



# OHIO STATE BOARD OF PHARMACY

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-Equal Opportunity Employer and Service Provider-

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Licensing Administrator &  
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## LICENSING ISSUES FOR PRESCRIBERS

### **What is the deal about a Terminal Distributor of Dangerous Drugs license?**

Back in 1998, the Ohio legislature changed section 4729.51 of the Ohio Revised Code. That section defines to whom a registered Wholesale Distributor of Dangerous Drugs may sell or distribute dangerous drugs. That list now includes Terminal Distributors of Dangerous Drugs, Wholesale Distributors of Dangerous Drugs, Manufacturers, and Licensed Health Professionals authorized to prescribe drugs (Prescribers). A prescriber is defined as an individual who is authorized by law to prescribe drugs or dangerous drugs in the course of the individual's professional practice (4729.01(I) ORC). Previously, this section used the term "practitioners" instead of prescribers and defined "practitioner" as a person or professional association or partnership of individuals authorized by law to write prescriptions for drugs or dangerous drugs.

This information has been shared in the past with professional associations and Wholesale Distributors but has not been aggressively enforced by the Ohio State Board of Pharmacy. In the recent past there has been a national focus on the wholesale distribution of prescription drugs including "pedigree" legislation designed to track drugs from manufacturers to vendors to the patient. As we have been inspecting Wholesale Distributors and clinic facilities in Ohio, we have been asking how Wholesale Distributors are complying with Ohio law in the distribution of dangerous drugs.

### **When does a prescriber need to obtain a license from the Board of Pharmacy?**

Dangerous drugs are defined in the Ohio Revised Code as any drug requiring a prescription or intended for injection into the human body. This includes antibiotics, vaccines, local anesthetic injectable products and medical oxygen. If the prescriber practices as an independent, unincorporated prescriber then the prescriber would be legally allowed to purchase, possess and distribute dangerous drugs without a license from the Board of Pharmacy since the prescriber would "own" the drugs.

If the prescriber is incorporated on his/her own or is part of a group practice, whether this is a corporation, partnership, limited liability company or a health care association, the business entity (corporation, LLC, or partnership) is required to be licensed as a terminal Distributor of Dangerous Drugs with the Board of Pharmacy. There is a two page application available from the Board office. In completing this application, one of the group's prescribers must sign the application as the Responsible Person for the group. This Responsible Person is accepting the responsibility of overseeing that proper records are kept of the receipt, usage and distribution of dangerous drugs.

All dangerous drugs must be kept in an environment that deters and detects unauthorized access to those dangerous drugs. This helps avoid theft but is also intended to reduce the risk of tampering with the drugs in the office setting. Many prescribers forget that there are cleaning people and maintenance people that enter the office after the prescriber and office staff leave for the day.

DEA registration is required of all practitioners who possess, distribute or prescribe controlled substances. There are some exceptions for military and hospital employees. This registration is done through the Central Office in Washington D.C. There are forms available on the Internet ([www.dea diversion.usdoj.gov](http://www.dea diversion.usdoj.gov)). Look for On-Line Forms. Federal rules and regulations are also available on this site. DEA also requires separate registration for each principal place of business or professional practice where controlled substances are distributed or dispensed. This separate registration is not necessary for an office used by a practitioner to prescribe controlled substances but neither administer or distribute controlled substances.

### **Does an individual prescriber need to be licensed to dispense?**

Numerous telephone calls have been received in the Board of Pharmacy office regarding the necessity of a prescriber having a "dispensing" license with the Board of Pharmacy so that the prescriber may dispense drugs from their office. The Ohio Revised Code does not require a separate license for prescribers to "dispense" drugs. Ohio law states that only a Registered Pharmacist may dispense dangerous drugs (4729.28 ORC). However, there is a law that exempts licensed health professionals authorized to prescribe drugs (or prescribers) from this law and allows them to "personally furnish" their patients with drugs, within the scope of the prescriber's professional practice, that seem proper to the prescriber (4729.29 ORC). A licensed healthcare professional authorized to prescribe drugs (or prescriber) is defined in the Ohio Revised Code as an individual who is authorized by law to prescribe drugs or dangerous drugs in the course of the individual's professional practice, including, in part, a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatry, a veterinarian licensed under Chapter 4741. of the Revised Code, a dentist licensed under Chapter 4715. of the Revised Code, an optometrist licensed under Chapter 4725. of the Revised code to practice optometry under a therapeutic pharmaceutical agents certificate.

