4729:5-9-03.2 **Security, storage and control of dangerous drugs in an institutional facility.**

(A) As used in this rule, "blind count" means a physical inventory taken by a person authorized by the institutional facility's responsible person who performs a physical inventory without knowledge of or access to the quantities currently shown on electronic or other inventory systems.

(B) Except as provided in this rule, all non-controlled dangerous drugs, including those dispensed by an institutional pharmacy to inpatients, shall be stored in a secure area to deter and detect unauthorized access.

(C) Non-controlled dangerous drug emergency or contingency kits may be secured using a tamper-evident method. Drugs stored using a tamper-evident method shall be routinely inspected to detect unauthorized access in accordance with a policy developed by the facility. The policy shall be made readily retrievable.

(D) All controlled substance dangerous drugs, including those dispensed by an institutional pharmacy to inpatients, maintained in areas outside of the institutional pharmacy that are not stored as part of an automated drug storage system, shall meet the following requirements, unless stored as part of an automated drug storage system that meets the requirements of paragraph (E) of this rule:

(1) The drugs shall be a securely locked in a substantially constructed cabinet or safe to deter and detect unauthorized access.

(2) At every change of shift, a reconciliation shall be conducted by both the departing and incoming licensed health care professional responsible for the security and control of the drugs in the area in which they are stored and shall include the following:

(a) A physical count and reconciliation of the controlled substances and proof-of-use sheets or electronic records to ensure the accountability of all doses;

(b) An inspection of the packaging to ensure its integrity;

(c) The positive identification of the persons conducting the reconciliation; and

(d) The immediate reporting of any unresolved discrepancy to the appropriate personnel within the institution, including the responsible person or the responsible person's designee.

(e) Paragraph (B)(2)(a) does not apply to emergency or contingency drug kits secured using a tamper-evident method.

(3) All controlled substances shall be packaged in tamper-evident containers, except multi-dose liquids and injectables where unit-of-use packaging is not available.

(4) Maintain a record keeping system for each drug in accordance with rule 4729:5-9-03.3 of the Administrative Code.

(E) All controlled substance dangerous drugs, including those dispensed by an institutional pharmacy to inpatients, maintained in areas outside of the institutional pharmacy that are stored in an automated drug storage system shall meet the following requirements:

(1) All controlled substances stored in automated drug storage systems shall be limited to one drug and strength at a time.

(2) For automated drug storage systems that cannot limit access to one dose at a time, authorized personnel shall conduct a blind count each time a controlled substance is removed from the system.

(3) The automated drug storage system shall be securely locked and substantially constructed to deter and detect unauthorized access.

(4) The system shall document the positive identification of every person accessing the system and shall record the date and time of access.

(5) The institutional facility shall maintain a recordkeeping system in accordance with rule 4729:5-9-03.3 of the Administrative Code.

(6) At least annually, the responsible person shall cause a reconciliation of all controlled substances within an automated drug storage system to be conducted. The reconciliation shall include the following:

(a) A physical count and reconciliation of the controlled substances to ensure the accountability of all doses;

(b) An inspection of the packaging to ensure its integrity;

(c) The positive identification of the persons conducting the reconciliation; and

(d) The immediate reporting of any unresolved discrepancy to the appropriate personnel within the institution, including the responsible person or the responsible person’s designee.

(F) 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.

(G) In accordance with section 3719.172 of the Revised Code, an institutional facility shall develop and implement policies to prevent hypodermics from theft or acquisition by any unauthorized person.

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

(I) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.

(J) Disposal of controlled substance dangerous drugs shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.

(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) Uncompleted prescription blanks shall be secured when not in use and access shall be limited to personnel authorized in policy by the institutional facility.

(M) 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.

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