business activities shall file a notice with the Board of Pharmacy. The	
notice shall be submitted, in a manner determined by the Board,	
within thirty days of discontinuation of business as a terminal	
distributor of dangerous drugs.	
Change of Responsible Person	Requires submission of a
OAC 4729:5-2-01	Change of Responsible
	Person Request in
A location licensed as a terminal distributor of dangerous drugs must	eLicense Ohio.
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.	
Notification of Off-Site Records Storage	Requires submission of an
OAC <u>4729:5-20-04</u>	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	For more information on
<u>Documents</u>	this requirement, the
OAC <u>4729:5-3-02</u>	Board developed this
	guidance document.
Licensees are required to report the theft or significant loss of	
dangerous drugs (controlled and non-controlled prescription drugs)	
and drug documents.	

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.

- "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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Veterinary Clinic - 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	Any change in the ownership, business or trade name, category, or	OAC <u>4729:5-2-03</u>
in the facility's ownership,	address of a terminal distributor of dangerous drugs requires a new	
business name or trade	application, required fee, and license. The new application and	
name, category, or address	required fee shall be submitted within thirty days of any change in the	
without submitting a new	ownership, business or trade name, category, or address.	
application to the Board?		
Does the responsible	A location licensed as a terminal distributor of dangerous drugs must	OAC <u>4729:5-2-01</u>
person/medical director	have a responsible person at all times. When there is a change of	
match what is indicated in	responsible person, the Board must be notified within ten days of the	
eLicense?	effective date of the appointment of the new responsible person. A	
	new responsible person must be designated using eLicense. For	
	detailed instructions, use this link: Change of Responsible Person	
	Request in eLicense Ohio.	

<u>Personnel</u>

Question	Guidance	Law/Rule
Have any licensed/registered	"Access to drug stock" includes not only physical access, but also any	OAC <u>4729:5-1-01</u>
employees at the facility	influence over the handling of dangerous drugs such as purchases,	
with access to drug stock	inventories, issuance of medical orders, etc. It does not include	OAC <u>4729:5-4-01</u>
ever been disciplined by an	employees or contractors such as maintenance, janitorial, IT or other	
Ohio licensing agency?	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;
- (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.

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 <u>4729:5-20-04</u>
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 <u>4729:5-20-04</u>
If using computerized record keeping system, is it standalone or able to be shared or accessed by another location?	If shared access, confirm that security features are in place to prevent unauthorized access from other locations.	OAC <u>4729:5-20-04</u>
Does the licensee maintain records of drug	Records of drug administration must be maintained for at least three years.	OAC <u>4729:5-20-04</u>

administration containing	Records of administration shall contain the name, strength, dosage	
the required information?	form, and quantity of the dangerous drugs administered, the name or	
	identification of the animal or animals 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 licensed or	
	registered health care professional 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.	
	NOTE: Board staff will review drug records to determine compliance.	
	NOTE. Board Staff with review drug records to determine compliance.	
Are orders for the	Records of controlled substances administered by a health care	OAC <u>4729:5-20-04</u>
administration of controlled	professional, acting within the professional's scope of practice, who is	
substances properly	not a prescriber must include documentation of an order issued by a	
documented?	prescriber or protocol authorizing the administration of the drug.	
	Orders for the administration of controlled substances shall be	
	documented using positive identification. 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 animal aides being used	If yes, Board staff will confirm that animal aides are only being utilized	OAC <u>4741-1-14</u>
to administer drugs?	to administer topical, oral and subcutaneous medications exclusive of	
	anesthetic agents and controlled substances.	
Are protocols being used to	Protocols may only be used as follows:	OAC <u>4729:5-3-12</u>
administer dangerous		
drugs?	(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 include cases such as heart	
	attacks, severe burns, hypoglycemia, extravasation, overdoses,	
	cyanide poisonings, electrocutions, or severe asthmatic attacks;	
	(2) The administration of biologicals (including monoclonal	
	antibodies) 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	
	(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.	OAC <u>4729:5-3-12</u>
	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 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 stored in a securely locked,	The cabinet or safe must meet the following requirements:	OAC <u>4729:5-20-03</u>
substantially constructed	(1) The cabinet or safe shall be placed in an area that is not readily	
cabinet or safe?	accessible to the public (ex. waiting areas or areas where the public are allowed without supervision by staff).	
	(2) During non-business hours, the cabinet or safe is stored in an area secured by a physical barrier with suitable locks, which may include a locked room or secured 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.	
Do the methods utilized for accessing the cabinet or safe	Access to the cabinet or safe must comply with the following:	OAC <u>4729:5-20-03</u>
containing controlled	(1) In the case of a key lock, all locks are kept in good working order	
substances prevent	with keys removed therefrom. All keys shall be maintained in a secure	
unauthorized access?	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	