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## I N S T R U C T I O N S

### TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS APPLICATION

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**BOTH FORMS PHA-0600 & PHA-0601 ARE REQUIRED**

***FORM PHA-0600 - Application For Registration As A Distributor Of Dangerous Drugs***

1. Indicate whether this application represents a new license or if this is a change to a current license. In the next box, **write in the proposed date**. If this site is already open and not a licensed facility, fill in "already open". Mark the type of change which is occurring. Write in the existing terminal distributor of dangerous drugs license number, if applicable. This number begins with "02-".
2. Must be completed with the name under which applicant will be doing business and the **street address** of the location where the drugs will be stored. Do not use a P. O. box number *only*. The address indicated on the application shall describe **only one establishment or place** which the licensee engages in the sale or distribution of dangerous drugs.
3. If the entity conducts business under any other name, please enter these names.
4. Is self-explanatory and must be completed.
5. **For contingency stock licenses only:** Indicate name of business servicing entity listed in 2 above. If this application is for a pharmacy or retail seller of medicinal oxygen to store drugs at a location other than their own licensed business, fill in pharmacy or retail seller of medicinal oxygen business name and terminal distributor license number.  
  
*The information requested in 6a, 6b, and 6c will be contained in papers usually maintained by the applicant's business office.*
- 6a. Mark the type of business the applicant intends doing business as.
- 6b. Pertains to corporations and limited liability companies, sole proprietorships, and partnerships.
- 6c. Pertains to government agencies only.
7. If incorporated, indicate the type of corporation. In Ohio, you will find the chapters in your articles of incorporation. In other states, you may need to look elsewhere. If you are having trouble obtaining your articles of incorporation, contact the Secretary of State. **You are required to submit a copy of your articles of incorporation with the application. Failure to do so will result in the application being returned, delaying the licensing process.**
8. a. and b. are self-explanatory - complete if applicable.
9. **Must be signed** and completed by the individual who can verify the information provided in this application is true, correct, and complete. **Failure to do so will result in the application being returned, delaying the licensing process.**

> > > MORE INSTRUCTIONS ON BACK OF THIS PAGE < < <

# INSTRUCTIONS

(continued)

## TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS APPLICATION

(BOTH FORMS PHA-0600 & PHA-0601 ARE REQUIRED)

### FORM PHA-0601 - Application For Registration As A Terminal Distributor

1. Category of License: Check the correct category based on the drugs your facility will acquire and possess (see below):

CATEGORY I - \$45.00 This licensee may possess, have custody or control of, and distribute only single dose injections of I.V. fluids, including Saline, Ringers Lactate, 5% Dextrose and distilled water & other intravenous fluids or parenteral solutions included in this category by rule of the Board of Pharmacy that have a volume of 100ml or more and contain no added substances. Less Than 100ml Requires A Category II License.

LIMITED CATEGORY I - \$45.00 This licensee may possess, have custody or control of, and distribute drugs in Category I that the Medical Advisor has approved..

CATEGORY II - \$112.50 This licensee may possess, have custody or control of, and distribute only the dangerous drugs carrying the Federal legend which are not controlled substances and those fluids in Category I and fluids with volume of less than 100ml. This category also includes Medicinal Oxygen.

LIMITED CATEGORY II - \$112.50 This licensee may possess, have custody or control of, and distribute drugs in Category II that the Medical Advisor has approved.

CATEGORY III - \$150.00 This licensee may possess, have custody or control of, and distribute drugs in Category I & II and any controlled substances contained in Schedule II, III, IV, or V.

LIMITED CATEGORY III - \$150.00 This licensee may possess, have custody or control of, and distribute drugs in Category III that the Medical Advisor has approved.

