



Animal Shelter Rules – Comments Requested

Date Issued: February 26, 2018

In accordance with sections 4729.26 and 3719.28 of the Ohio Revised Code, the State of Ohio Board of Pharmacy is proposing the adoption of new rules governing the operation of animal shelters.

At this time, public comment is being sought on this rule package prior to the rules being filed with the [Common-Sense Initiative](#).

Comments on the proposed rules will be accepted until 5:00 pm (EST) on **March 26, 2018**.

Please send all comments to the following email address:
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4729:5-15 – Animal Shelters

4729:5-15-01 – Animal Shelters – Definitions.

As used in Chapter 4729:5-15 of the Administrative Code:

(A) "Animal shelter" means a facility licensed as a limited terminal distributor of dangerous drugs in accordance with sections 4729.531 and 4729.532 of the Revised Code, where a licensed veterinarian serves as the responsible person on the license. An animal shelter shall be operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code and shall comply with all requirements set forth in this chapter.

(1) An animal shelter shall ensure that all agents and employees who have access to dangerous drugs, other than a registered veterinary technician as defined in section 4741.01 of the Revised Code, shall successfully complete a euthanasia technician certification course described in section 4729.532 of the Revised Code.

(2) An animal shelter shall comply with the initial licensure and renewal requirements set forth in rule 4729:5-2-02 of the Administrative Code.

(3) The board may suspend, revoke, restrict, limit, or refuse to grant or renew any animal shelter license in accordance with rule 4729:5-4-01 of the Administrative Code.

(B) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(C) "Direct supervision" or "personal supervision" means licensed veterinarian shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs.

(D) "Euthanasia technician" is an individual that has successfully completed a euthanasia certification course, the curriculum of which has been approved by the veterinary medical licensing board pursuant to section 4729.532 of the Revised Code, and is in possession of a certificate which documents the successful completion of the certification course.

(E) "Personally furnish" or "personally furnishing" means the final association of a drug with a patient by a veterinarian prior to the distribution to a patient for use outside the veterinarian's practice setting. A veterinarian at an animal shelter who personally furnishes a dangerous drug shall comply with the requirements of rule 4729:5-20-02 of the Administrative Code.

(F)

(1) "Positive identification" means a method of identifying a person that does not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as 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 available on request to those individuals authorized by law to review such records; 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, such as a password, for entry into a secure mechanical or electronic system.

(G) "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.

(H) "Registered veterinary technician" has the same meaning as in section 4741.01 of the Revised Code.

(I) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(J) "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.

(K) "Tamper-evident" means a package, storage container or other physical barrier is sealed or secured in such a way that access to the drugs or hypodermics stored within is not possible without leaving visible proof that such access has been attempted or made.

(L) "Veterinarian" means an individual licensed by the state of Ohio to practice veterinary medicine pursuant to Chapter 4741. of the Revised Code.

4729:5-15-02 – Security and control of dangerous drugs.

(A) The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license.

(B) Controlled substance dangerous drugs, dangerous drugs containing propofol, uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms, and poisons must be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, to deter and detect unauthorized access.

(1) Only a veterinarian shall have possession of the keys or access codes to the secure area or areas specified in paragraph (B) of this rule. Any additional keys shall be maintained in a secure place that is inaccessible to unauthorized persons.

(2) A registered veterinary technician or euthanasia technician may have access to controlled substances, dangerous drugs containing propofol, and poisons only under the direct supervision of a veterinarian.

(3) Only a veterinarian shall have access to uncompleted prescription blank(s) used for writing a prescription.

(4) Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the direct supervision of a veterinarian.

(5) Only prescribers may have unsupervised access to controlled substance dangerous drugs.

(C) Non-controlled dangerous drugs and hypodermics shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) All records relating to the administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access.

(E) All areas where dangerous drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures 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.

(F) Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code.

(G) Disposal of controlled substances shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.

(H) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.

4729:5-15-03 – Record Keeping.

(A) An animal shelter shall keep a record of all dangerous drugs received, administered, personally furnished, disposed or transferred.

(B) The acts of prescribing, administering, and disposing of controlled substance dangerous drugs shall be documented with positive identification.

(C) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the persons from whom received and the date of receipt.

(D) Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the owner's name, the positive identification of the veterinarian personally furnishing the drug, address and the identification of the animal to whom or for whose use the dangerous drug were personally furnished, the date the drug is personally furnished and the date the drug is received by the owner or caregiver.

(E) Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the identification of the animal to whom or for whose use the dangerous drugs were administered, the identification of the person administering the drug and the date of administration.

(1) Records of non-controlled substance dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(2) Records of controlled substance dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph if documented using positive identification.

(F) Records of dangerous drug disposed, 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 licensed or registered health care professional 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.

(H) Records of transfer conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, and quantity of the dangerous drug transferred, the address of the location where the drugs were transferred and the date of transfer.

(I) All records maintained in accordance with this chapter shall be readily retrievable and shall be kept for a period of three years at the place where the dangerous drugs are located.

(1) A terminal distributor intending to maintain records, described in this rule, at a location other than the place 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 representatives of the terminal distributor of dangerous drugs.

(J) 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) 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;

(2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted.

(3) Contains security features to prevent unauthorized access to the records; and

(4) Contains daily back-up functionality to protect against record loss.