

**WHOLESALE SALE OF DANGEROUS DRUGS**  
**(04/01/99)**

**KEY:**    **ORC** - *Ohio Revised Code*    **OAC** - *Ohio Administrative Code*

**Section 4729.01 Definitions.** (Dangerous Drug Distribution Act) [ORC: 07/22/98]

As used in this chapter [Chapter 4729. of the Ohio Revised Code]:

\* \* \*

- (F) "Dangerous drug" means any of the following:
- (1) Any drug to which either of the following applies:
    - (a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription;
    - (b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.
  - (2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;
  - (3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body.
- (G) "Federal drug abuse control laws" has the same meaning as in section 3719.01 of the Revised Code.
- (H) "Prescription" means a written, electronic, or oral order for drugs or combinations or mixtures of drugs to be used by a particular individual or for treating a particular animal, issued by a licensed health professional authorized to prescribe drugs.
- (I) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following:
- (1) A dentist licensed under Chapter 4715. of the Revised Code;
  - (2) An advanced practice nurse approved under section 4723.56 of the Revised Code to prescribe drugs and therapeutic devices;
  - (3) An optometrist licensed under Chapter 4725. of the Revised Code to practice optometry under a therapeutic pharmaceutical agents certificate;

- (4) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatry;
- (5) A veterinarian licensed under Chapter 4741. of the Revised Code.
- (J) "Sale" and "sell" include delivery, transfer, barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as principal proprietor, agent, or employee.
- (K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.
- (L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale.
- (M) "Retail seller" means any person that sells any dangerous drug to consumers without assuming control over and responsibility for its administration. Mere advice or instructions regarding administration do not constitute control or establish responsibility.
- (N) \* \* \*
- (O) "Wholesale distributor of dangerous drugs" means a person engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.
- (P) "Manufacturer of dangerous drugs" means a person, other than a pharmacist, who manufactures dangerous drugs and who is engaged in the sale of those dangerous drugs within this state.
- (Q) "Terminal distributor of dangerous drugs" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.
- (R) \* \* \*
- (S) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions.

\* \* \*

**Rule 4729-9-01 Definitions.** (Dangerous Drugs) [OAC: 03/01/99]

(Amplifies 3719.01, 3719.03, 3719.28, 4729.01, 4729.16, 4729.26, 4729.56, 4729.57, 4729.66)

- (A) "Dangerous drug," as defined in section 4729.01 of the Revised Code, means any drug or drug product whose commercial package bears a label containing the symbol "Rx only", the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Licensed Veterinarian", or any similar restrictive statement.
- (B) A dangerous drug is adulterated if beyond the expiration date as stated by the manufacturer, packer, or distributor in its labeling or if it is not stored or dispensed according to the requirement of the federal act as indicated in the product labeling.
- (C) \* \* \*

- (D) As used in Chapters 3719. and 4729. of the Revised Code, "registered" and "licensed" mean that an individual or facility has met the initial qualifications for registration and licensure with the state board of pharmacy and, if they are still actively practicing pharmacy or distributing drugs, have complied with annual renewal procedures, including payment of applicable fees.

\* \* \*

Section 3719.01 Definitions. (Controlled Substances) [ORC: 07/22/98]

As used in this chapter:

- (A) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion, or any other means to a person or an animal.
- (B) "Drug enforcement administration" means the drug enforcement administration of the United States department of justice or its successor agency.
- (C) "Controlled substance" means a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V.
- (D) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.
- (E) "Dispense" means to sell, leave with, give away, dispose of, or deliver.
- (F) "Distribute" means to deal in, ship, transport, or deliver but does not include administering or dispensing a drug.

\* \* \*

- (N) "Manufacturer" means a person who manufactures a controlled substance, as "manufacture" is defined in section 3715.01 of the Revised Code.

\* \* \*

- (Q) "Official written order" means an order written on a form provided for that purpose by the director of the United States drug enforcement administration, under any laws of the United States making provision for the order, if the order forms are authorized and required by federal law.

\* \* \*

- (T) "Person" means any individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership, association, or other legal entity.

\* \* \*

- (AA) "Sale" includes delivery, barter, exchange, transfer, or gift, or offer thereof, and each transaction of those natures made by any person, whether as principal, proprietor, agent, servant, or employee.
- (BB) "Schedule I," "schedule II," "schedule III," "schedule IV," and "schedule V" mean controlled substance schedules I, II, III, IV, and V, respectively, established pursuant to section 3719.41 of the Revised Code, as amended pursuant to section 3719.43 or 3719.44 of the Revised Code.
- (CC) "Wholesaler" means a person who, on official written orders other than prescriptions, supplies controlled substances that the person has not manufactured, produced, or prepared personally and includes a "wholesale distributor of dangerous drugs" as defined in section 4729.01 of the Revised Code.

\* \* \*

**Rule 4729-9-10 Occasional sale.** [OAC: 03/01/99]  
(Amplifies 4729.51, 4729.66)

The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a drug by a pharmacist who is a terminal distributor of dangerous drugs or is employed by a terminal distributor of dangerous drugs and the buyer shall be a wholesale distributor of dangerous drugs, a terminal distributor of dangerous drugs, or a prescriber as defined in section 4729.01 of the Revised Code.

The total value of all dangerous drugs distributed by the terminal distributor of dangerous drugs pursuant to this rule shall not exceed five per cent of the total value of dangerous drugs purchased by the terminal distributor of dangerous drugs during the same calendar year. In addition, the total amount of controlled substances sold pursuant to this rule shall not exceed the allowable amount as specified in section 1307.11 of the Code of Federal Regulations.

The value of the dangerous drugs shall be based on the cost of the dangerous drugs to the terminal distributor of dangerous drugs.

