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Rules for Stakeholder Feedback - Veterinary Clinics

Date Issued: 3/28/2025 Comments Due: 4/25/2025

The Ohio Board of Pharmacy is required to review all administrative rules every five years. In accordance with Chapter 119. of the Revised Code, the Ohio Board Pharmacy proposes amendments, in track changes, to the following rules:

- Rule 4729:5-20-01 | Veterinary Clinics Definitions. (AMEND)
- Rule 4729:5-20-02 | Personally furnishing dangerous drugs. (AMEND)
- Rule 4729:5-20-03 | Security and control of dangerous drugs. (AMEND)
- Rule 4729:5-20-04 | Record keeping. (AMEND)

These rules <u>only</u> apply to those holding a terminal distributor of dangerous drugs license with a veterinary clinic classification.

Comments on the proposed rules will be accepted until the close of business on Friday, April 25, 2025. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov.



Rule 4729:5-20-01 | Veterinary Clinics - Definitions. (AMEND)

As used in Chapter 4729:5-20 of the Administrative Code:

- (A) "Veterinary clinic" or "clinic" means a facility licensed as a terminal distributor of dangerous drugs in accordance with section <u>4729.54</u> 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. The facility shall comply with all requirements set forth in this chapter.
- (B) "Animal aide" has the same meaning as in section <u>4741.01</u> of the Revised Code.
- (C) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.
- (D) "Dangerous drug" has the same meaning as in section <u>4729.01</u> of the Revised Code.
- (E) "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.
- (F) "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.

(G)

- (1) "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:
- (a) A manual signature on a hard copy record;
- (b) A magnetic card reader;
- (c) A bar code reader;
- (d) A biometric method;
- (e) A proximity badge reader;
- (f) A board approved system of randomly generated personal questions;

- (g) 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
- (h) Other effective methods for identifying individuals that have been approved by the board.
- (2) 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.

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.

- (H) "Readily retrievable" means that records maintained in accordance with this chapter 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.
- (I) "Registered veterinary technician" has the same meaning as in section <u>4741.01</u> of the Revised Code.
- (J) "Responsible person" has the same meaning as defined in rule <u>4729:5-2-01</u> of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section <u>4729.55</u> of the Revised Code, adequate safeguards as required in division (C) of section <u>4729.55</u> of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.
- (K) "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.
- (L) "Veterinarian" means an individual licensed by the state of Ohio to practice veterinary medicine pursuant to Chapter 4741. of the Revised Code.

Rule 4729:5-20-02 | Personally furnishing dangerous drugs. (AMEND)

- (A) A veterinarian who personally furnishes a dangerous drug, other than a sample drug pursuant to section <u>3719.81</u> of the Revised Code, shall 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 dangerous 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.
- (B) 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, the veterinarian shall affix a label to the sample container or provide written documentation accompanying the sample that includes the following:
- (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; and
- (3) Directions for use.
- (C) 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.
- (D) A veterinarian shall conduct the final association of a controlled substance dangerous drug with a patient prior to personally furnishing the drug to the patient's owner or caregiver.
- (E) Counseling.

- (1) A veterinarian or the veterinarian's designee shall personally offer to provide, or may provide in writing, the service of counseling pursuant to paragraph (E)(2) of this rule to an owner or caregiver whenever any dangerous drug is personally furnished. A veterinarian shall not be required to counsel an owner or caregiver when the owner or caregiver refuses, either verbally or in writing, the offer of counseling or does not respond to the written offer to counsel.
- (2) Veterinarian counseling may include, but is not limited to, the following:
- (a) The name and description of the drug;
- (b) The dosage form, dose, route of administration, and duration of drug therapy;
- (c) The intended use of the drug and the expected action;
- (d) Special directions and precautions for preparation, administration, and use;
- (e) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;
- (f) Techniques for monitoring drug therapy;
- (g) Proper storage and disposal;
- (h) Action to be taken in the event of a missed dose; and
- (i) The veterinarian's comments relevant to the patient's drug therapy, including other necessary information unique to the specific patient or drug.
- (F) Provision of dangerous drugs.
- (1) A veterinarian may delegate an individual or individuals to distribute dangerous drugs that are personally furnished if all the following apply:
- (a) A veterinarian provides personal supervision;
- (b) Counseling is offered in accordance with paragraph (E) of this rule;
- (c) This task may be delegated in accordance with applicable state laws and rules.
- (2) Paragraph (F)(1)(a) of this rule does not apply if a non-controlled dangerous drug is provided to the owner or caregiver 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.

- (G) No veterinarian may personally furnish to an owner or caregiver to whom there is no veterinary-client-patient relationship, pursuant to applicable state and federal laws, regulations, and rules.
- (H) Any patient specific dangerous drug dispensed by a pharmacy that is provided to an owner or caregiver by a veterinarian pursuant to rule <u>4729:5-5-14</u> of the Administrative Code is the property of that owner or caregiver and is not considered personally furnishing. No veterinarian that provides an owner or caregiver with a drug pursuant to rule <u>4729:5-5-14</u> of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.
- (I) Paragraph (H) of this rule does not prohibit a veterinarian from charging an owner or caregiver for any of the following:
- (1) The cost of an office visit or any expense related to the administration of a dangerous drug; or
- (2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the veterinarian.
- (J) A veterinarian may mail or provide delivery of a dangerous drug that has been personally furnished if the prescriber includes in the records required for personally furnishing the name of the common carrier (including the United State Postal Service), contract carrier, or employee of the terminal distributor who performed, or attempted to perform, the delivery.
- (K) Any drug that has left the possession of the terminal distributor of dangerous drugs shall comply with the requirements of rule 4729:5-3-16 of the Administrative Code.