maintained under appropriate security and control?		OAC <u>4729:5-20-03</u> will be updated to
controlled substances	controlled substances in accordance with the following:	Resolution.
Are patient-specific	A registered veterinary technician, may have unsupervised access to	Authorized by Board
	REMINDER: A veterinary technician may have access to controlled substances only under the personal supervision of a veterinarian.	
	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 4729:5-20-03 (B)(6)(c)].	
	(b) The room is locked during non-business hours or when there is no longer a veterinarian available to provide personal supervision.	
	(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	
	(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:	
	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.	

(1) The drugs have been personally furnished by a veterinarian and
are intended for administration to patients undergoing treatment
and/or boarding within the veterinary clinic.

incorporate resolution text.

- (2) The drugs must be stored in a securely locked, substantially constructed cabinet or safe with access that is limited to veterinarians and veterinary technicians. The cabinet or safe must be separate from those required for non-patient specific controlled substance medications.
- (a) The cabinet or safe shall be placed in an area that is not readily accessible to the public.
- (b) The cabinet or safe shall remain locked and secured when not in use.
- (c) 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.
- (d) 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 and veterinary technician.
- (e) During non-business hours, 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: A record of drug administration must be maintained for the on-site administration of patient-specific controlled substances in accordance with the requirements of OAC 4729:5-20-04 (E). The record shall also include the date and time the drugs are accessed from the cabinet or safe. Additionally, the veterinary clinic's responsible person is responsible for reporting any theft or significant loss of controlled substances maintained for patient administration.	
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 4729:5-20-03 (F) for additional information on the storage of thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine.	OAC <u>4729:5-20-03</u>
Are non-controlled dangerous drugs maintained under appropriate supervision and control?	During normal business hours, 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. During non-business hours, 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. NOTE: Generally, non-controlled dangerous drugs must be maintained under the supervision of staff (i.e. patients and the	OAC <u>4729:5-20-03</u> OAC <u>4729:5-3-14</u>

Are hypodermics maintained under appropriate supervision and control?	During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections. During non-business hours, hypodermics must 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.	OAC <u>4729:5-20-03</u> ORC <u>3719.172</u>
	general public should not have unsupervised access to dangerous drugs). By law, staff (i.e. animal aides) are permitted to administer most dangerous drugs. Exclusions to this include anesthetics and controlled substances. If dangerous drugs cannot be maintained under the supervision of staff authorized to administer such drugs during normal business hours, the drugs must be secured to prevent unauthorized access. Effective controls to secure non-controlled drugs from unauthorized access may include any of the following: a locked drawer, filing cabinet, safe, lock box, or any other method that can be locked to prevent unauthorized access. For non-business hours, the goal is to ensure the facility can be secured to prevent unauthorized access (i.e. individuals who are not employed by the licensee).	

NOTE: Generally, hypodermics should be maintained under the supervision of staff. By <u>law</u>, staff (i.e. animal aides) are permitted to administer injections.

For non-business hours, the goal is to ensure the facility can be secured to prevent unauthorized access (i.e. individuals who are not employed by the licensee).

REMINDER: Ohio law (ORC <u>3719.172</u>) requires reasonable precautions to prevent any hypodermic in the person's possession from theft or acquisition by any unauthorized person.

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 <u>4729:5-20-03</u>
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 <u>4729:5-20-03</u>
Are refrigerators and 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:	OAC <u>4729:5-20-03</u> OAC <u>4729:5-20-04</u>

	(1) For temperature logs, either:	
	(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	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.	OAC <u>4729:5-20-03</u>
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). 	
Are refrigerators and/or	A licensee is required to develop and implement a policy that no food	OAC <u>4729:5-20-03</u>
freezers used for the storage	or beverage products are permitted to be stored in refrigerators or	
of drugs free of food or	freezers used to store drugs.	
beverage products?	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.	