2. Check the appropriate box for the type of establishment being licensed\*\*. If your type is not listed, please mark "Other" and write a brief description.

**\*\* ON A SEPARATE PAPER (i.e.-BUSINESS LETTERHEAD), PROVIDE A NARRATIVE DESCRIPTION OF THE TYPE OF BUSINESS ACTIVITIES (PLEASE BE SPECIFIC!) CONDUCTED WHICH REQUIRE THE APPLICANT TO BE GRANTED A TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE. Failure to do so will result in the application being returned, delaying the licensing process.**

3. Self-explanatory. The license number(s) will begin with "01-" or "02-".
4. Must be answered. **Failure to do so will result in the application being returned, delaying the licensing process.**
5. Must be answered. **Failure to do so will result in the application being returned, delaying the licensing process.**
6. Depending on the type of business being licensed - Statement of individual responsible for supervision and control of dangerous drugs must be a registered Ohio M.D., D.O., R.Ph., D.V.M., or D.P.M. Ohio Pharmacies must have a licensed Ohio R.Ph. **Laboratories only** may have a Ph.D. or chemist responsible. Print name legibly and sign. Social security number and professional license number are required to be filled in. **Failure to sign application will result in the application being returned, delaying the licensing process.**

OHIO STATE BOARD OF PHARMACY  
 77 S. HIGH STREET, ROOM 1702, COLUMBUS, OHIO 43215-6126  
 614/466-4143

Read ENCLOSED INSTRUCTIONS carefully before completing this application.  
 Make check/money order payable to "Treasurer, State of Ohio".

- PLEASE PRINT OR TYPE -

THIS FORM MUST BE COMPLETED AND RETURNED WITH:

- Form PHA-0801 for Terminal Distributors of Dangerous Drugs OR
- Form PHA-0802 for Wholesale Distributors of Dangerous Drugs OR
- Forms PHA-0802 and PHA-0700 for Wholesalers/Manufacturers of Controlled Substances

FOR STATE BOARD OF PHARMACY USE ONLY			
Class	Category -- L U	Fee	License No.
Received			
Control No.	Amount Rec'd	Audit No.	

## APPLICATION FOR REGISTRATION AS A DISTRIBUTOR OF DANGEROUS DRUGS (FORM PHA-0600)

### 1. LICENSE REQUEST FOR: → MUST BE COMPLETED ←

<input type="checkbox"/> NEW <input type="checkbox"/> CHANGE	Proposed Opening Date or Date of Change:	Change Of:	If Change, give current Distributor License No.:
		<input type="checkbox"/> Address <input type="checkbox"/> Owner <input type="checkbox"/> Name <input type="checkbox"/> Category <input type="checkbox"/> Other--please state here:	

### 2. LOCATION BEING LICENSED:

Name under which the applicant will be doing business	County
Number and street address (DO NOT USE P.O. BOX NUMBER)	City, State      Zip Code

### 3. LIST ANY OTHER NAMES THE ENTITY WILL BE CONDUCTING BUSINESS UNDER: (Attach separate sheet if necessary)

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### 4. INDIVIDUAL TO CONTACT REGARDING ABOVE LOCATION, BETWEEN 8 AM AND 5 PM WEEKDAYS:

Name	Title	Area Code/Phone Number
Address	City, State	Zip Code

### 5. NAME OF BUSINESS SERVICING ENTITY LISTED IN 2 ABOVE: (if applicable for contingency stock)

Name as listed on its Terminal Distributor license	Terminal Distributor License No.
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### 6a. APPLICANT INTENDS DOING BUSINESS AS: (Check ONE):

<input type="checkbox"/> Sole Proprietorship	<input type="checkbox"/> Partnership	<input type="checkbox"/> Corporation	<input type="checkbox"/> Limited Liability Company	<input type="checkbox"/> Government Agency
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### 6b. NAME OF OWNER(S); OR, IF INCORPORATED, NAME AND TITLE OF OFFICERS: (Attach separate sheet, if necessary)

Name	Title	Date of Birth or Soc. Sec. No.
Name	Title	Date of Birth or Soc. Sec. No.

