

4729:5-9-02.2**Security, storage and control of dangerous drugs in an institutional pharmacy.**

(A) All areas of an institutional pharmacy shall be capable of being secured by key, or other effective mechanism, to prevent access by unauthorized personnel.

(1) Except as provided in paragraph (C)(5) of this rule and rule 4729:5-9-03.1 of the Administrative Code, only a licensed pharmacist may have access to keys, alarm codes, or other methods of gaining access to the pharmacy when the pharmacy is closed.

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

(3) 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.

(B) Except as provided in rules 4729:5-9-02.10 and 4729:5-9-03.1 of the Administrative Code, a pharmacist shall provide supervision of the dangerous drugs, exempt narcotics, D.E.A. controlled substance order forms, and all 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 in accordance with this chapter, at all times in order to deter and detect theft or diversion.

(C) Except as provided in rule 4729:5-9-02.10 of the Administrative Code, in the absence of a licensed pharmacist, an institutional pharmacy must be secured by either:

(1) 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.

(2) 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 (C)(1) of this rule.

- (3) Except as provided in paragraph (C)(5) of this rule and rule 4729:5-9-03.1 of the Administrative Code, only a pharmacist may have access to an institutional 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.
- (4) 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.
- (5) Any designated area located outside an institutional pharmacy at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of D.E.A. controlled substance order forms, 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, shall be secured by an physical barrier with suitable locks to detect unauthorized entry.
- (6) Dangerous drugs maintained outside of an institutional pharmacy but located on the premises of an institutional facility shall comply with the security and control requirements set forth in this chapter of the Administrative Code.
- (D) Refrigerators and freezers used for the storage of dangerous drugs by an institutional pharmacy 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 pharmacy 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 pharmacy 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.

- (E) In accordance with section 3719.172 of the Revised Code, an institutional pharmacy shall develop and implement policies to prevent hypodermics from theft or acquisition by any unauthorized person.
- (F) Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code.
- (G) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.
- (H) Disposal of controlled substance dangerous drugs shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.
- (I) 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.

Replaces: 4729-17-03  
Effective: 12/1/2021  
Five Year Review (FYR) Dates: 12/01/2026

CERTIFIED ELECTRONICALLY

---

Certification

06/29/2021

---

Date

Promulgated Under: 119.03  
Statutory Authority: 3719.28, 4729.26  
Rule Amplifies: 3719.09, 4729.28, 4729.51  
Prior Effective Dates: 09/10/1976, 09/01/1985, 07/01/1991, 01/10/1996,  
03/01/1999, 01/01/2006, 01/01/2009, 01/01/2011,  
09/01/2016