

4729:5-20-03

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) Except as provided in paragraph (F) 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;

- (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) 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.
- (H) 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.
- (I) 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.
- (J) 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.

(K) 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).

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

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

(N) 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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CERTIFIED ELECTRONICALLY

Certification

12/06/2019

Date

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