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. 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 <u>4729:5-3-02</u>
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 <u>4729:5-3-02</u>

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 <u>4729:5-20-04</u>
Are DEA Forms 222 secured when not in use?	Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms (DEA Form 222) only under the personal supervision of a prescriber. 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 4729:5-20-03

Controlled Substance Inventory

Question	Guidance	Law/Rule
Does the licensee conduct an	All Category III licensees must complete an annual inventory even if	OAC <u>4729:5-3-07</u>
annual inventory of	drugs are not on-site (zero balance). Records of inventories must be	
controlled substances?	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.	

How does the licensee	Board staff will review and document how the licensee monitors its	
monitor its inventory of	inventory of controlled substances (e.g. daily count, perpetual	
controlled substances?	inventory, etc.).	

Drug Purchases and Online Sales

Question	Guidance	Law/Rule
Does the licensee maintain	Records of receipt shall contain the name, strength, dosage form, and	OAC <u>4729:5-20-04</u>
complete and accurate	quantity of the dangerous drugs received, the name and address of	
records of drugs purchased?	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.	
Has the licensee performed	Before a terminal distributor of dangerous drugs may purchase	OAC <u>4729:5-3-04</u>
and documented an annual	dangerous drugs at wholesale (including samples), the terminal	
query of <u>eLicense</u> prior to	distributor shall query the Board's <u>online roster</u> to confirm any of the	
purchasing drugs at	following:	
wholesale?		
	(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. 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.	
Does the licensee sell or offer to sell dangerous drugs on its website?	If yes, Board staff will confirm that the licensee is using a pharmacy or service that maintains accreditation as a digital pharmacy from the National Association of Boards of Pharmacy. A list of digital pharmacy accreditations can be accessed here. NOTE: This requirement does not apply to a licensee using online services to distribute naloxone.	OAC <u>4729:5-3-08</u>

Drug Disposal

Question	Guidance	Rule/Law
Does the licensee dispose of	Any person legally authorized under Chapters 3719. and 4729. of the	OAC <u>4729:5-3-01</u>
controlled substances on-	Revised Code to possess dangerous drugs which are controlled	
site using a method that	substances shall dispose of such drugs in accordance with 21 C.F.R.	
renders the drug non-	1317 (1/1/2016). The method of destruction must render the	
retrievable?	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.	

Does the licensee use a reverse distributor for the disposal of controlled substances?	A licensee is responsible for maintaining documentation demonstrating that the method of disposal meets the requirement to render controlled substances non-retrievable. 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 licensed or registered healthcare professionals (veterinarians, veterinary technicians) conducting and witnessing the disposal, one of whom shall be the responsible person or the responsible person's designee. A veterinarian may use an animal aide in lieu of one of the licensed or registered healthcare professionals required to conduct and witness the disposal of controlled substances from inventory. All records must be maintained for a period of three years.	OAC <u>4729:5-3-01</u> OAC <u>4729:5-20-04</u>

		I
	Board staff will review records of disposal to determine compliance.	
Does the licensee maintain	Records must include the name of the drug, the quantity disposed,	OAC <u>4729:5-3-01</u>
complete and accurate	the date and manner of disposal, and the positive identification of	
records of the disposal of	two licensed or registered healthcare professionals (veterinarians,	OAC <u>4729:5-20-04</u>
unused portions of controlled substances	veterinary technicians) conducting and witnessing the disposal.	
resulting from patient administration?	A veterinarian may use an animal aide in lieu of one of the licensed or registered healthcare professionals required to conduct and witness the disposal of controlled substances 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.	
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 <u>4729:5-3-06</u>

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.

OAC 4729:5-20-04

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.

To assist licensees in complying with the record keeping requirements for the disposal of non-controlled drugs from inventory, the Board developed a sample form that can be accessed by visiting: www.pharmacy.ohio.gov/NCdispose

Board staff will review records of disposal to determine compliance.