### 6c. NAME OF GOVERNMENT AGENCY: (if applicable)

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### 7. TYPE OF CORPORATION, IF INCORPORATED: → COPY OF CORPORATION PAPERS MUST ACCOMPANY THIS APPLICATION ←

<input type="checkbox"/> General (ORC Ch 1701)	<input type="checkbox"/> Non-Profit (ORC Ch 1702)	<input type="checkbox"/> Limited Liability (ORC Ch 1705)	<input type="checkbox"/> Medical Care (ORC Ch 1737)	<input type="checkbox"/> Health Care (ORC Ch 1738)	<input type="checkbox"/> Dental Care (ORC Ch 1740)	<input type="checkbox"/> Professional Assoc. (ORC Ch 1785)
State Where Incorporated			Charter Number			

### 8a. TRADE, CORPORATE, OR PARTNERSHIP NAME AND ADDRESS: (if different than name and location being licensed)

Name	Area Code/Phone Number	Ext.
Address	City, State, Zip Code	

### 8b. PREVIOUS TRADE, CORPORATE, OR PARTNERSHIP NAMES & ADDRESSES, IF ANY: (Attach separate sheet if necessary)

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### 9. STATEMENT OF APPLICANT:

I DECLARE under penalties of Section 2921.13 of the Ohio Revised Code, that this application has been examined by me and, to the best of my knowledge and belief, is a true, correct, and complete application.

SIGNATURE of Applicant	DOB/SSN	Date
PRINT NAME	Title	Area Code/Phone Number    Ext.

No license or registration may be issued unless a completed application form (including fee & any required documents) has been received. [Sections 4729.52 and 4729.54, ORC]  
 PHA-0600 (Rev. 07/96)

# APPLICATION FOR REGISTRATION AS A TERMINAL DISTRIBUTOR (FORM PHA-0601)

*See ENCLOSED INSTRUCTIONS for aid in properly completing this application.*  
**-- THIS FORM MUST BE COMPLETED AND RETURNED WITH FORM PHA-0600 --**

**-- PLEASE PRINT OR TYPE --**

**1. CATEGORY OF LICENSE: (Check Only ONE)**

Application is hereby made for a license as a TERMINAL DISTRIBUTOR of Dangerous Drugs, as provided in Sections 4729.54 and 4729.55 of the Ohio Revised Code, as follows:     Category I     Limited Category I     Category II     Limited Category II     Category III     Limited Category III

**2. TYPE OF ESTABLISHMENT BEING LICENSED:**

- |  |  |  |   |
|--|--|--|---|
| <input type="checkbox"/> Retail Pharmacy   | <input type="checkbox"/> Convalescent-Rest-Nursing Home                | <input type="checkbox"/> Correctional Institution                                | <input type="checkbox"/> Pharmacy That Services Other Institutions Only |
| <input type="checkbox"/> Dog Warden/Animal Euthanasia                                    | <input type="checkbox"/> Dog Pound/Animal Shelter                      | <input type="checkbox"/> Veterinary Facility                                     | <input type="checkbox"/> Dog Trainer                                    |
| <input type="checkbox"/> Specialty Pharmacy  | <input type="checkbox"/> Home Health Care Agency                       | <input type="checkbox"/> HMO Pharmacy  | <input type="checkbox"/> Fluid Therapy Pharmacy/HHC                     |
| <input type="checkbox"/> Emergency Medical Services                                      | <input type="checkbox"/> Hospice-Inpatient                             | <input type="checkbox"/> Private Practitioner                                    | <input type="checkbox"/> Employee Script Fill Only                      |
| <input type="checkbox"/> Corporate Headquarters  | <input type="checkbox"/> Hospice-Outpatient                            | <input type="checkbox"/> DME Pharmacy  | <input type="checkbox"/> Nuclear Pharmacy                               |
| <input type="checkbox"/> Practitioner Corporation  | <input type="checkbox"/> Clinic  | <input type="checkbox"/> Teaching Institution                                    | <input type="checkbox"/> Waste Disposal Only                            |
| <input type="checkbox"/> Hospital  | <input type="checkbox"/> First Aid Room/Dispensary/Occupational Health | <input type="checkbox"/> Physical Therapy Facility                               | <input type="checkbox"/> Manufacturer-Process Use                       |
| <input type="checkbox"/> Mail Order Pharmacy   | <input type="checkbox"/> Laboratory/Research                           | <input type="checkbox"/> Sports Training Facility                                | <input type="checkbox"/> Food Processor-Nitrous Oxide                   |
| <input type="checkbox"/> Non-Territorial Pharmacy  | <input type="checkbox"/> Mobile Pharmacy                               | <input type="checkbox"/> Reseller of Medicinal Oxygen                            |   |
| <input type="checkbox"/> Pharmacy Servicing Other Institution/Contingency Stock Location |  | <input type="checkbox"/> Reseller of Medicinal Oxygen/Contingency Stock Location |   |
| <input type="checkbox"/> Other: (describe type of business conducted) _____              |  |  |   |

