



Ohio Administrative Code

Rule 4729:5-5-23 Security, control and storage of dangerous drugs in an outpatient pharmacy.

Effective: December 1, 2020

(A) The following applies to an outpatient pharmacy licensed as a terminal distributor of dangerous drugs:

(1) Except as provided in paragraph (A)(6) of this rule, a pharmacist shall provide supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted permission for such records to be stored at a secure off-site location in accordance with this chapter of the Administrative Code, at all times in order to deter and detect theft or diversion.

(2) The pharmacy shall be separated from the merchandising or public areas.

(3) The pharmacist or pharmacists on duty:

(a) Shall be physically present at the licensed location and responsible for the security of the pharmacy and supervision of pharmacy personnel.

(b) If the pharmacy is located within a store or business, shall ensure that all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control of the pharmacist or pharmacists on duty or secured in a designated area in accordance with paragraph (A)(6)(i) of this rule.

(4) No person, other than a licensed pharmacist, may enter the pharmacy unless the person is on business directly concerning the operation, maintenance or repair of the pharmacy and a pharmacist employed by the pharmacy is physically present at the same time.

(5) All schedule II controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe and shall not be dispersed through the stock of dangerous



drugs. The cabinet or safe shall remain locked and secured when not in use. Schedule III through V controlled substance dangerous drugs may be stored with Schedule II controlled substance dangerous drugs.

(6) Whenever a pharmacist cannot meet the supervision requirements in paragraph (A)(3)(a) of this rule, security of the pharmacy must be provided in accordance with the following:

(a) The pharmacy must be secured by either:

(i) A physical barrier (i.e. barricade) with suitable locks approved by the board. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.

(ii) An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. The alarm system shall be tested on a biannual basis. The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to an alarm system prior to implementation. This notification requirement does not apply if a pharmacy also utilizes an approved physical barrier in accordance with paragraph (A)(6)(a)(i) of this rule.

(b) Except as provided in paragraph (A)(6)(i) of this rule, the pharmacy must contain all dangerous drugs, hypodermics, and D.E.A. controlled substance order forms and every other item or product that requires the supervision or sale by a pharmacist.

(c) Only a licensed pharmacist may have access to keys or other methods of gaining access to the pharmacy.

(i) Keys to the pharmacy that are not in the possession of a licensed pharmacist that are maintained on-site shall be secured to prevent unauthorized access.



(ii) All combinations or access codes, including alarm codes, shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(d) All records relating to the distribution of dangerous drugs must be maintained in the pharmacy, except as follows:

(i) The board has granted permission for such records to be stored at a secure off-site location in accordance with this chapter of the Administrative Code; or

(ii) Any designated area outside the pharmacy used to store records that complies with paragraph (A)(6)(i) of this rule.

(e) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the pharmacy.

(f) Only a pharmacist may have access to the pharmacy or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, hypodermics, and any other item or product that requires the supervision or sale by a pharmacist.

(g) No prescription, dangerous drug, hypodermic, nor any other item or product that requires the supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the pharmacy is closed.

(h) New or refill prescription orders may be deposited into a secured area within the building where the pharmacy is located when a pharmacist is not present. Only a pharmacist may have access to this secured area.

(i) Any designated area outside the pharmacy at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of dangerous drugs, D.E.A. controlled substance order forms, hypodermics, and records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to this chapter of the Administrative Code, and every other item or product that requires the supervision or sale by a pharmacist shall meet the following requirements:



(i) The designated area shall be secured by an approved physical barrier with suitable locks to detect unauthorized entry. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.

(ii) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the board of pharmacy.

(iii) Authorized personnel may have access if there is supervision by a pharmacist.

(iv) No controlled substances may be stored outside of the pharmacy, except as authorized under division 4729:10 of the Administrative Code.

(j) If an outpatient pharmacy provides services by means of a drive-through facility, the drive-through facility shall be constructed and maintained in a manner, and with materials, that secures the premises of the pharmacy from unauthorized access.

(B) Refrigerators and freezers used for the storage of dangerous 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 dangerous drugs.

(C) 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.