

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

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

Ohio's laws governing the legal distribution of dangerous drugs are intended to provide a closed system of drug distribution. The Dangerous Drug Distribution Act was enacted in 1962 and provides for the licensing of individuals who wish to sell dangerous drugs in Ohio at wholesale<sup>1</sup> and for the licensing of sites where dangerous drugs are stored for distribution at wholesale or retail. The wholesale or terminal distributor of dangerous drugs may not store dangerous drugs at any site in Ohio other than the location licensed with the Board of Pharmacy.

Consequently, **a wholesaler should not ship dangerous drugs to any site in Ohio unless such site is licensed with the Board or to sites identified pursuant to paragraph (C)(2)(b) of OAC Rule 4729-9-12.** The name and address to which dangerous drugs are shipped should be the same as that appearing on the wholesale or terminal distributor license or in the documentation provided to the wholesale distributor of dangerous drugs by an exempt prescriber pursuant to paragraph (C)(2) of OAC Rule 4729-9-12.

**CERTIFICATE OF LICENSURE/RENEWAL/ADDENDUM**

Terminal distributors are issued a certificate of licensure when obtaining their first license and each year when renewing their license. Terminal distributors who hold a limited license also receive an addendum which lists the dangerous drugs that they are authorized to purchase and possess in Ohio.

Each manufacturer or wholesaler distributing dangerous drugs at wholesale into or in the state of Ohio must be licensed as a wholesale distributor of dangerous drugs and also licensed as a wholesaler of controlled substances if the dangerous drugs being distributed are controlled substances.

It is illegal for any terminal distributor of dangerous drugs licensed with the Board to purchase dangerous drugs from anyone other than a wholesale distributor of dangerous drugs who is licensed with the Ohio Board of Pharmacy. Terminal distributors who purchase dangerous drugs from persons not licensed as a wholesale distributor with the Ohio Board may have their license revoked or be fined \$5,000.00.

Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs or an exempt prescriber, the wholesaler must verify that the terminal distributor of dangerous drugs is licensed to purchase the dangerous drugs requested or verify the exempt status of a prescriber.

It is also illegal for any wholesaler to sell dangerous drugs at wholesale to terminal distributors that are not authorized by their category of license (i.e., I, II, or III), or which does not appear on their addendum if they have a "limited" license (see Page 4 for descriptions of the categories).

A **DANGEROUS DRUG** is:

- (1) Any drug or drug product which may be obtained **ONLY UPON PRESCRIPTION**. This includes those drugs or drug products whose commercial package label bears any of the following:
  - (a) The symbol "Rx only";

- (b) "Caution: Federal Law Prohibits Dispensing Without Prescription";
  - (c) "Caution: Federal Law Restricts This Drug to Use By Or On the Order of A Licensed Veterinarian"; or
  - (d) any other similar restrictive statement.
- (2) Any Schedule V drug product which contains a narcotic and does not bear a Federal Legend (e.g., over-the-counter cough preparations, etc.).
- (3) Any injectable drug or drug product for human use (e.g., insulin, biologicals, vaccines, allergenic extracts, etc.).

Wholesalers of dangerous drugs licensed with the Board may legally sell<sup>2</sup> dangerous drugs at wholesale to the following persons:

- (1) Individual prescribers whose licenses to practice are current and in-good-standing with their licensing board. If any of the dangerous drugs are controlled substances<sup>3</sup>, the prescriber also must hold a current D.E.A. registration.

**NOTE:** Prescribers may purchase and possess only those drugs which they are authorized to prescribe in the course of their professional practice. Dentists, podiatrists, and optometrists<sup>4</sup> are limited prescribers and they may legally purchase and possess only those drugs which may be used in their professional practice.

The offices of individual prescribers may or may not be licensed with the Board of Pharmacy as a terminal distributor of dangerous drugs. If they are not licensed as a terminal distributor of dangerous drugs, the wholesaler should ship controlled substances which they order **only** to the location(s) licensed with the federal Drug Enforcement Administration. Dangerous drugs may only be shipped to those location(s) identified by a prescriber, exempt from licensure as a terminal distributor of dangerous drugs, in the documentation provided pursuant to paragraph (C)(2)(b) of OAC Rule 4729-9-12.