**Section 4729.51 Persons who may sell, deliver, distribute and possess dangerous drugs.**  
[ORC: 03/09/99]

- (A) No person other than a registered wholesale distributor of dangerous drugs shall possess for sale, sell, distribute, or deliver, at wholesale, dangerous drugs except as follows:
- (1) A pharmacist who is a licensed terminal distributor of dangerous drugs or who is employed by a licensed terminal distributor of dangerous drugs may make occasional sales of dangerous drugs at wholesale;
  - (2) A licensed terminal distributor of dangerous drugs having more than one establishment or place may transfer or deliver dangerous drugs from one establishment or place for which a license has been issued to the terminal distributor to another establishment or place for which a license has been issued to the terminal distributor if the license issued for each establishment or place is in effect at the time of the transfer or delivery.
- (B) (1) No registered wholesale distributor of dangerous drugs shall possess for sale, or sell, at wholesale dangerous drugs to any person other than the following:
- (a) A licensed health professional authorized to prescribe drugs;
  - (b) An optometrist licensed under Chapter 4725. of the Revised Code who holds a topical ocular pharmaceutical agents certificate;
  - (c) A registered wholesale distributor of dangerous drugs;
  - (d) A manufacturer of dangerous drugs;
  - (e) A licensed terminal distributor of dangerous drugs, subject to division (B)(2) of this section;
  - (f) Carriers or warehousemen for the purpose of carriage or storage;

- (g) Terminal or wholesale distributors of dangerous drugs who are not engaged in the sale of dangerous drugs in this state;
  - (h) An individual who holds a current license, certificate, or registration issued under Title 47 of the Revised Code and has been certified to conduct diabetes education by a national certifying body specified in rules adopted by the state board of pharmacy under section 4729.68 of the Revised Code, but only with respect to insulin that will be used for the purpose of diabetes education and only if diabetes education is within the individual's scope of practice under statutes and rules regulating the individual's profession.
- (2) No registered wholesale distributor of dangerous drugs shall possess dangerous drugs for sale at wholesale, or sell such drugs at wholesale, to a licensed terminal distributor of dangerous drugs, except to:
- (a) A terminal distributor who has a category I license, only dangerous drugs described in category I, as defined in division (A)(1) of section 4729.54 of the Revised Code;
  - (b) A terminal distributor who has a category II license, only dangerous drugs described in category II, as defined in divisions (A)(1) and (2) of section 4729.54 of the Revised Code;
  - (c) A terminal distributor who has a category III license, only dangerous drugs described in category III, as defined in divisions (A)(1), (2), and (3) of section 4729.54 of the Revised Code;
  - (d) A terminal distributor who has a limited category I, II, or III license, only the dangerous drugs specified in the certificate furnished by the terminal distributor in accordance with section 4729.60 of the Revised Code.
- (C) (1) Except as provided in division (C)(4) of this section, no person shall sell, at retail, dangerous drugs.
- (2) Except as provided in division (C)(4) of this section, no person shall possess for sale, at retail, dangerous drugs.
- (3) Except as provided in division (C)(4) of this section, no person shall possess dangerous drugs.
- (4) Divisions (C)(1), (2), and (3) of this section do not apply to a registered wholesale distributor of dangerous drugs, a licensed terminal distributor of dangerous drugs, or a person who possesses, or possesses for sale or sells, at retail, a dangerous drug in accordance with Chapters 3719., 4715., 4729., 4731., and 4741. or section 4723.56 of the Revised Code.
- Divisions (C)(1), (2), and (3) of this section do not apply to an individual who holds a current license, certificate, or registration issued under Title 47 of the Revised Code and has been certified to conduct diabetes education by a national certifying body specified in rules adopted by the state board of pharmacy under section 4729.68 of the Revised Code, but only to the extent that the individual possesses insulin or personally supplies insulin solely for the purpose of diabetes education and only if diabetes education is within the individual's scope of practice under statutes and rules regulating the individual's profession.
- (D) No licensed terminal distributor of dangerous drugs shall purchase for the purpose of resale dangerous drugs from any person other than a registered wholesale distributor of dangerous drugs, except as follows:
- (1) A licensed terminal distributor of dangerous drugs may make occasional purchases of dangerous drugs for resale from a pharmacist who is a licensed terminal distributor of dangerous drugs or who is employed by a licensed terminal distributor of dangerous drugs;

- (2) A licensed terminal distributor of dangerous drugs having more than one establishment or place may transfer or receive dangerous drugs from one establishment or place for which a license has been issued to the terminal distributor to another establishment or place for which a license has been issued to the terminal distributor if the license issued for each establishment or place is in effect at the time of the transfer or receipt.
- (E) No licensed terminal distributor of dangerous drugs shall engage in the sale or other distribution of dangerous drugs at retail or maintain possession, custody, or control of dangerous drugs for any purpose other than the distributor's personal use or consumption, at any establishment or place other than that or those described in the license issued by the board of pharmacy to such terminal distributor.

\* \* \*

**Rule 4729-9-24 Retail and wholesale sales of dangerous drugs on-line.** [OAC: 03/01/99]  
(Amplifies 3715.69, 3719.04, 3719.05, 3719.28, 4729.26, 4729.51, 4729.551, 4729.66)

- (A) All persons selling or offering to sell dangerous drugs at retail or wholesale in Ohio must be licensed or registered with the Ohio state board of pharmacy as a dangerous drug distributor.
- (B) All dangerous drug distributors registered or licensed with the Ohio state board of pharmacy and who sell or offer to sell dangerous drugs at retail or wholesale on the "Internet" to persons located in Ohio or any other state must make such sales only in compliance with all state and federal laws governing the legal distribution of dangerous drugs.
- (C) "Internet" sites owned and/or maintained by Ohio registered or licensed dangerous drug distributors must provide the following information to the public on the "Internet" site and no drugs are to be shipped at wholesale or retail except in accordance with Ohio's drug laws:
  - (1) Name dangerous drug distributor is licensed to do business as in Ohio.
  - (2) Full address of licensed or registered site.
  - (3) Name of responsible person as it appears on the dangerous drug distributor license.
  - (4) Telephone number where responsible person may be contacted.
  - (5) A list of the states in which the dangerous drug distributor may legally sell prescription drugs at wholesale or retail.
  - (6) The name, address, and how the drug law enforcement agency may be contacted in each state in which the person is authorized to do business. This may include a link to the drug law enforcement agency's "Internet" site and/or their e-mail address.
- (D) Any Ohio licensed or registered dangerous drug distributor requesting personal information from the public by way of the "Internet" site (questionnaire forms or e-mail) must provide for security and confidentiality of the information. This portion of the "Internet" site must also provide information regarding how the personal information will be used and ensure that such information is not used for purposes not disclosed without the written informed consent of the patient or person submitting personal information.

