4729:5-16-02 **Security, control and storage of dangerous drugs.**

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

(B) Except as provided in paragraph (H) of this rule, controlled substances 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.

(4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than the responsible person or the responsible person's designee if not being used by the responsible person, responsible person's designee, or a laboratory employee or researcher 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) When the laboratory is not in use by authorized 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 (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule, only the responsible person or the responsible person's designee shall have possession of keys, combinations or access codes to the cabinet or safe.

(a) A responsible person or the responsible person's designee may provide a laboratory employee or researcher with a temporary key for the purposes of accessing the cabinet or safe. An employee or researcher shall return the key provided in accordance with this paragraph to the responsible person or responsible person's designee or a secured location with restricted access (such as a lockbox) no later than the end of the employee's shift, the end of the researcher's activity, or if there is no longer a responsible person or designee available to provide personal supervision.

(b) A responsible person or the responsible person's designee may provide an employee or researcher 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 the responsible person or the responsible person’s designee;

(ii) The room is locked during non-business hours or when there is no longer a responsible person or responsible person's designee 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) An employee or researcher of the laboratory may have access to controlled substances only under the personal supervision of the laboratory's responsible person or the responsible person's designee. A responsible person may have more than one designee. All designees shall meet the requirements of the responsible person set forth in rule 4729:5-2-01 of the Administrative Code. A laboratory shall maintain a current list of all approved designees for immediate inspection by an agent, officer or inspector of the board.

(D) Only a prescriber shall only have access to uncompleted prescription blank(s) used for writing a prescription. Uncompleted prescription blank(s) 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 under the personal supervision of the laboratory’s responsible person. D.E.A. controlled substance order forms shall be secured when not in use.

(F) Controlled substances in the process of testing, use, or research shall be returned to the required storage location upon completion of each such process.

(G) All samples containing, or suspected of containing, a dangerous drug or controlled substance shall be treated as schedule I and II controlled substances.

(H) 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.

(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 the responsible person or the responsible person's designee if not being used by the responsible person or the responsible person's designee. All locks shall be kept in good working order with keys removed therefrom.

(6) When the laboratory is not in use by authorized 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 the responsible person or the responsible person's designee shall have possession of the key, combination or access code to the safe or cabinet.

(I) When the laboratory is not in use by authorized personnel, non-controlled dangerous drugs and hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet or safe, drawer, locked room, or secured facility.

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

(K) All areas where dangerous drugs and controlled substances are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Unless otherwise required by a documented research study, 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 controlled substances 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 and controlled substances.

(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 and controlled substances.

(L) 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.

(M) Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code. This paragraph does not apply to drugs submitted to crime laboratories for analysis or laboratories conducting research using adulterated drugs.

(N) Laboratories shall comply with all state and federal laws, rules and regulations governing the use of controlled substances for the purpose of research or chemical analysis.

(O) Unless consumed as part of an analysis, disposal of controlled substance dangerous drugs shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.

(P) Unless consumed as part of an analysis, disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.

(Q) Unless consumed as part of an analysis, disposal of controlled substances that are not dangerous drugs or any unused portion of a submitted anonymous sample for scientific analysis shall be conducted as follows:

(1) The method of disposal shall render the drug or substance non-retrievable as defined in rule 4729:5-3-01 of the Administrative Code.

(2) Disposal shall be conducted by any of the following:

(a) The responsible person or the responsible person's designee and one other employee of the laboratory;

(b) Two employees of the laboratory designated by the responsible person; or

(c) A contracted waste disposal company in compliance with all federal, state and local laws, rules and regulations.

(3) Records for the disposal of the drug or substance shall contain the actual identification of the drug or substance, form, and quantity disposed, the date disposed, the method of disposal and, if disposal is conducted on-site, the positive identification of the two personnel conducting and witnessing the disposal.

Effective:

Five Year Review (FYR) Dates:

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Certification

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