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

Personally Furnishing

Question	Guidance	Rule/Law
Does the licensee personally furnish any dangerous drugs	Are dangerous drugs, including any drug samples, personally furnished to patients?	
to patients/caregivers?	Turnished to putients.	
	Board staff will document the types of drugs personally furnished by the licensee.	
If personally furnishing controlled substances, list	If yes, Board staff will document the controlled substances that the licensee has on hand with dosage forms.	
the controlled substances the licensee has in stock with		
dosage forms.		
Are non-sample drugs that	Drugs personally furnished to a patient must be labelled and	OAC <u>4729:5-20-02</u>
are personally furnished to patients properly labeled?	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 (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:	OAC <u>4729:5-20-02</u>
	 (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.	
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. 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.	OAC <u>4729:5-20-02</u>
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.	OAC <u>4729:5-20-04</u>

	NOTE: If dangerous drugs are personally furnished for administration at an animal shelter as defined in rule 4729:5-15-01 of the Administrative Code, the records shall include the name of the employee who was provided the drugs and the name and address of the animal shelter in lieu of the owner or caregiver's name and address. Records of personally furnishing must be maintained for at least three years. Board staff will review records to determine compliance.	
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 <u>4729:5-20-02</u>
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: (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.	OAC <u>4729:5-20-02</u>

	-AND- (2) Counseling is offered.	
Does the licensee personally	A veterinarian may personally furnish up to a seven-day supply of a	OAC <u>4729:7-2-05</u>
furnish compounded drugs	compounded drug obtained by a pharmacy to a patient when, in their	
that were initially prepared	professional judgment, failure to provide the drug would result in	
by a pharmacy for in-office	potential harm to the patient. See <u>page 4</u> of this guide for more	
use?	information on personally furnishing compounded medications	
	obtained from an outsourcing facility.	

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 <u>4729:6-3-08</u>
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 <u>3719.81</u>

OARRS

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

Drug Compounding

Question	Guidance	Rule/Law
Does the licensee engage in sterile or non-sterile	A veterinarian engaged in the compounding of sterile and non-sterile drug preparations shall comply with the following:	OAC <u>4729:7-3-03</u>
compounding?	(1) Unless administered immediately, the compounded drug preparation shall bear a label listing all of the following:(a) Patient identification information, including the full name of the	
	owner, if applicable, and the name or identification of the animal; (b) The name and quantity of each ingredient; (c) The date and time prepared;	
	(d) The name or initials of the person who prepared the compounded drug preparation.	
	IMPORTANT: This is the only requirement applicable to veterinarians engaged in non-hazardous drug compounding [see OAC 4729:7-3-03 (L)]	
Is the licensee engaged in hazardous drug compounding?	If engaged in hazardous drug compounding, a veterinary clinic may be subject to an additional inspection by a Board Specialist (i.e. pharmacist).	OAC <u>4729:7-3-05</u>

"Hazardous drug" means any antineoplastic drug listed in table one on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.
For more information on the requirements for hazardous drug compounding the Board has developed an inspection guide, which can be accessed here: www.pharmacy.ohio.gov/prescribercomp .

Prescriptions

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

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 <u>4729:5-5-05</u>
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 <u>4729:5-3-11</u>
Are uncompleted	Only a veterinarian shall have access to uncompleted prescription	OAC <u>4729:5-20-03</u>
prescription blanks secured	blanks used for writing a prescription. Uncompleted prescription	
when not in use?	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.	

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 <u>4729:5-20-03</u>
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 <u>4729:5-20-03</u>
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 <u>4729:5-3-06</u>
Are expired/adulterated drugs appropriately	Expired/adulterated drugs must be segregated from active drug stock in a manner that prohibits access by unauthorized persons.	OAC <u>4729:5-3-06</u>

segregated from the licensee's active drug stock?	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 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 <u>4729:5-3-06</u>

General Record Keeping

Question	Guidance	Rule/Law
Does the licensee maintain	All records maintained in accordance with this rule shall be readily	OAC <u>4729:5-20-04</u>
all required records on-site	retrievable and shall be kept on-site for a period of three years.	
for a period of three years in		
a readily retrievable	If stored off-site, Board staff will document the off-site location and	
manner?	confirm the licensee submitted proper <u>notification to the Board</u> .	
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.	OAC <u>4729:5-20-03</u>
	Generally, a licensee should avoid having any required 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).	
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):	OAC <u>4729:5-20-04</u>
	(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. Board staff will ask the licensee to provide documentation demonstrating daily back-up functionality to protect against record 	
	loss.	
Does the licensee engage in	If yes, records of transfer or sale conducted in accordance with rule	OAC <u>4729:5-20-04</u>
the transfer or sale of dangerous drugs?	4729:5-3-09 of the Administrative Code must contain the name, strength, dosage form, national drug code, 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.	OAC <u>4729:5-3-09</u>
	NOTE: This includes intracompany transfers/sales and occasional sales. It does not apply to the transfer of patient-specific drugs to new owners/caregivers.	
	Except for <u>local health departments</u> , 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.	