**Section 3719.09 Authorized possession of controlled substances.** [ORC: 07/22/98]

Possession or control of controlled substances is authorized in the following instances and subject to the following conditions:

- (A) Possession of controlled substances in the course of business by a manufacturer, wholesaler, licensed health professional authorized to prescribe drugs, pharmacist, category III terminal distributor of dangerous drugs, or other person authorized to possess controlled substances under this chapter or Chapter 4729. of the Revised Code;
- (B) Possession by any person of any schedule V narcotic drug exempted under section 3719.15 of the Revised Code, where the quantity of the drug does not exceed one hundred thirty milligrams of opium, thirty-two and five-tenths milligrams of morphine or any of its salts, two hundred sixty milligrams of codeine or any of its salts, one hundred thirty milligrams of dihydrocodeine, or any of its salts, or thirty-two and five-tenths of ethylmorphine or any of its salts, or, in the case of any other schedule V controlled substance or any combination of narcotic drugs, where the quantity does not exceed in pharmacologic potency any one of the drugs named above in the quantity stated;
- (C) Possession by any person of any controlled substance that the person obtained pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs or that was obtained for the person pursuant to a prescription issued by a prescriber, when the drug is in a container regardless of whether the container is the original container in which the drug was dispensed to that person directly or indirectly by a pharmacist or personally furnished to that person by the prescriber;
- (D) Possession in the course of business of combination drugs that contain pentobarbital and at least one noncontrolled substance active ingredient, in a manufactured dosage form, the only indication of which is for euthanizing animals, or other substance that the state veterinary medical licensing board and the state board of pharmacy both approve under division (A) of section 4729.532 of the Revised Code, by an agent or employee of an animal shelter who is authorized by the licensure of the animal shelter with the state board of pharmacy to purchase and possess the drug solely for use as specified in that section. As used in this division, "in the course of business" means possession or use at an establishment described in a license issued under section 4729.54 of the Revised Code, or outside that establishment when necessary because of a risk to the health or safety of any person, provided that the substance is in a quantity no greater than reasonably could be used to alleviate the risk, is in the original manufacturer's container, and is returned to the establishment as soon as possible after the risk has passed.

**Section 3719.14 Exemptions.** [ORC: 07/01/96]

- (A) A common carrier or warehouse while engaged in lawfully transporting or storing any controlled substance or an employee of a common carrier or warehouse of that nature who is acting within the scope of the employee's employment may control and possess any controlled substance.

\* \* \*

**Section 3719.04 Regulations for sale by manufacturer or wholesaler; official written orders.**  
[ORC: 06/29/94]

- (A) A licensed manufacturer or wholesaler of controlled substances may sell at wholesale controlled substances to any of the following persons and subject to the following conditions:
  - (1) To a licensed manufacturer or wholesaler of controlled substances, or a terminal distributor of dangerous drugs having a category III license;

- (2) To a person in the employ of the United States government or of any state, territorial, district, county, municipal, or insular government, purchasing, receiving, possessing, or dispensing controlled substances by reason of his official duties;
  - (3) To a master of a ship or a person in charge of any aircraft upon which no physician is regularly employed for the actual medical needs of persons on board the ship or aircraft, when not in port; provided such controlled substances shall be sold to the master of the ship or person in charge of the aircraft only in pursuance of a special official written order approved by a commissioned medical officer or acting assistant surgeon of the United States public health service;
  - (4) To a person in a foreign country, if the federal drug abuse control laws are complied with.
- (B) An official written order for any schedule II controlled substances shall be signed in triplicate by the person giving the order or by his authorized agent. The original shall be presented to the person who sells or dispenses the schedule II controlled substances named in the order and, if that person accepts the order, each party to the transaction shall preserve his copy of the order for a period of two years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of Chapter 3719. of the Revised Code. Compliance with the federal drug abuse control laws, respecting the requirements governing the use of a special official written order constitutes compliance with this division.

**Section 3719.81 Illegal use and distribution of drug samples; exceptions.** [ORC: 07/22/98]

- (A) A person may furnish another a sample of any drug of abuse, or of any drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, if all of the following apply:
- (1) The sample is furnished by a manufacturer, manufacturer's representative, or wholesale dealer in pharmaceuticals to a licensed health professional authorized to prescribe drugs, or is furnished by such a professional to a patient for use as medication;
  - (2) The drug is in the original container in which it was placed by the manufacturer, and the container is plainly marked as a sample;
  - (3) Prior to its being furnished, the drug sample has been stored under the proper conditions to prevent its deterioration or contamination;
  - (4) If the drug is of a type which deteriorates with time, the sample container is plainly marked with the date beyond which the drug sample is unsafe to use, and the date has not expired on the sample furnished. Compliance with the labeling requirements of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, shall be deemed compliance with this section.
  - (5) The drug is distributed, stored, or discarded in such a way that the drug sample may not be acquired or used by any unauthorized person, or by any person, including a child, for whom it may present a health or safety hazard.
- (B) Division (A) of this section does not do any of the following:
- (1) Apply to or restrict the furnishing of any sample of a nonnarcotic substance if the substance may, under the "Federal Food, Drug, and Cosmetic Act" and under the laws of this state, otherwise be lawfully sold over the counter without a prescription;
  - (2) Authorize an advanced practice nurse to furnish a sample of any drug;

- (3) Authorize an optometrist to furnish a sample of a drug that is not a drug the optometrist is authorized to prescribe.
- (C) The state board of pharmacy shall, in accordance with Chapter 119. of the Revised Code, adopt rules as necessary to give effect to this section.

