Ohio State Board of Pharmacy - Rules Regarding Laboratories

Chapter 4729-13 Approved Laboratories Definitions

Rule update effective 7/1/94

As used in Chapter 4729-13 of the Administrative Code:

A. "Laboratory" means any establishment or place where dangerous drugs are possessed for scientific and clinical purposes and for purposes of instruction that has been approved by the state board of pharmacy.

B. "Registration numbers" means the numbers assigned to each person registered under the federal drug abuse control laws, sections 4729.52 and/or 4729.54 of the Revised Code.

C. "Responsible person" means the individual who the licensee has designated as the person who will maintain supervision and control over the possession and custody of such dangerous drugs that may be acquired and utilized by the licensee.

"D.E.A." means the federal drug enforcement administration.

OAC 4729-9-05 Security requirements

Rule update effective 3/1/99

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.

OAC 4729-9-06 Disposal of dangerous drugs which are controlled substances

Rule update effective 3/1/99

A. Any person legally authorized under Chapters 3719 and 4729 of the Revised Code to possess dangerous drugs which are controlled substances may dispose of such drugs by the following procedure:

1. If the person is a registrant or prescriber required to keep records pursuant to Chapters 3719 and 4729 of the Revised Code, the responsible pharmacist or prescriber shall send the state board of pharmacy a list of the dangerous drugs which are controlled substances containing the name and quantity to be disposed of.

2. If the person is not a registrant or prescriber, he shall submit to the state board of pharmacy a letter stating:

a. The name and address of the person possessing the dangerous drugs which are controlled substances to be disposed of;

b. The name and quantity of each controlled substance;

c. How the applicant obtained the controlled substances; and

d. The name, address, and registration number of the person who possessed the controlled substances prior to the applicant, if known.

B. The executive director shall authorize and instruct the applicant to dispose of the dangerous drugs which are controlled substances in one of the following manners:

1. By transfer to persons registered under Chapters 3719 and 4729 of the Revised Code, and authorized to possess the controlled substances;

2. By destruction in the presence of a state board of pharmacy officer, agent, or inspector or other authorized person; or

3. By such other means as the state board of pharmacy may determine to assure that the controlled substances do not become available to unauthorized persons.

C. In the event that a registrant is required regularly to dispose of dangerous drugs which are controlled substances…

OAC 4729-9-07 Procedure for discontinuing business as a wholesaler or a terminal distributor of dangerous drugs

Rule update effective 1/1/01

A. A wholesale or terminal distributor of dangerous drugs who plans to discontinue business activities shall file a written notice with the board of pharmacy. The written notice shall be submitted to the board of pharmacy in person, by verified facsimile, or by registered or certified mail, return receipt requested, at least fourteen days in advance of the proposed date of discontinuing business. This notice shall include the following information:

1. The name, address, and wholesale or terminal distributor of dangerous drugs number of the registrant discontinuing business.

2. The name, address, and wholesale or terminal distributor of dangerous drugs number to whom the dangerous drugs will be transferred.

3. The name and address of the secured location where the records of purchase and dispensing will be kept in accordance with section 4729.37 of the Revised Code. The storage of dispensing records must comply with the confidentiality requirements of rule 4729-5-29 of the Administrative Code.

4. The proposed date of discontinuing business.

B. Unless the registrant is informed by the executive director before the proposed date of discontinuing business that the transfer of dangerous drugs and records may not occur, the registrant discontinuing business may transfer the dangerous drugs and records in accordance with the following:

1. On the date of discontinuing business, a complete inventory of all controlled substances being transferred, or disposed of according to rule 4729-9-06 of the Administrative Code, shall be made. The inventory shall list the name and quantity of all controlled substances transferred or disposed of.

2. This inventory shall serve as the final inventory of the registrant discontinuing business and the initial inventory of the registrant to whom the controlled substances are being transferred. A copy of the inventory shall be included in the records of each registrant involved in the transfer.

