Ohio Administrative Code

Rule 4729:5-21-03 Security and control of dangerous drugs.

Effective: February 4, 2021

(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) All schedule II controlled substances shall be maintained in accordance with 21 CFR 1301.72 (12/5/2018). Only prescribers, pharmacists, and nurses licensed under Chapter 4723. of the Revised Code may have access to schedule II controlled substances maintained in accordance with this paragraph.

(C) All schedule III through V controlled substances shall be maintained in accordance with 21 CFR 1301.72 (12/5/2018). Only prescribers, pharmacists, and nurses licensed under Chapter 4723. of the Revised Code may have access to controlled substances maintained in accordance with this paragraph.

(D) When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through storage areas maintained in accordance with paragraphs (B) and (C) of this rule, the opioid treatment program shall provide for adequate observation of the area by a prescriber, pharmacist or nurse specifically authorized in writing.

(E) Controlled substances administered for the treatment of opioid dependence or addiction may be administered directly to the patient by any of the following:

(1) A licensed prescriber, in accordance with the prescriber's scope of practice and as authorized by federal or state law.

(2) A registered nurse or licensed practical nurse pursuant to a valid order issued by a licensed prescriber.

(3) A pharmacist in accordance with a consult agreement pursuant section 4729.39 of the Revised Code. The pharmacist shall only administer the drug pursuant to a valid order by the consulting physician.

(F) Persons enrolled in an opioid treatment program will be required to wait in an area physically separated from the drug storage and preparation areas. This requirement shall be enforced by the responsible person and program employees.

(G) 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.

(H) 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 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.

(I) 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.

(J) 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.

(K) 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.

(L) 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.

(M) 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.

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

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

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