Rule 4729:5-20-03 | Security and control of dangerous drugs. (AMEND)

- (A) The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs.
- (B) Except as provided in paragraphs (F) and (G) of this rule, controlled substances 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.
- (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 if not being used by a veterinarian or a veterinary technician in accordance with paragraph (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule. All locks shall be kept in good working order with keys removed therefrom.
- (5) 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.
- (6) Except as provided in paragraph (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule, only a veterinarian shall be able to access the cabinet or safe.
- (a) A veterinarian may provide a veterinary technician with a temporary key for the purposes of accessing the cabinet or safe. A veterinary technician shall return the key provided in accordance with this paragraph to the veterinarian or a secured location with restricted access (such as a lockbox) no later than the end of the technician's shift or if there is no longer a veterinarian available to provide personal supervision.
- (b) 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:
- (i) 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;

- (ii) The room is locked during non-business hours or when there is no longer a veterinarian available to provide personal supervision.
- (c) Any other method approved by the executive director or the director's designee that provides effective controls and procedures to guard against theft and diversion.
- (C) A registered veterinary technician may have access to controlled substances only under the personal supervision of a veterinarian.
- (D) 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.
- (E) 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 or a person delegated power of attorney in accordance with 21 CFR 1305.05 (9/30/2019). D.E.A. controlled substance order forms shall be secured when not in use.
- (F) 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.
- (1) There is no minimum size or weight requirement but if the cabinet or safe weighs less than seven hundred fifty pounds, it must be secured to the floor or wall in such a way that it cannot be readily removed.
- (2) Except as provided for in this paragraph, the cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, patients, business guests, or visitors to be present in or pass through areas containing the cabinet or safe, a veterinarian or veterinary technician shall provide for adequate observation of the area.
- (3) The cabinet or safe shall remain locked and secured when not in use.
- (4) 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.

- (5) 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 if not being used by a veterinarian. All locks shall be kept in good working order with keys removed therefrom.
- (6) 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.
- (7) Only a veterinarian shall be able to access the safe or cabinet.
- (G) A registered veterinary technician may have unsupervised access to controlled substances in accordance with the following:
- (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.
- (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 in paragraphs (B) and (F) of this rule.
- (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.
- (3) A record of drug administration shall be maintained in accordance with paragraph (E) of rule <u>4729:5-20-04</u> of the Administrative Code and shall also include the date and time the drugs are accessed from the cabinet or safe.
- (4) The responsible person shall report the theft or significant loss of drugs maintained pursuant to this paragraph in accordance with rule <u>4729:5-3-02</u> of the Administrative Code.

- (H) During non-business hours, 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, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections.
- (I) 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. 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.
- (J) 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.
- (K) All areas where dangerous drugs are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall 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. Refrigerators and freezers used for the storage of drugs shall comply with the following:
- (1) Maintain either to ensure proper refrigeration and/or freezer temperatures are maintained:
- (a) Temperature logs with, at a minimum, daily observations; or
- (b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.
- (2) The terminal distributor shall 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.
- (3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs.
- (L) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a date opened. 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).
- (M) Adulterated drugs, including expired drugs, shall be stored in accordance with rule <u>4729:5-</u> <u>3-06</u> of the Administrative Code.
- (N) Disposal of controlled substances shall be conducted in accordance with rule <u>4729:5-3-</u> <u>01</u> of the Administrative Code.
- (O) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.

Rule 4729:5-20-04 | Record keeping. (AMEND)

- (A) A veterinary clinic shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold, or transferred.
- (B) 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.
- (C) Records of temperature control monitoring described in paragraph (J) of rule <u>4729:5-20-03</u> of the Administrative Code shall include any of the following:
- (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.
- (D) 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.

If dangerous drugs are personally furnished for administration at an animal shelter as defined in rule <u>4729:5-15-01</u> 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.

- (1) Records of administration shall contain the name, strength, dosage 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.
- (2) Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.
- (3) 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 this paragraph.
- (F) 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 health care professional or animal aide that performed the disposal.
- (G) Records of controlled substance drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.
- (1) If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification of two licensed or registered healthcare professionals conducting and witnessing the disposal, one of whom shall be the responsible person or the responsible person's designee.
- (2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient, records shall also include the positive identification of two licensed or registered healthcare professionals conducting and witnessing the disposal.
- (3) 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 pursuant to paragraphs (G)(1) and (G)(2) of this rule.

- (H) Records of transfer or sale conducted in accordance with rule <u>4729:5-3-09</u> of the Administrative Code shall 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.
- (I) Controlled substance inventory records shall be maintained in accordance with rule 4729:5-3-07 of the Administrative Code.
- (J) All records maintained in accordance with this rule shall be readily retrievable and shall be kept on-site for a period of three years.
- (1) 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 in a manner determined by the board.
- (2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.
- (K) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:
- (1) Complies with the requirements of this rule;
- (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, such as unique user names and passwords, to prevent unauthorized access; and
- (4) Contains daily back-up functionality to protect against record loss.