C. Upon discontinuing business, the registrant shall return to the board of pharmacy, in person or by registered or certified mail, return receipt requested, the wholesale distributor of dangerous drugs license or the terminal distributor of dangerous drugs license for cancellation.

OAC 4729-9-11 Security and control of dangerous drugs

Rule update effective 1/1/01

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…..

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.

OAC 4729-9-12 Verification of license as a distributor of dangerous drugs or exempt status of a prescriber *Rule update effective 3/1/99*

A. Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A) of section 4729.60 of the Revised Code.

    1. The purchaser shall furnish a copy of the certificate of license as a terminal distributor to the wholesale distributor of dangerous drugs. If the certificate of license indicates a limited category I, II, or III license, the terminal distributor shall furnish the wholesale distributor a copy of the current license addendum listing those drugs the purchaser is authorized to possess.

    2. If no certificate of license as a terminal distributor is obtained or furnished before the sale, both the seller and the purchaser shall be considered to be in violation of section 4729.60 of the Revised Code.

B. Before a terminal distributor of dangerous drugs may make a purchase of dangerous drugs at wholesale, the purchaser must obtain from the seller the wholesale distributor registration number pursuant to division (B) of section 4729.60 of the Revised Code.

    1. The seller shall furnish the wholesale distributor registration number and registration expiration date to the terminal distributor of dangerous drugs.

2. If no registration number of the wholesale distributor is obtained or furnished before the purchase, both the purchaser and the seller shall be considered to be in violation of section 4729.60 of the Revised Code.

C. Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a prescriber …

OAC 4729-9-14 Records of controlled substances

Rule update effective 1/1/04

A. Each prescriber or terminal distributor of dangerous drugs shall keep a record of all controlled substances received, administered, dispensed, sold, or used.

1. Records of receipt shall contain a description of all controlled substances received, the kind and quantity of controlled substances received, the name and address of the persons from who received, and the date of receipt.

2. Records of administering, dispensing, or using controlled substances shall contain a description of the kind and quantity of the controlled substance administered, dispensed, or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the controlled substance was administered, dispensed, or used.

3. Records of drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the name and address requirements of paragraph (A)(2) of this rule.

B. Each prescriber or terminal distributor of dangerous drugs shall maintain an inventory of all controlled substances as follows:

1. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

a. The name of the substance.

b. The total quantity of the substance.

i. Each finished form (e.g., ten-milligram tablet or tenmilligram concentration per fluid ounce or milliliter).

ii. The number of units or volume of each finished form in each commercial container (e.g., one-hundred-tablet bottle or ten-milliliter vial).

iii. The number of commercial containers of each such finished form (e.g., three one-hundred-tablet bottles or ten one-milliliter vials).

c. If the substance is listed in schedule I or II, the prescriber or terminal distributor of dangerous drugs shall make an exact count or measure of the contents.

d. If the substance is listed in schedule III, IV, or V, the prescriber or terminal distributor of dangerous drugs may make an estimated count or measure of the contents, unless the container holds more than one thousand tablets or capsules in which an exact count of the contents must be made.

2. A separate inventory shall be made for each place or establishment where controlled substances are in the possession or under the control of the prescriber or terminal distributor. Each inventory for each place or establishment shall be kept at the place or establishment.

3. An inventory of all stocks of controlled substances on hand on the date the prescriber or terminal distributor first engages in the administering, dispensing, or use of controlled substances. In the event the prescriber or terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.

4. Each prescriber or terminal distributor of dangerous drugs shall take a new inventory of all stocks of controlled substances on hand every two years following the date on which the initial inventory is taken.

5. When a substance is added to the schedule of controlled substances by the federal drug enforcement administration or the state board of pharmacy, each prescriber or terminal distributor of dangerous drugs shall take an inventory of all stock of such substance on hand at that time.

6. All records of receipt, distribution, administering, dispensing, inventory, or using controlled substances shall be kept for a period of three years at the place where the controlled substances are located. Any prescriber or terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send notification to the state board of pharmacy; if not contested by the board within sixty days, it will stand as approved.