**Rule 4729-9-13 Distributor of dangerous drug samples.** [OAC: 03/01/99]  
(Amplifies 3719.81)

No manufacturer, manufacturer's representative or wholesale dealer in pharmaceuticals may furnish a sample of a drug of abuse as defined in section 3719.011 of the Revised Code to a prescriber unless requested by the prescriber and unless the company is registered as a wholesale distributor of dangerous drugs and maintains a record of such distribution which will be available to the state board of pharmacy.

**Section 3719.31 Prohibition against careless distribution of samples containing drug or poison.**  
[ORC: 10/01/53]

No person shall leave, throw, or deposit upon the doorstep or premises owned or occupied by another, or hand, give, or deliver to any person, except in a place where it is kept for sale, a patent or proprietary medicine, preparation, pill, tablet, powder, cosmetic, disinfectant, or antiseptic, or a drug or medicine that contains poison or any ingredient that is deleterious to health, as a sample or for the purpose of advertising.

As used in this section "drug," "medicine," "patent or proprietary medicine," "pill," "tablet," "powder," "cosmetic," "disinfectant," or "antiseptic" includes all remedies for internal or external use.

**Section 4729.52 Registration as wholesale distributor; fees.** [ORC: 07/22/98]

- (A) A person desiring to be registered as a wholesale distributor of dangerous drugs shall file with the executive director of the state board of pharmacy a verified application containing such information as the board requires of the applicant relative to the qualifications to be registered as a wholesale distributor of dangerous drugs set forth in section 4729.53 of the Revised Code and the rules adopted under that section. The board shall register as a wholesale distributor of dangerous drugs each applicant who has paid the required registration fee, if the board determines that the applicant meets the qualifications to be registered as a wholesale distributor of dangerous drugs set forth in section 4729.53 of the Revised Code and the rules adopted under that section.
- (B) The board may register and issue to a person who does not reside in this state a registration certificate as a wholesale distributor of dangerous drugs if the person possesses a current and valid wholesale distributor of dangerous drugs registration certificate or license issued by another state that has qualifications for licensure or registration comparable to the registration requirements in this state and pays the required registration fee.
- (C) All registration certificates issued pursuant to this section are effective for a period of twelve months from the first day of July of each year. A registration certificate shall be renewed annually by the board for a like period, pursuant to this section and the standard renewal procedure of Chapter 4745. of the Revised Code. A person desiring to renew a registration certificate shall submit an application for renewal and pay the required renewal fee before the first day of July each year.
- (D) Each registration certificate and its application shall describe not more than one establishment or place where the registrant or applicant may engage in the sale of dangerous drugs at wholesale.

No registration certificate shall authorize or permit the wholesale distributor of dangerous drugs named therein to engage in the sale of drugs at wholesale or to maintain possession, custody, or control of dangerous drugs for any purpose other than for the registrant's own use and consumption at any establishment or place other than that described in the certificate.

- (E) (1) The registration fee is one hundred fifty dollars and shall accompany each application for registration. The registration renewal fee is one hundred fifty dollars and shall accompany each renewal application. A registration certificate that has not been renewed in any year by the first day of August may be reinstated upon payment of the renewal fee and a penalty of fifty-five dollars.
- (2) Renewal fees and penalties assessed under division (E)(1) of this section shall not be returned if the applicant fails to qualify for renewal.
- (F) The registration of any person as a wholesale distributor of dangerous drugs subjects the person and the person's agents and employees to the jurisdiction of the board and to the laws of this state for the purpose of the enforcement of this chapter and the rules of the board. However, the filing of an application for registration as a wholesale distributor of dangerous drugs by, or on behalf of, any person or the registration of any person as a wholesale distributor of dangerous drugs shall not, of itself, constitute evidence that the person is doing business within this state.

**Section 4729.53 Qualifications of wholesale distributor; statutory agent.** [ORC: 07/01/92]

- (A) The board of pharmacy shall not register any person as a wholesale distributor of dangerous drugs unless the applicant for registration furnishes satisfactory proof to the board of pharmacy that he meets all of the following:
  - (1) That if the applicant has been convicted of a violation of any federal, state, or local law relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances or of a felony, or if a federal, state, or local governmental entity has suspended or revoked any current or prior license or registration of the applicant for the manufacture or sale of any dangerous drugs, including controlled substances, the applicant, to the satisfaction of the board, assures that he has in place adequate safeguards to prevent the recurrence of any such violations.
  - (2) The applicant's past experience in the manufacture or distribution of dangerous drugs, including controlled substances, is acceptable to the board.
  - (3) The applicant is equipped as to land, buildings, equipment, and personnel to properly carry on the business of a wholesale distributor of dangerous drugs, including providing adequate security for and proper storage conditions and handling for dangerous drugs, and is complying with the requirements under this chapter and the rules adopted pursuant thereto for maintaining and making available records to properly identified board officials and federal, state, and local law enforcement agencies.
  - (4) Personnel employed by the applicant have the appropriate education or experience, as determined by the board, to assume responsibility for positions related to compliance with this chapter and the rules adopted pursuant thereto.
  - (5) The applicant has designated the name and address of a person to whom communications from the board may be directed and upon whom the notices and citations provided for in section 4729.56 of the Revised Code may be served.
  - (6) Adequate safeguards are assured to prevent the sale of dangerous drugs to any person other than those named in division (B) of section 4729.51 of the Revised Code.

- (7) Any other requirement or qualification the board, by rule adopted in accordance with Chapter 119. of the Revised Code, considers relevant to and consistent with the public safety and health.
- (B) The board may refuse to register or renew the registration certificate of any person if the board determines that the granting of the registration certificate or its renewal is not in the public interest.

**Rule 4729-9-08 Change in description of terminal or wholesale dangerous drug facility.**

[OAC: 02/01/98]

(Amplifies 4729.51, 4729.52, 4729.54, 4729.66)

For the purpose of division (E) of section 4729.51 and division (D) of section 4729.52 of the Revised Code, any change in the ownership, business or trade name, or address of a terminal or wholesale distributor of dangerous drugs requires a new application and license.

