

4729:5-11-03

Security, control and storage 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 substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe to deter and detect unauthorized access.
- (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 prescriber or pharmacist if not being used by a prescriber, pharmacist or a licensed health care professional 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 prescriber or pharmacist shall be able to access the cabinet or safe.
 - (a) A prescriber or pharmacist may provide a licensed health care professional with a temporary key for the purposes of accessing the cabinet or safe. A licensed health care professional shall return the key provided in accordance with this paragraph to the prescriber or pharmacist or to a secured location with restricted access (such as a lockbox) no later than the end of the provider's shift or if there is no longer a prescriber or pharmacist available to provide personal supervision.
 - (b) A prescriber or pharmacist may provide a licensed health care professional 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 prescriber or pharmacist; and
 - (ii) The room is locked during non-business hours or when there is no longer a prescriber or pharmacist 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.
- (C) A licensed health care professional, acting within the scope of the professional's practice, may have access to controlled substances only under the personal supervision of a prescriber or pharmacist.
- (D) Only a prescriber 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 prescriber. 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 750 pounds, it must be secured to the floor or wall in such a way that it cannot be readily removed.
 - (2) The cabinet or safe shall be placed in an area that is not readily accessible to the public. During non-business hours, the cabinet or safe shall be stored in an area secured by a physical barrier with suitable locks, which may include a locked room or secured facility.
 - (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 codes.
 - (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 prescriber or pharmacist if not being used

by a prescriber or pharmacist. 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 prescriber or pharmacist 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, personal 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 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.
- (K) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.
- (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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