OAC 4729-9-15 Report of theft or loss of dangerous drugs, controlled substances, and drug documents

Rule update effective 3/1/99

A. Each prescriber and terminal or wholesale distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance:

1. The state board of pharmacy, by telephone immediately upon discovery of the theft or significant loss;

2. If a controlled substance, the drug enforcement administration (DEA) pursuant to section 1301.76(b), Code of Federal Regulations;

3. Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

B. Controlled substance thefts must also be reported by using the federal DEA report form whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them. A copy of the federal form regarding such theft or loss shall be filed with the state board of pharmacy within thirty days following the discovery of such theft or loss.

1. An exemption may be obtained upon sufficient cause if the federal form cannot be filed within thirty days.

2. A request for a waiver of the thirty-day limit must be requested in writing.

C. Each prescriber and terminal or wholesale distributor of dangerous drugs immediately upon discovery of any theft or loss of:

1. Uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed, shall notify the state board of pharmacy and law enforcement authorities.

2. Official written order form(s) as defined in division (U) of section 3719.01 of the Revised Code shall notify the state board of pharmacy and law enforcement authorities, and the drug enforcement administration (DEA) pursuant to section 1305.12(b), Code of Federal Regulations.

OAC 4729-9-22 Records of dangerous drugs

Rule update effective 1/1/04

Each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, distributed, sold, destroyed, or used.

A. Records of receipt shall contain a description of all dangerous drugs received, the kind and quantity of dangerous drugs received, the name and address of the persons from who received, and the date of receipt.

B. Records of administering, dispensing, or using dangerous drugs shall contain a description of the kind and quantity of the dangerous drugs administered, dispensed, sold, or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the dangerous drug was administered, dispensed, or used.

C. Records of dangerous drugs, other than controlled substances, administered, dispensed, or used which become a permanent part of the patient's medical record shall be deemed to meet the requirements of paragraph (B) of this rule.

D. All records of receipt, distribution, administering, dispensing, selling, destroying, or using dangerous drugs shall be kept for a period of three years at the place where the dangerous drugs are located. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send notification to the state board of pharmacy by certified mail, return receipt requested; if not contested by the board within sixty days, it will stand as approved. A copy of the request with the return receipt shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor.

OAC 4729-13-02 Procedure for state board of pharmacy approval as a laboratory

Rule update effective 1/1/04

A. A person, as defined in division (S) of section 4729.01 of the Revised Code, desiring to be approved by the state board of pharmacy as a laboratory shall file with the state board of pharmacy a completed application containing information relative to the qualifications for approval as set forth in rule 4729-13-03 of the Administrative Code.

B. The state board of pharmacy shall issue a terminal distributor of dangerous drugs license to purchase, possess, and utilize dangerous drugs for scientific and clinical purposes and for purposes of instruction at the establishment or place described in the application to each person who has submitted an application and has paid the required license fee if the board determines that such applicant meets the requirements set forth in this chapter.

C. All licenses issued pursuant to this rule shall be effective for a period of twelve months from the first day of January of each year. A license shall be renewed by the state board of pharmacy for a like period, annually, according to the provisions of this rule, and the standard renewal procedure of sections 4745.01 to 4745.03 of the Revised Code.

D. The fee required for issuance of the license shall be the same as that required in section 4729.54 of the Revised Code.

E. A person desiring to renew the license shall submit a completed application for such renewal and pay the required fee on or before the thirty-first day of December each year.

F. The state board of pharmacy, within thirty days after receipt of an application filed in the form and manner set forth in this rule for the issuance of a new or renewal license, shall notify the applicant whether or not such license will be issued or renewed. If the board determines that such license will not be issued or renewed, such notice to the applicant shall set forth the reason or reasons that such license will not be issued or renewed.

