



Ohio Administrative Code

Rule 4729:5-3-14 General security requirements.

Effective: March 1, 2020

(A) All terminal distributors of dangerous drugs shall provide effective controls and procedures to:

(1) Deter and detect the theft and diversion of dangerous drugs; and

(2) Ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code.

(B) Substantial compliance with the standards set forth in this division of the Administrative Code may be deemed sufficient by the state board of pharmacy after evaluation of the overall security system and needs of the licensee or applicant. In evaluating the overall security system of a licensee or applicant, the state board of pharmacy may consider any of the following factors, as deemed relevant, for compliance with security requirements:

(1) The type of activity conducted;

(2) Type and form of dangerous drugs handled;

(3) Quantity of dangerous drugs handled;

(4) Location of the premises and the relationship such location bears on security needs;

(5) Type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) Type of vaults, safes, and secure enclosures or other storage system (e.g. automatic storage and retrieval system) used;



- (7) Type of closures on vaults, safes, and secure enclosures;
 - (8) Adequacy of key control systems and/or combination lock control systems;
 - (9) Adequacy of electronic detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;
 - (10) Extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
 - (11) Adequacy of supervision over authorized employees having access to areas containing dangerous drugs;
 - (12) Procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel; and
 - (13) Adequacy of the licensee's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of dangerous drugs in its operation.
- (C) When physical security controls become inadequate as a result of a significant increase in the quantity of dangerous drugs in the possession of the licensee during normal business operation, the physical security controls shall be expanded and extended accordingly.
- (D) Any applicant seeking to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in this division of the Administrative Code may submit any plans, blueprints, sketches, or other materials regarding the proposed security system to the state board of pharmacy.