**3. LIST OTHER DRUG DISTRIBUTOR LICENSES, ISSUED BY THE OHIO STATE BOARD OF PHARMACY, WHICH YOU POSSESS: [Give Identification Number(s)]**

**4. RECORD OF ADJUDICATIONS AND FINES IMPOSED:**

Has the applicant or owner(s), or any agent or employee of the applicant/owner(s), or any officer of the corporation, ever been the subject of disciplinary action by any state or federal agency?

- NO     YES (If yes, give reason and detailed explanation on separate sheet)

**5. RECORD OF CHARGES, CONVICTIONS, AND FINES IMPOSED:**

Does the applicant or owner(s), or any agent or employee of the applicant/owner(s), or any officer of the corporation, have charges pending or have a conviction of a felony or a misdemeanor other than a minor traffic violation (even if expunged or sealed)?

- NO     YES (If yes, explain in detail on separate sheet; listing names and addresses of the court or government agency and dates such charges were filed)

NOTE: Pursuant to Section 2953.33(B) of the Ohio Revised Code, you must answer in the affirmative if you have a record of a charge or conviction that has subsequently been sealed or expunged. Pursuant to Section 2953.35 of the Ohio Revised Code, the Board of Pharmacy's records regarding the applicant's sealed or expunged records will be kept confidential.

**6. STATEMENT OF INDIVIDUAL RESPONSIBLE FOR SUPERVISION AND CONTROL OF DANGEROUS DRUGS:**

I HEREBY AGREE to and do submit to the jurisdiction of the Ohio State Board of Pharmacy and to the laws of Ohio for the purposes of the enforcement of Chapters 2925., 3715., 3719., and 4729. of the Ohio Revised Code, and Chapter 4729 of the Ohio Administrative Code; and, I assume the responsibility for supervision and control over the possession and custody of the dangerous drugs that may be acquired by, or on behalf of, the applicant pursuant to Section 4729.55(B), O.R.C.

I FULLY UNDERSTAND that, as a licensed Terminal Distributor, drugs may be purchased only within the category of license requested from Wholesale Distributors of Dangerous Drugs registered in the State of Ohio with the Ohio State Board of Pharmacy. I also understand that if and when this business is discontinued that a "Written Notice of Discontinuing Business" form must be secured from the Ohio State Board of Pharmacy, completed by me, and returned to their offices with the license being discontinued as required in Rule 4729-9-07 of the Ohio Administrative Code.

<b>SIGNATURE of Responsible Person:</b> _____	<b>DATE of Signature</b> _____	<b>PRINT NAME:</b> _____
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**QUALIFICATIONS:**

<input type="checkbox"/> M.D. License No.: _____	<input type="checkbox"/> D.O. License No.: _____	<input type="checkbox"/> R.Ph. License No.: _____
<input type="checkbox"/> D.V.M. License No.: _____	<input type="checkbox"/> D.D.S. License No.: _____	<input type="checkbox"/> D.P.M. License No.: _____
<input type="checkbox"/> Ph.D./Chemist - Laboratories Only    Title: _____	Social Sec. No.: _____	
<input type="checkbox"/> Other: _____	Title: _____	Prof. License No.: _____ (if applicable)