OAC 4729-13-03 Qualifications for a laboratory

Rule update effective 3/1/99

A laboratory to be approved by the state board of pharmacy to be entrusted with the custody and utilization of dangerous drugs and controlled substances for scientific and clinical purposes and for purposes of instruction must furnish satisfactory proof to the state board of pharmacy that:

A. The applicant is qualified to conduct the business of an approved laboratory.

B. The applicant will, on behalf of the applicant, the applicant's agents, and employees, submit to the jurisdiction of the state board of pharmacy and to the laws of this state for the purposes of the enforcement of Chapters 3719. and 4729. of the Revised Code.

C. Adequate safeguards are assured to prevent the illegal acquisition, distribution, or utilization of dangerous drugs or their diversion into illicit channels.

OAC 4729-13-04 Recordkeeping

Rule update effective 7/1/94

Each laboratory approved by the state board of pharmacy pursuant to this chapter shall keep records pursuant to paragraph (B) of rule 4729-9-14 of the Administrative Code, and as follows:

A. Each approved laboratory conducting chemical analysis with dangerous drugs or controlled substances shall maintain records with the following information for each dangerous drug or controlled substance:

1. The name.

2. The form or forms received or manufactured by the registrant (e.g., powder, granulation, tablet, capsule, or solution) and the concentration in such form (e.g., "C.P.," "U.S.P.," "N.F.," ten-milligram tablet, or ten-milligram concentration per milliliter).

3. The total number of the forms received or manufactured (e.g., one hundred tablets, thirty one-milliliter vials), including the date and quantity of each receipt or manufacture, and the name, address, and registration number, if any, of the person from whom received.

4. The quantity utilized in any manner by the laboratory including the date and manner of utilization, and the name, address, and registration numbers, if any, of each person to whom provided for utilization.

5. Destruction of controlled substances shall be conducted in accordance with rule 4729-9-06 of the Administrative Code.

6. Records relating to known or suspected controlled substances received as evidentiary material for analysis are not required under paragraph (A)(1) of this rule.

B. Each approved laboratory conducting research with dangerous drugs or controlled substances shall maintain records with the following information for each dangerous drug or controlled substance:

1. The name.

2. Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one-hundred-tablet bottle or five-milliliter vial).

3. The number of commercial containers of each such finished form received from other persons including the date of and the number of containers in each receipt

and the name, address, and registration numbers of the persons from whom the containers were received.

4. The number of units or volume of such finished dosage form or commercial containers provided. The date and name and address of the person to whom it was provided. The date and name and address of the person utilizing or administering the drug and the quantity utilized on behalf of the researcher.

5. Destruction of controlled substances shall be conducted in accordance with rule 4729-9-06 of the Administrative Code.

OAC 4729-13-05 Security controls for laboratories

Rule update effective 3/1/99

A. Areas designated for the storage of dangerous drugs shall meet the security requirements in paragraph (B) of rule 4729-9-11 of the Administrative Code.

B. Controlled substances shall be stored in a securely locked, substantially constructed cabinet.

C. Etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. government class V security container.

D. The responsible person shall notify the state board of pharmacy, law enforcement authorities, and the regional office of the drug enforcement administration in his region of the theft or significant loss of any dangerous drugs or controlled substances upon discovery of such loss or theft pursuant to rule 4729-9-15 of the Administrative Code.

OAC 4729-13-06 Responsible person for approved laboratories

Rule update effective 1/1/04

A. The responsible person whose name appears on the terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.

B. The responsible person is responsible for maintaining adequate supervision and control over the dangerous drugs and controlled substances acquired, utilized, destroyed, or administered by the approved laboratory and maintaining all records required by this chapter and federal law to be kept at the establishment or place described in the license.

C. If there is a change in the responsible person, the board of pharmacy shall be notified within thirty days thereof of the date of change and the name of the new responsible person.

   1. This notice to the board of pharmacy shall be made by completing, signing, and returning the form supplied by the board by certified mail, return receipt requested.

   2. A complete inventory of the controlled substances on hand shall be taken, pursuant to federal regulations, with the new responsible person. The new responsible person shall be responsible for this inventory.