To assist licensees in complying with the record keeping requirements for occasional sales or intracompany transfers, the Board developed a sample form that can be accessed by visiting: www.pharmacy.ohio.gov/SampleSale	
Board staff will review records to determine compliance.	

Prescription Pick-Up Station

Question	Guidance	Rule/Law
Does the licensee act as a	A pick-up station is a facility that receives patient-specific	OAC <u>4729:5-5-14</u>
pick-up station by receiving	prescriptions from the pharmacy and then distributes/administers	
patient-specific	the drugs to the patient.	
prescriptions from		
pharmacies for final	Board staff will document the types of prescriptions that are received	
distribution/administration	by licensee.	
to ultimate users?		
Is there clear and convincing	To serve as a pick-up station, there must be clear and convincing	OAC <u>4729:5-5-14</u>
evidence that the facility	evidence that delivery of a prescription medication directly to the	
acts as a pick-up station in	patient would result in:	
the interest of the patient or		
public health?	(a) Danger to public health or safety, or	
	(b) Danger to the patient without increased involvement by a health	
	care professional in the patient's drug therapy.	
	A pick-up station only valid for those situations where there is	
	evidence it is in the best interest of the patient or the public to have	
	the drug be provided by the prescriber.	
	Examples include:	
	 Injectable drugs the prescriber will administer on-site. 	

	 Distribution of specialty medications which require specialized storage or administration education, medications for patients in a mental health clinic, who should not (for safety reasons) have possession of large quantities of their medications without increased medical supervision. NOTE: Non-self-injectable cancer drugs are generally required by law (ORC 4729.43) to be sent from a pharmacy directly to a prescriber for administration. 	
Is the receipt, storage, control and distribution of prescriptions or drugs in the full and actual charge of a licensed health care professional at the pick-up station location?	The receipt, storage, control, and distribution of prescriptions or drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4715. (Dental Practice Act), 4723. (Nurse Practice Act), 4729. (Pharmacy Practice Act), 4730. (Physician Assistant Practice Act), 4731. (Medical Practice Act), or 4741. (Veterinary Medical Practice Act) of the Revised Code. Board staff will inspect the location to ensure a licensed health care professional overseeing the delivery and distribution of drugs received by the pharmacy. Drugs must be maintained under the same security and storage conditions as regular inventory.	OAC 4729:5-5-14
Is there a record keeping system in place to provide accountability for the proper receipt delivery and return	Record keeping systems must include a record of patient specific prescriptions delivered to the facility, a record of distribution or administration of the drugs to the individual patient, and a record of all medications returned to the pharmacy.	OAC <u>4729:5-5-14</u>

of all prescription
medications?

Receipt of prescriptions should be an invoice such that each patient specific prescription is identifiable, including a date of delivery, and documentation of receipt.

Any medications returned to the pharmacy (patient failed to pick up, etc.) should also be documented with an invoice/log that is maintained on file at the facility and provided to the pharmacy. Documentation must include patient name, prescription information, and date returned (or date disposed).

NOTE: A prescription delivered to the facility that is abandoned by the patient (i.e. never picked up by the patient) must be destroyed onsite or returned to the dispensing pharmacy for destruction. Prescriptions which are abandoned by the patient may not be redispensed to another patient, unless the facility is acting as a drug repository (see Drug Repository section).

Temporary Removal of Drugs

REMINDER: Any drugs maintained pursuant to this paragraph are subject to inspection by a Board of Pharmacy agent and shall be subject to all recordkeeping, labeling, theft or significant loss reporting, disposal and inventory requirements of division 4729:5 of the Administrative Code.

Clarification (6/19/2020): Rule <u>4729:5-3-13</u> permits a veterinarian to remove drugs from a licensed location and maintain those drugs at an off-site location, in excess of twenty-four hours, to treat current or prospective patients. This rule is intended to permit a veterinarian to maintain <u>a single</u> separate supply of drugs at an off-site location or, if there are several veterinarians, each veterinarian may do so. The intent of the rule is to reduce any potential delays in patient care and avoid the need to extend licensure to personal residences of veterinarians.

