

## **SECURITY AND CONTROL OF DANGEROUS DRUGS**

### **Rule 4729-9-11 [Update effective 10/19/2007]**

A pharmacist, prescriber, or responsible person pursuant to paragraph (C) of rule 4729-13-01 or paragraph (C) of rule 4729-14-01 of the Administrative Code, who has signed as being responsible for a terminal distributor of dangerous drugs license, shall provide "supervision and control" of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, and "adequate safeguards" to assure that dangerous drugs are being distributed in accordance with all state and federal laws as required in section 4729.55 of the Revised Code, by the following procedures:

- (A) In a pharmacy.
  - (1) Personal supervision by a pharmacist of the dangerous drugs at all times to deter and detect theft or diversion; except,
  - (2) Whenever personal supervision of the dangerous drugs is not provided by a pharmacist, physical or electronic security of the dangerous drugs must be provided according to the following requirements:
    - (a) The prescription department or stock of dangerous drugs must be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time the pharmacist is not present. Such a barrier, before being put into use, must be approved by the state board of pharmacy.
    - (b) The prescription department must contain all dangerous drugs, exempt narcotics, hypodermics, poisons, and every other item or product that requires the personal supervision or sale by a pharmacist.
    - (c) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the prescription department.
    - (d) Except as provided in rule 4729-17-03 of the Administrative Code, only a pharmacist may have access to the prescription department or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, exempt narcotics, hypodermics, poisons, and any other item or product that requires the personal supervision or sale by a pharmacist.
    - (e) No prescription, dangerous drug, exempt narcotic, hypodermic, nor any other item or product that requires the personal supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the prescription department is closed.
    - (f) 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.

- (g) If a pharmacy utilizes a board approved delivery system that securely stores and releases a dispensed prescription drug to a patient the pharmacy must be open for business and a pharmacist must be physically present and available for consultation.
- (3) Areas designated for the dispensing, compounding, and storage of dangerous drugs shall meet the security requirements in rule 4729-9-05 of the Administrative Code. No person may be within the physical confines of the area designated for the dispensing, compounding, and storage of dangerous drugs unless under the personal supervision of a pharmacist.
- (B) In other terminal distributors of dangerous drugs, including but not limited to, emergency medical services pursuant to division (C) of section 4729.54 of the Revised Code, first-aid departments pursuant to rule 4729-9-04 of the Administrative Code, approved laboratories pursuant to paragraph (A) of rule 4729-13-01 of the Administrative Code, and animal shelters pursuant to paragraph (A) of rule 4729-14-01 of the Administrative Code, dangerous drugs must be stored in an area secured by either a physical barrier with suitable locks and/or an electronic barrier to deter and detect unauthorized access.
- (C) A pharmacist, prescriber, or responsible person for a terminal distributor of dangerous drugs license pursuant to paragraph (C) of rule 4729-13-01 or paragraph (C) of rule 4729-14-01 of the Administrative Code who has signed as being responsible for a terminal distributor of dangerous drugs license is responsible to monitor for suspicious orders, unusual usage, or questionable disposition of dangerous drugs.
- (D) All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will insure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board.

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