**Rule 4729-9-16 Minimum requirements for wholesalers.** [OAC: 03/01/99]

(Amplifies 3719.03, 3719.28, 4729.53, 4729.66)

The following minimum requirements shall apply to all persons distributing dangerous drugs at wholesale in Ohio.

- (A) The following information shall be required on a form supplied by the state board of pharmacy from each person making application for a license as a wholesale distributor of dangerous drugs:
  - (1) The name, full business address (not a post office box), and telephone number;
  - (2) All trade or business names used by the licensee, any trade or business names under which licensee was previously or is presently licensed;
  - (3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of dangerous drugs;
  - (4) The type of ownership or operation (i.e., sole proprietorship, partnership, corporation, or government agency);
  - (5) The name(s) of the owner and/or operator of the licensee, including:
    - (a) If a sole proprietorship, the full name of the sole proprietor, and the name of the business entity;
    - (b) If a partnership, the name of each partner, and the name of the partnership;
    - (c) If a corporation, the name and title of each corporate officer and director, the corporate names, the name of the state of incorporation, the corporation number, and a copy of the corporation papers;
    - (d) If a government agency, the name of the agency, and the name of each officer and director of the agency.
  - (6) If the entity making application for a wholesale distributor of dangerous drugs license is located outside the boundaries of the state of Ohio, part of the licensing process shall be an inquiry to the licensing authority of the state in which that entity is located. This inquiry will determine whether the entity possesses a current and valid license to distribute dangerous drugs in that state and the experience the licensing authority has had with the entity. This

information will be used as part of the consideration in licensing the entity by the Ohio state board of pharmacy. The Ohio board will respond to inquiries of a similar nature from other states about licensees in Ohio.

- (B) Prior to the end of the licensing period a renewal application, requesting such information as the state board of pharmacy may require, will be sent to the address of record to the attention of the responsible person. Such renewal application form shall be completed and returned with the applicable fee on or before the established deadline.
- (C) All facilities where dangerous drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:
  - (1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
  - (2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
  - (3) Have a quarantine area for storage of dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened. Such drugs shall be stored no longer than two years pursuant to rule 4729-9-17 of the Administrative Code;
  - (4) Be maintained in a clean and orderly condition;
  - (5) Be free from infestation by insects, rodents, birds, or vermin of any kind.
- (D) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
  - (1) Access from outside the premises shall be kept to a minimum and be well controlled.
  - (2) The outside perimeter of the premises shall be well lighted.
  - (3) Entry into areas where dangerous drugs are held shall be limited to authorized personnel.
  - (4) All facilities where dangerous drugs are held shall be equipped with a state board of pharmacy approved alarm system to detect unauthorized entry after hours.
  - (5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (E) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).
  - (1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
  - (2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.

- (3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all stored drugs.
- (F) All shipments of dangerous drugs shall be examined in accordance with the following:
- (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;
  - (2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions;
  - (3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all incoming and outgoing dangerous drugs.
- (G) All returned, damaged, and outdated dangerous drugs shall be handled in the following manner:
- (1) Dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to their supplier.
  - (2) Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.
  - (3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.
  - (4) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated dangerous drugs.
- (H) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.
- (1) These records shall include but not be limited to the following information:
    - (a) The source of the drugs, including the name and principle address of the seller or transferor, and the address of the location from which the drugs were shipped.
    - (b) The identity and quantity of the drugs received and distributed or disposed of.
    - (c) The dates of receipt and distribution of the drugs.
    - (d) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized by division (B) of section 4729.51 of the Revised Code.

- (e) A system of procedures shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse.
  - (i) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs, as described in paragraph (H)(1)(e) of this rule, when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.
  - (ii) Reports, generated by the system as described in paragraph (H)(1)(e) of this rule, shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.
- (2) Inventories and records shall be made available for inspection and photocopying by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.
- (3) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.
  - (a) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials.
  - (b) Wholesalers intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must first send notification to the board.
- (l) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:
  - (1) A procedure whereby the oldest approved stock of a dangerous drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.
  - (2) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:
    - (a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;
    - (b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;
    - (c) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

- (3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
- (4) A procedure to ensure that any outdated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated dangerous drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.
- (J) Wholesale distributors of dangerous drugs shall establish and maintain accurate and current lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
- (K) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.
- (L) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
  - (1) Wholesale drug distributors shall permit properly identified and authorized state board of pharmacy designated agents, federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures at reasonable times and in a reasonable manner, to the extent authorized by law.
  - (2) Any entity making a wholesale sale of a controlled substance shall be required to possess a license as a wholesale distributor of dangerous drugs and a license as a wholesaler or manufacturer of controlled substances, except that a licensed terminal distributor of dangerous drugs may make an occasional sale of a controlled substance pursuant to rule 4729-9-10 of the Administrative Code.
- (M) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

**Section 3719.02 Manufacturer of controlled substances; license; fee.** [ORC: 06/30/97]

A person may cultivate, grow, or by other process produce or manufacture, and a person on land owned, occupied, or controlled by such person may knowingly allow to be cultivated, grown, or produced, any controlled substance if the person first obtains a license as a manufacturer of controlled substances from the state board of pharmacy.

All licenses issued pursuant to this section shall be for a period of one year from the last day of June and may be renewed for a like period annually according to the standard renewal procedure of sections 4745.01 to 4745.03 of the Revised Code.

The annual license fee shall be thirty-seven dollars and fifty cents and shall accompany each application for a license or renewal thereof. A license that has not been renewed by the first day of August in any year may be reinstated upon payment of the renewal fee and a penalty of fifty-five dollars.

\* \* \*

Section 3719.021 **Wholesaler of controlled substances; license; fee.** [ORC: 06/30/97]

Persons other than a licensed manufacturer, pharmacist, or owner of a pharmacy who possess for sale, sell, or dispense controlled substances at wholesale shall first obtain a license as a wholesaler of controlled substances from the state board of pharmacy.

All licenses issued pursuant to this section shall be for a period of one year from the thirtieth day of June and may be renewed for a like period annually according to the standard renewal procedure of sections 4745.01 to 4745.03 of the Revised Code.