It is **not intended** to permit a veterinarian to maintain several supplies of dangerous drugs at various unlicensed locations for more than 24-hours. A veterinarian who seeks to maintain more than one off-site supply must apply for a terminal distributor license for any additional locations.

Question	Description / Guidance	Law/Rule
Does the licensee engage in	A veterinarian licensed pursuant to Chapter 4741. of the Revised Code	OAC <u>4729:5-3-13</u>
the temporary off-site	may maintain a supply of dangerous drugs obtained from a licensed	
storage of dangerous drugs?	terminal distributor of dangerous drugs at another location in order	
	to treat current or prospective patients.	
Does the licensee maintain	The terminal distributor of dangerous drugs shall also maintain the	OAC <u>4729:5-3-13</u>
records of all controlled	following records for controlled substance dangerous drugs removed	
substances stored off-site	from the terminal distributor of dangerous drugs that are stored off-	
for more than twenty-four	site for more than twenty-four hours: name, strength, dosage form,	
hours?	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. NOTE: If a veterinarian maintains a separate stock of controlled substances off-site, staff will confirm the veterinarian holds a valid DEA registration.	
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 <u>4729:5-3-13</u>
If direct supervision is not provided, are the drugs that are temporarily removed securely stored at temperatures and conditions which will ensure the integrity of the drugs?	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 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.	OAC <u>4729:5-3-13</u>

Online Sales of Dangerous Drugs

Question	Guidance	Rule/Law
Does the veterinary clinic	If yes, Board staff will confirm that the veterinarian is using a	OAC <u>4729:5-3-08</u>
sell, offer, or facilitate the	pharmacy or service that maintains accreditation as a Verified	
sale of dangerous drugs on	Internet Pharmacy Practice Site (VIPPS) from the National Association	
its website?	of Boards of Pharmacy.	
	A list of VIPPS-Accredited sites can be accessed here: https://nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/	

Recall Procedures

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

Question	Description / Guidance	Law/Rule
Does the facility have a written procedure in place to manage recalls for the	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.	OAC <u>4729:5-3-18</u>
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.	
Do the facility's written recall procedures include all the requirements established in rule?	 The written recall procedures must include all of the following: The terminal distributor must, where appropriate, contact patients to whom the recalled drug products have been dispensed or personally furnished. 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 	OAC <u>4729:5-3-18</u>

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

Mobile Clinics and Medication Units

NOTE: OAC <u>4729:5-3-13</u> (E) permits a veterinarian to 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. This permits the use of mobile units by veterinarians that can comply with OAC 4729:5-3-13 (see <u>Temporary Removal of Drugs</u>).

For more information on registering a mobile clinic or medication unit, visit: www.pharmacy.ohio.gov/mobile.

Question	Description/Guidance	Law/Rule
Does the licensee meet the criteria to operate a mobile clinic or medication unit?	 OAC 4729:5-3-23 authorizes the following terminal distributors of dangerous drugs to operate a mobile clinic or medication unit: 1. A nonprofit* organization, corporation, or association as defined in the Ohio Revised Code; or 2. A for-profit entity for the purpose of providing services to an individual needing treatment for a substance use disorder, a mental health condition, and any related medical issue. *For the purposes of this rule, nonprofit organization also includes state and local governmental entities. 	OAC <u>4729:5-3-23</u>
Does the mobile clinic or medication unit have a satellite license affiliated with an existing terminal distributor of dangerous drugs?	no-cost, satellite license affiliated with an existing terminal distributor of dangerous drugs. For more information, visit: www.pharmacy.ohio.gov/mobile.	