- (2) Optometrists licensed with the Ohio Board of Optometry and who are certified by the Ohio Board of Optometry to administer Topical Ocular Pharmaceutical Agents may purchase the following dangerous drugs for use in their professional practice:

- (a) Proparacaine hydrochloride in a potency not exceeding five-tenths of one per cent ophthalmic solution;
- (b) Benoxinate hydrochloride in a potency not exceeding four-tenths of one per cent ophthalmic solution;
- (c) Phenylephrine hydrochloride in a potency not exceeding two and five-tenths per cent ophthalmic solution;
- (d) Hydroxyamphetamine hydrobromide in a potency not exceeding one per cent ophthalmic solution;
- (e) Tropicamide in a potency not exceeding one per cent ophthalmic solution;
- (f) Cyclopentolate in a potency not exceeding one per cent ophthalmic solution;
- (g) Dapiprazole hydrochloride in a potency not exceeding five-tenths of one per cent ophthalmic solution (also known as "Rev-Eyes").

- (3) Optometrists licensed with the Ohio Board of Optometry and who are currently certified to prescribe Therapeutic Pharmaceutical Agents and administer such drugs to their patients may purchase the following dangerous drugs for administration to their patients in accordance with Division (D) of ORC Section 4725.02:

- (a) A topical ophthalmic preparation;
- (b) Oral dosage of any of the following drugs:
  - Acetazolamide,
  - Astemizole,
  - Dichlorphenamide,

- Diphenhydramine,
- Glycerin in a fifty per cent solution,
- Isosorbide in a forty-five per cent solution,
- Methazolamide,
- Analgesics that may be legally sold without prescription,
- Terfenadine,
- Ampicillin in a two hundred fifty milligram or five hundred milligram dosage,
- Cefaclor in a two hundred fifty milligram or five hundred milligram dosage,
- Cephalexin in a two hundred fifty milligram or five hundred milligram dosage,
- Dicloxacillin in a two hundred fifty milligram or five hundred milligram dosage,
- Doxycycline in a fifty milligram or one hundred milligram dosage,
- Erythromycin in a two hundred fifty milligram, three hundred and thirty-three milligram, or five hundred milligram dosage,
- Penicillin VK in a two hundred fifty milligram or five hundred milligram dosage,
- Tetracycline in a two hundred fifty milligram or five hundred milligram dosage,
- Amoxicillin up to and including five hundred milligram dosage,
- Erythromycin up to and including five hundred milligram dosage,
- Ibuprofen up to and including eight hundred milligram dosage,
- Loratadine,
- Naproxen up to and including five hundred fifty milligram dosage,
- Terfenadine with pseudoephedrine hydrochloride.

An Optometrist's license to practice, and his certification to purchase and use topical ocular pharmaceutical agents or therapeutic pharmaceutical agents in his practice, must be renewed each year by December 31st. An optometrist must hold not only a current license to practice in Ohio, but also a current certification in order to legally purchase and use these products in his professional practice. THE OFFICES OF OPTOMETRISTS ARE NOT LICENSED BY ANY FEDERAL OR STATE AGENCY. ACCORDINGLY, WHOLESALERS MUST DETERMINE WHERE THE OPTOMETRIST'S LICENSE TO PRACTICE AND CERTIFICATION TO USE TOPICAL OCULAR PHARMACEUTICAL AGENTS IS POSTED AND SHIP THE DANGEROUS DRUGS<sup>3</sup> THAT THE OPTOMETRIST IS AUTHORIZED TO PURCHASE AND USE IN PRACTICE TO THAT LOCATION ONLY. These locations should be the same as that identified by the exempt practitioner pursuant to paragraph (C)(2)(b) of OAC Rule 4729-9-12.

- (4) Persons licensed with the Ohio Board of Pharmacy as a wholesale distributor of dangerous drugs and who hold a license to sell controlled substances.
- (5) Persons **currently** licensed as a terminal distributor of dangerous drugs with the Ohio Board of Pharmacy and **who are authorized by their dangerous drug distributor license to purchase and possess** the dangerous drugs which they have ordered. There are **three** categories of dangerous drugs and **six** different terminal dangerous drug distributor licenses, as follows:

#### Categories of Dangerous Drugs

- Category I:** 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 ORC Sections 4765.38 and 4765.39.
- Category II:** Any dangerous drug (i.e., drugs bearing the federal legend or injectables for human use) that is not included in Category I or III.
- Category III:** Any controlled substance that is contained in Schedule I, II, III, IV, or V.

## Categories of Terminal Distributor Of Dangerous Drugs Licenses

### **Category I license:**

A person who obtains this license may possess, have custody or control of, and distribute only Category I dangerous drugs.

### **Limited Category I license:**

A person who obtains this license may possess, have custody or control of, and distribute only Category I dangerous drugs which appear on the addendum<sup>5</sup> to their license.

### **Category II license:**

A person who obtains this license may possess, have custody or control of, and distribute only Category I and Category II dangerous drugs.