The annual license fee shall be thirty-seven dollars and fifty cents and shall accompany each application for such license or renewal thereof. All such renewal fees shall be paid in advance by the renewal applicant to the treasurer of state, and entered by the treasurer of state on the records of the state board of pharmacy. A license that has not been renewed by the first day of August in any year may be reinstated upon payment of the renewal fee and a penalty of fifty-five dollars.

\* \* \*

Section 3719.03 **Qualifications of applicant; revocation.** [ORC: 07/01/76]

No license shall be issued under section 3719.02 or 3719.021 of the Revised Code unless and until the applicant therefor has furnished proof satisfactory to the state board of pharmacy:

- (A) That the applicant is of good moral character or, if the applicant be an association or corporation, that the managing officers are of good moral character;
- (B) That the applicant is equipped as to land, buildings, and paraphernalia properly to carry on the business described in his application;
- (C) That the applicant's trade connections are such that there is a reasonable probability that he will apply all controlled substances grown, cultivated, processed, produced, or possessed by him to scientific, experimental, medicinal, or instructive purposes;
- (D) That the applicant is in sufficiently good financial condition to carry out his obligation;
- (E) That the applicant has satisfactorily shown that the granting of such license is in the public interest.

No license shall be granted to any person who has, within five years, been convicted of a drug abuse offense as defined in section 3719.01 of the Revised Code, or to any person who is a drug dependent person.

The board may suspend or revoke, for cause, any license issued under section 3719.02 or 3719.021 of the Revised Code.

Rule 4729-9-19 **Violations as evidence for denial of terminal, wholesale, or manufacturer license.** [OAC: 03/01/99]

(Amplifies 3719.03, 3719.28, 4729.53, 4729.55, 4729.66)

- (A) The state board of pharmacy may consider as evidence of a person not meeting the requirements provided in sections 4729.53 and 4729.55 of the Revised Code, and may deny a person registration as a wholesale distributor of dangerous drugs or licensure as a terminal distributor of dangerous drugs in Ohio if such person:
  - (1) Has been convicted of a felony;

- (2) Has been convicted of violating any state or federal pharmacy or drug law;
  - (3) Is not of good moral character and habits;
  - (4) Is addicted to or abusing liquor or drugs;
  - (5) Has been disciplined by the Ohio state board of pharmacy pursuant to section 4729.16 of the Revised Code; or
  - (6) Has been disciplined by any board of pharmacy.
- (B) When a request for licensure as a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or as a wholesaler or manufacturer of controlled substances is made, the state board of pharmacy may consider as evidence of the facility not meeting the requirements for licensure as provided in Chapters 3719. and 4729. of the Revised Code, or may deny issuance of such licensure, if:
- (1) The ownership of such facility, or pharmacy previously located in such facility, has been transferred from a licensee whose license has been revoked by the state board of pharmacy to the spouse or other family member;
  - (2) The ownership of such facility, or pharmacy previously located in such facility, has been transferred from a licensee whose license has been revoked by the state board of pharmacy to another who employs the former owner or who allows the former owner to be present within the physical confines of the location to be licensed.
  - (3) The facility knowingly employs a person who has been denied the right to work in such a facility by the state board of pharmacy as part of an official order of the board.

**Section 4729.56 Revocation of license of wholesale distributor; monetary penalty.** [ORC: 07/01/92]

- (A) In accordance with Chapter 119. of the Revised Code, the board of pharmacy may suspend, revoke, or refuse to renew any registration certificate issued to a wholesale distributor of dangerous drugs pursuant to section 4729.52 of the Revised Code or may impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or one thousand dollars if the acts committed are not classified as an offense by the Revised Code for any of the following causes:
- (1) Making any false material statements in an application for registration as a wholesale distributor of dangerous drugs;
  - (2) Violating any federal, state, or local drug law; any provision of this chapter or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the board;
  - (3) A conviction of a felony;
  - (4) Ceasing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the board.
- (B) Upon the suspension or revocation of the registration certificate of any wholesale distributor of dangerous drugs, the distributor shall immediately surrender his registration certificate to the board.

- (C) If the board suspends, revokes, or refuses to renew any registration certificate issued to a wholesale distributor of dangerous drugs and determines that there is clear and convincing evidence of a danger of immediate and serious harm to any person, the board may place under seal all dangerous drugs owned by or in the possession, custody, or control of the affected wholesale distributor of dangerous drugs. Except as provided in this division, the board shall not dispose of the dangerous drugs sealed under this division until the wholesale distributor of dangerous drugs exhausts all of his appeal rights under Chapter 119. of the Revised Code. The court involved in such an appeal may order the board, during the pendency of the appeal, to sell sealed dangerous drugs that are perishable. The board shall deposit the proceeds of the sale with the court.

**Section 3719.12 Procedure upon conviction; suspension or revocation of license or registration.**  
[ORC: 07/22/98]

Unless a report has been made pursuant to section 2929.24 of the Revised Code, on the conviction of a manufacturer, wholesaler, terminal distributor of dangerous drugs, pharmacist, pharmacy intern, dentist, doctor of medicine or osteopathic medicine, podiatrist, registered nurse, licensed practical nurse, physician assistant, optometrist, or veterinarian of the violation of this chapter or Chapter 2925. of the Revised Code, the prosecutor in the case promptly shall report the conviction to the board that licensed, certified, or registered the person to practice or to carry on business. The responsible board shall provide forms to the prosecutor. Within thirty days of the receipt of this information, the board shall initiate action in accordance with Chapter 119. of the Revised Code to determine whether to suspend or revoke the person's license, certificate, or registration.

