



Ohio Administrative Code

Rule 4729:5-20-03 Security and control of dangerous drugs.

Effective: August 3, 2020

(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 4729:5-20-04 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 4729:5-3-02 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 4729:5-3-06



of the Administrative Code.

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