### **Limited Category II license:**

A person who obtains this license may possess, have custody or control of, and distribute only Category I and Category II dangerous drugs which appear on the addendum<sup>5</sup> to their license.

### **Category III license:**

A person who obtains this license may possess, have custody or control of, and distribute Category I, Category II, and Category III dangerous drugs.

### **Limited Category III license:**

A person who obtains this license may possess, have custody or control of, and distribute only Category I, Category II, and Category III dangerous drugs which appear on the addendum<sup>5</sup> to their license.

A licensed wholesale distributor of dangerous drugs may sell to a terminal distributor **ONLY** those dangerous drugs which the terminal distributor is licensed to purchase and possess. Consequently, persons selling dangerous drugs at wholesale must determine the category of dangerous drug license held by a terminal distributor and whether or not it is a limited license. If the person holds a limited license, the wholesaler must also determine which drugs<sup>5</sup> the terminal distributor may purchase.

Persons holding a limited terminal distributor of dangerous drugs license receive an addendum listing the drugs included in their application for licensure. Wholesalers should request a copy of the current license and addendum for limited licenses before selling drugs at wholesale to a terminal distributor. A wholesaler **MAY NOT** legally sell controlled substances to a terminal distributor unless they hold a Category III or Limited Category III dangerous drug license.

Terminal dangerous drug distributor licenses expire on December 31st of each year and Wholesale dangerous drug distributor licenses expire on June 30th of each year. Each must be renewed prior to the expiration date if the person wishes to continue to distribute, purchase, and/or possess dangerous drugs in Ohio.

- (6) Distributors of dangerous drugs who are located in other states not engaged in the sale of dangerous drugs in Ohio.

## LEGAL WHOLESALE SALES OF DANGEROUS DRUGS

- (A) Each person licensed with the Ohio Board of Pharmacy to sell dangerous drugs at wholesale shall:
  - (1) Obtain a copy of the terminal dangerous drug distributor's current "Certificate of License" before selling dangerous drugs at wholesale to the terminal distributor. If the category of license is limited, the wholesaler must obtain a copy of the current license addendum before selling any dangerous drug listed on the addendum to the terminal distributor. [ORC Section 4729.60]

- (2) Maintain a system of records and procedures which prevent the sale or other distribution of dangerous drugs to any person not authorized by Division (B) of ORC Section 4729.51 to purchase or possess such dangerous drugs. [OAC Rule 4729-9-16(H)(1)(d)]
  - (3) Maintain copies of all invoices of sales of dangerous drugs at wholesale for two years and make them available for inspection by the Ohio Board of Pharmacy or its agents. [OAC Rule 4729-9-16(H)(2)]
  - (4) Design and operate a system that will disclose orders for dangerous drugs subject to abuse and which have been designated by the Ohio Board of Pharmacy. [OAC Rule 4729-9-16(H)(1)(e)]
  - (5) Inform the Ohio Board of Pharmacy of suspicious orders for drugs when discovered. The reports shall include the name and address of the purchaser as it appears on their wholesale or terminal distributor of dangerous drugs license or their license to practice if they are a prescriber or optometrist, the date of purchases, product trade name, size of package, and quantity of packages purchased. [OAC Rule 4729-9-16(H)(1)(e)]
- (B) The term "occasional sale" as used in ORC Section 4729.51 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 ORC Section 4729.01. [OAC Rule 4729-9-10]

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. [OAC Rule 4729-9-10]

The value of the dangerous drugs shall be based on the cost of the dangerous drugs to the terminal distributor of dangerous drugs. [OAC Rule 4729-9-10]

If the total amount of drugs sold at wholesale exceed the definition of an occasional sale, the terminal distributor must obtain a wholesale license to sell dangerous drugs and, if applicable, a wholesale license to sell controlled substances.

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- 1 "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.
  - 2 "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 (ORC Section 4729.01).
  - 3 Ohio's drug laws do not permit Optometrists to purchase or prescribe controlled substances in the course of their professional practice in Ohio.
  - 4 Licensed to prescribe therapeutic pharmaceuticals.
  - 5 The drugs are listed with an NDC number for licensing and reference purposes only. The licensee is not restricted to that particular manufacturer's or distributor's product. However, the licensee is restricted to using the same strength and dosage form of each drug listed.

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**OTHER AGENCIES TO CONTACT FOR LICENSE VERIFICATION**

Ohio State Medical Board: 614/466-3934

Drug Enforcement Administration: 800/230-6844

Ohio State Nursing Board: 614/466-3947

Ohio State Dental Board: 614/466-2580

Ohio State Optometry Board: 614/466-5115

Ohio State Veterinary Medical Board: 614/644-5281