**Section 3719.121 Suspension of licenses or registrations of addicts.** [ORC: 07/22/98]

- (A) Except as otherwise provided in section 4723.28, 4723.35, 4730.25, or 4731.22 of the Revised Code, the license, certificate, or registration of any dentist, doctor of medicine or osteopathic medicine, podiatrist, registered nurse, licensed practical nurse, physician assistant, pharmacist, pharmacy intern, optometrist, or veterinarian who is or becomes addicted to the use of controlled substances shall be suspended by the board that authorized the person's license, certificate, or registration until the person offers satisfactory proof to the board that the person no longer is addicted to the use of controlled substances.
- (B) If the board under which a person has been issued a license, certificate, or evidence of registration determines that there is clear and convincing evidence that continuation of the person's professional practice or method of prescribing or personally furnishing controlled substances presents a danger of immediate and serious harm to others, the board may suspend the person's license, certificate, or registration without a hearing. Except as otherwise provided in sections 4715.30, 4723.281, 4730.25, and 4731.22 of the Revised Code, the board shall follow the procedure for suspension without a prior hearing in section 119.07 of the Revised Code. The suspension shall remain in effect, unless removed by the board, until the board's final adjudication order becomes effective, except that if the board does not issue its final adjudication order within ninety days after the hearing, the suspension shall be void on the ninety-first day after the hearing.
- (C) On receiving notification pursuant to section 2929.24 or 3719.12 of the Revised Code, the board under which a person has been issued a license, certificate, or evidence of registration immediately shall suspend the license, certificate, or registration of that person on a plea of guilty to, a finding by a jury or court of the person's guilt of, or conviction of a felony drug abuse offense; a finding by a court of the person's eligibility for treatment in lieu of conviction; a plea of guilty to, or a finding by a jury or court of the person's guilt of, or the person's conviction of an offense in another jurisdiction that is essentially the same as a felony drug abuse offense; or a finding by a court of the person's eligibility for treatment in lieu of conviction in another jurisdiction. The board shall notify the holder of the license, certificate, or registration of the suspension, which shall remain in effect until the board holds an adjudicatory hearing under Chapter 119. of the Revised Code.

**Section 4729.54 Categories of licenses of terminal distributors of dangerous drugs; applications; authority; fees; requirements upon licensure. [ORC: 07/22/98]**

(A) As used in this section:

- (1) "Category I" means single dose injections of intravenous fluids, including saline, Ringer's lactate, five per cent dextrose and distilled water, and other intravenous fluids or parenteral solutions included in this category by rule of the board of pharmacy, that have a volume of one hundred milliliters or more and that contain no added substances, or single-dose injections of epinephrine to be administered pursuant to sections 4765.38 and 4765.39 of the Revised Code.
- (2) "Category II" means any dangerous drug that is not included in category I or III.
- (3) "Category III" means any controlled substance that is contained in schedule I, II, III, IV, or V.
- (4) "Emergency medical service organization" has the same meaning as in section 4765.01 of the Revised Code.
- (5) "Person" includes an emergency medical service organization.
- (6) "Schedule I, schedule II, schedule III, schedule IV, and schedule V" mean controlled substance schedules I, II, III, IV, and V, respectively, as established pursuant to section 3719.41 of the Revised Code and as amended.

\* \* \*

(E) There shall be six categories of terminal distributor of dangerous drugs licenses, which categories shall be as follows:

- (1) Category I license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category I.
- (2) Limited category I license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category I that were listed in the application for licensure.
- (3) Category II license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category I and category II.
- (4) Limited category II license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category I or category II that were listed in the application for licensure.
- (5) Category III license. A person who obtains this license may possess, have custody or control of, and distribute the dangerous drugs described in category I, category II, and category III.
- (6) Limited category III license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category I, category II, or category III that were listed in the application for licensure.

\* \* \*

(I) All licenses issued pursuant to this section 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 board for a like period, annually, according to the provisions of this section, and the standard renewal procedure of

Chapter 4745. of the Revised Code. A person who desires to renew a license shall submit an application for renewal and pay the required fee on or before the thirty-first day of December each year. The fee required for the renewal of a license shall be the same as the fee paid for the license being renewed, and shall accompany the application for renewal.

\* \* \*

(J) \* \* \*

- (3) No licensed terminal distributor of dangerous drugs shall possess, have custody or control of, or distribute dangerous drugs that the terminal distributor is not entitled to possess, have custody or control of, or distribute by virtue of its category of licensure.

\* \* \*

**Section 4729.60 Certificate required by wholesale distributor.** [ORC: 03/09/99]

- (A) Before a registered wholesale distributor of dangerous drugs may sell dangerous drugs at wholesale to any person, other than the persons specified in divisions (B)(1)(a) to (d) and (B)(1)(f) to (h) of Section 4729.51 of the Revised Code, such wholesale distributor shall obtain from the purchaser and the purchaser shall furnish to the wholesale distributor a certificate indicating that the purchaser is a licensed terminal distributor of dangerous drugs. The certificate shall be in the form that the state board of pharmacy shall prescribe, and shall set forth the name of the licensee, the number of the license, a description of the place or establishment or each place or establishment for which the license was issued, the category of licensure, and, if the license is a limited category I, II, or III license, the dangerous drugs that the licensee is authorized to possess, have custody or control of, and distribute.

If no certificate is obtained or furnished before a sale is made, it shall be presumed that the sale of dangerous drugs by the wholesale distributor is in violation of division (B) of section 4729.51 of the Revised Code and the purchase of dangerous drugs by the purchaser is in violation of division (C) of section 4729.51 of the Revised Code. If a registered wholesale distributor of dangerous drugs obtains or is furnished a certificate form a terminal distributor of dangerous drugs and relies on the certificate in selling dangerous drugs at wholesale to the terminal distributor of dangerous drugs, the wholesale distributor of dangerous drugs shall be deemed not to have violated division (B) of section 4729.51 of the Revised Code in making the sale.

- (B) Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall obtain from the seller and the seller shall furnish to the terminal distributor the number of the seller's registration certificate to engage in the sale of dangerous drugs at wholesale.

If no registration number is obtained or furnished before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of division (D) of section 4729.51 of the Revised Code and the sale of dangerous drugs by the seller is in violation of division (A) of section 4729.51 of the Revised Code. If a licensed terminal distributor of dangerous drugs obtains or is furnished a registration number from a wholesale distributor of dangerous drugs and relies on the registration number in purchasing dangerous drugs at wholesale from the wholesale distributor of dangerous drugs, the terminal distributor shall be deemed not to have violated division (D) of section 4729.51 of the Revised Code in making the purchase.

