

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 and the terminal distributor of dangerous drugs.
- (B) Controlled substance dangerous drugs used to perform euthanasia shall be stored in a securely locked, substantially constructed cabinet or safe.
- (1) The cabinet or safe shall be placed in an area that is not readily accessible to the public. The public does not include volunteers of the animal shelter.
 - (2) The cabinet or safe shall remain locked and secured when not in use.
 - (3) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.
 - (4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian, registered veterinary technician, responsible person, euthanasia technician, or executive director of the shelter. All locks shall be kept in good working order with keys removed therefrom.
 - (5) When not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.
 - (6) Only a veterinarian, registered veterinary technician, euthanasia technician, or executive director of the shelter shall be able to access the cabinet or safe.
- (C) Except as provided in paragraph (E) of this rule, controlled substance dangerous drugs that are not used to perform euthanasia shall be stored in a securely locked, substantially constructed cabinet or safe.
- (1) The cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public. The public does not include volunteers of the animal shelter.
 - (2) The cabinet or safe shall remain locked and secured when not in use.
 - (3) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

- (4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian if not being used by a veterinarian or a veterinary technician in accordance with paragraph (C)(6)(a), (C)(6)(b), or (C)(6)(c) of this rule. All locks shall be kept in good working order with keys removed therefrom.
- (5) When not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.
- (6) Except as provided in paragraph (C)(6)(a), (C)(6)(b), or (C)(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 when not staffed by shelter personnel or when there is no longer a veterinarian available to provide personal supervision.
 - (c) Any other method approved by the board's executive director or the director's designee that provides effective controls and procedures to guard against theft and diversion.
- (D) Except as provided in paragraphs (B) and (E) of this rule, a registered veterinary technician may have access to controlled substances only under the personal supervision of a veterinarian.
- (E) Employees or volunteers of an animal shelter that are designated by the responsible person or the shelter's executive director may have unsupervised access to controlled substances only under the following conditions:

- (1) The drugs have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration to an animal.
- (2) The drugs must be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, safe, or room. Access to the cabinet, safe, or room shall be limited to designated staff. The cabinet or safe must be separate from those required in paragraphs (B), (C), and (I) of this rule.

 - (a) The cabinet or safe shall be placed in an area that is not readily accessible to the public. The public does not include volunteers of the animal shelter.
 - (b) The cabinet, safe, or room shall remain locked and secured when not in use.
 - (c) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than designated staff. All locks shall be kept in good working order with keys removed therefrom.
 - (d) When not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.
- (3) A record of drug administration shall be maintained in accordance with paragraph (E) of rule 4729:5-15-03 of the Administrative Code.
- (4) The responsible person shall report the theft or significant loss of drugs maintained pursuant to this paragraph in accordance with rule 4729:5-3-02 of the Administrative Code.
- (5) The responsible person or shelter's executive director shall maintain a current list of all designated employees or volunteers for immediate inspection by an agent, officer or inspector of the board.
- (F) Non-controlled dangerous drugs that have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration may be administered by an animal shelter employee or volunteer.
- (G) 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.
- (H)

- (1) For an animal shelter that is licensed in accordance with section 4729.54 of the Revised Code: personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of a veterinarian. D.E.A. controlled substance order forms shall be secured when not in use.
- (2) For an animal shelter that is licensed in accordance with section 4729.531 of the Revised Code: personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of the responsible person. D.E.A. controlled substance order forms shall be secured when not in use.
- (I) 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 750 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) When not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.
 - (7) Only a veterinarian shall be able to access the safe or cabinet.

- (J) When not staffed by shelter personnel, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections. Members of the public do not include volunteers of the animal shelter.
- (K) When not staffed by shelter personnel, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, non-controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs. Members of the public do not include volunteers of the animal shelter.
- (L) In the event of a change of ownership of an animal, a shelter employee or volunteer may transfer dangerous drugs that have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration to an animal to the animal's new owner or caregiver. The transfer of controlled substances shall be documented in accordance with paragraph (I) of rule 4729:5-15-03 of the Administrative Code.
- (M) All records relating to the receipt, administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict access by those who neither work for, or volunteer at, the shelter.
- (N) All areas where dangerous drugs and devices 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 and devices shall comply with the following:
- (1) Maintain either of the following 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.
- (O) 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).
- (P) Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code.
- (Q) Disposal of controlled substances shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.
- (R) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.

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