

SECURITY REQUIREMENTS

Rule 4729-9-05 [Update effective 03/01/1999]

- (A) All registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion.
- (B) Substantial compliance with the standards set forth in rule 4729-9-11 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 applicant or registrant. In evaluating the overall security system of a registrant or applicant, the state board of pharmacy may consider any of the following factors, as they deem relevant, for strict 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 electric 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 employees having access to areas containing dangerous drugs;
 - (12) Procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;
 - (13) Availability of local police protection or of the registrant's or applicant's security personnel, and;
 - (14) Adequacy of the registrant'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 registrant during normal business operation, the physical security controls shall be expanded and extended accordingly.
- (D) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in rule 4729-9-11 of the Administrative Code may submit any plans, blueprints, sketches, or other materials regarding the proposed security system to the state board of pharmacy.
- (E) The state board of pharmacy shall be notified of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs or of any changes in operation of the registrant before being used or implemented.

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