**Rule 4729-9-12 Verification of license as a distributor of dangerous drugs or exempt status of a prescriber.** [OAC: 03/01/99]

(Amplifies 3719.04, 3719.28, 4729.51, 4729.60, 4729.66)

- (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 as defined in division (I) of section 4729.01 of the Revised Code, the wholesale distributor must obtain:
- (1) A copy of the current certificate of license as a terminal distributor from the prescriber pursuant to division (A) of section 4729.60 of the Revised Code and, if the license is limited, a copy of the addendum listing the drugs the licensee is authorized to purchase and possess; or
  - (2) Copies of all documents required to establish that the prescriber is exempt from licensure as a terminal distributor of dangerous drugs and is authorized by federal and state laws to purchase the dangerous drugs for use in the course of his/her professional practice. The required documents are as follows:
    - (a) An individual prescriber doing business as a sole proprietor (not incorporated in any manner) must provide a copy of his/her current license to practice and the license must authorize the use of the drugs requested from the wholesaler in his/her practice;
    - (b) The address of all sites of practice where the drugs will be delivered to and stored for use by the prescriber in his/her professional practice pursuant to federal and state laws;
    - (c) Verification from the licensing board that the prescriber's license is in good standing and that there are no restrictions on his/her license to practice and use drugs in his/her practice. If the license has been restricted by the licensing board, a copy of the official documents restricting the license to practice and use drugs in the course of professional practice must be furnished to the wholesaler and maintained by the wholesaler with all other documents establishing the prescriber's exemption from licensure as a terminal distributor of dangerous drugs;

- (d) If an exempted prescriber wishes to purchase and possess dangerous drugs which are also controlled substances, the prescriber must submit a copy of his/her current registration with the federal drug enforcement administration and provide verification that the DEA registration and authority to use controlled substances in the course of professional practice has not been restricted by the appropriate professional licensing board or the federal drug enforcement administration.
- (D) Dangerous drugs may not be shipped by a wholesale distributor of dangerous drugs to any address other than those listed by the business entity meeting the definition of a prescriber and filed with the wholesale distributor in paragraph (B) of this rule. Controlled substances may only be shipped to those addresses registered with the federal drug enforcement administration for the purpose of storing controlled substances.
- (E) All documents establishing the fact that a prescriber is exempt from licensure as a terminal distributor of dangerous drugs shall be current and maintained for a period of three years by the wholesale distributor of dangerous drugs.
- (F) Copies of licenses to practice and verification that there are no restrictions on a prescriber's license by either the appropriate professional licensing board or the federal drug enforcement administration shall be obtained within fifteen days of the date of renewal of such licenses. No dangerous drugs may be sold and delivered to a prescriber until the required documentation has been obtained by the wholesale distributor.
- (G) Each wholesale distributor of dangerous drugs registered with the state board of pharmacy shall report any suspicious purchases of any dangerous drugs by a prescriber exempted from licensure as a terminal distributor of dangerous drugs. A suspicious purchase includes, but is not limited to, any drugs that the prescriber is not authorized to use in the course of his/her professional practice.

**Rule 4729-9-18 Availability of terminal, wholesale, or manufacturer license.** [OAC: 02/01/98]  
(Amplifies 4729.51, 4729.66)

Each entity possessing a current license as a terminal distributor of dangerous drugs, wholesale distributor of dangerous drugs, wholesaler of controlled substances, or manufacturer of controlled substances shall maintain such license in a readily available place in the principal location of such business.

**Rule 4729-9-17 Storage of adulterated drugs.** [OAC: 07/01/93]  
(Amplifies 4729.56, 4729.57, 4729.66)

To prevent their use, adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for dispensing and administration.

- (A) Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license or two years by those holding a wholesale distributor of dangerous drugs license only.
- (B) Drugs, other than controlled substances, shall be destroyed utilizing proper methods of disposal.
- (C) Drugs that are controlled substances may be disposed of pursuant to rule 4729-9-06 of the Administrative Code.
- (D) Methods of disposal shall prevent the possession of the drugs by unauthorized persons.

Section 3719.07 **Records of controlled substances handled.** [ORC: 07/22/98]

(A) As used in this section, "description" means the dosage form, strength, and quantity, and the brand name, if any, or the generic name, of a drug or controlled substance.

(B) \* \* \*

(2) Manufacturers and wholesalers shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared by them, and of all controlled substances received or sold by them. The records shall be kept in accordance with division (C)(2) of this section.

\* \* \*

(C) \* \* \*

(2) The records required by divisions (B)(2) and (4) of this section shall contain the following

(a) The description of all controlled substances produced or prepared, the name and address of the person from whom received, and the date of receipt;

(b) The description of controlled substances sold, the name and address of each person to whom a controlled substance is sold, the amount of the controlled substance sold to each person, and the date it was so sold.

\* \* \*

(D) Every record required by this section shall be kept for a period of two years.

The keeping of a record required by or under the federal drug abuse control laws, containing substantially the same information as specified in this section, constitutes compliance with this section.

Every person who purchases for resale or who sells controlled substance preparations exempted by section 3719.15 of the Revised Code shall keep the record required by or under the federal drug abuse control laws.

Section 3719.08 **Labeling.** [ORC: 07/22/98]

(A) Whenever a manufacturer sells a controlled substance, and whenever a wholesaler sells a controlled substance in a package the wholesaler has prepared, the manufacturer or wholesaler shall securely affix to each package in which the controlled substance is contained a label showing in legible English the name and address of the vendor and the quantity, kind, and form of controlled substance contained therein. No person, except a pharmacist for the purpose of dispensing a controlled substance upon a prescription shall alter, deface, or remove any label so affixed.

\* \* \*

(E) No person shall alter, deface, or remove any label affixed pursuant to this section as long as any of the original contents remain.

(F) Every label for a schedule II, III, or IV controlled substance shall contain the following warning:

"Caution: federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

<><><>