Are the drugs in the mobile clinic or medication unit in full charge of a licensed or registered health care professional, or else secured to provide unauthorized access?	If the mobile clinic is distributing dangerous drugs that have already been dispensed or personally furnished, the drugs must be in full and actual charge of a licensed or registered health care professional authorized under Chapter 4715., 4723., 4729., 4730., 4731., or 4741. of the Revised Code. If there is no health care professional present on the mobile unit, all	OAC <u>4729:5-3-23</u>
	dangerous drugs shall be secured using physical locks to prevent unauthorized access. NOTE: This requirement does NOT apply to overdose reversal medications (e.g., naloxone).	
Does the mobile unit maintain records for prescription medications in a readily retrievable manner?	Mobile units are required to implement a record keeping system that will provide accountability for proper receipt, delivery, disposal, and return of all prescription medications in accordance with applicable record keeping provisions in division 4729:5 of the Administrative Code.	OAC <u>4729:5-3-23</u>
Are dangerous drugs removed from the mobile unit when the unit is not in operation?	Except for mobile units that are stored in a locked garage with access control, dangerous drugs shall not be left in the mobile unit during the hours that the mobile unit is not in operation. Without exception, a terminal distributor shall not maintain controlled substances in the mobile unit when the unit is not in use.	OAC <u>4729:5-3-23</u>
Is the mobile unit dry, well- lit, well-ventilated, and maintained in a clean,	All mobile units shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas for dangerous drugs shall be maintained at temperatures and conditions which will ensure	OAC <u>4729:5-3-23</u>

sanitary, and orderly condition?	the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.	
Is the mobile unit secured with a lock?	Mobile units are required to be secured with suitable locks capable of preventing unauthorized access.	OAC <u>4729:5-3-23</u>

Veterinary Clinic - Update History

Update Date	Section Update	Update
3/2/2020	Drug and Hypodermic Security	Adds provision permitting a registered veterinary technician access to controlled substances that are personally furnished or dispensed for administration to patients undergoing treatment and/or boarding within the veterinary clinic. NOTE: This provision was added via Board resolution but will be incorporated in a subsequent rule amendment.
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.
6/19/2020	Temporary Removal of Drugs	Clarifies the Board's off-site storage rule is intended to permit a veterinarian to maintain a single separate supply of drugs at an off-site location or, if there are several veterinarians, each veterinarian may do so. The intent of the rule is to reduce any potential delays in patient

		care and avoid the need to extend licensure to personal residences of veterinarians.
6/19/2020	Changed "Drug Purchases" section to "Drug Purchases and Online Sales"	Added new question to inspect for compliance with OAC <u>4729:5-3-08</u> (Online Sales of Dangerous Drugs).
3/23/2021	Drug Compounding	Added new question to inspect for compliance with a provision OAC 4729:7-3-03 (Non-Hazardous Drugs Compounded by a Prescriber). Added reference to new prescriber compounding guide for the compounding of hazardous drugs.
8/27/2021	Personally Furnishing Compounded Drugs Obtained from an Outsourcing Facility (<u>Page 4</u>)	Provides clarification regarding the personally furnishing of compounded drugs obtained from an Ohio-licensed outsourcing facility.
3/10/2022	Prescriptions	Updated rule reference for the Board's prescription formatting rule.
3/10/2022	Prescription Pick-Up Station	Updated rule reference for the Board's pick-up station rule.
8/14/2024	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
12/19/2024	Drug Purchases and Online Sales	Updates the type of accreditation required for online sales of dangerous drugs.
12/19/2024	Mobile Clinics or Medication Units	Added section to inspect for compliance with OAC <u>4729:5-3-23</u> .
1/16/2025	Mobile Clinics or Medication Units	Clarified that the requirement to securely store drugs within a mobile clinic or medication unit that are not under the supervision of a licensed healthcare professional does not apply to overdose reversal medications (e.g., naloxone).
3/7/2025	Patient Records and Drug Administration	Added clarification that protocols for emergency purposes include the treatment of hypoglycemia. Added clarification that biologics include monoclonal antibodies and may be administered via protocol.
3/24/2025	Required Notifications or Document Submissions	Updated Discontinuation of Business section to require businesses submit a notice to the Board within 30 days of discontinuation of business and removing the mention of a waiver for extraordinary circumstances.

4/18/2025	General Recordkeeping	Added a link to a sample form to help licensees comply with the record keeping requirements for occasional sales or intra-company transfers.
4/18/2025	Drug Disposal	Added a link to a sample form to help licensees comply with the record keeping requirements for the disposal of non-controlled dangerous drugs from inventory.
7/14/2025	Required Notifications or Document Submissions	Updated link from Change of Responsible Person Form to the Change of Responsible Person Request in eLicense Ohio.
7/30/2025	Mobile Clinics or Medication Units	Clarifies that veterinarians can operate mobile clinics under OAC 4729:5-3-13 (see <u>Temporary Removal of Drugs</u>).