



Terminal Distributor Licensing of Prescriber Practices

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What is a Terminal Distributor of Dangerous Drugs (TDDD) license?

A Terminal Distributor of Dangerous Drugs license allows a business entity to purchase and possess dangerous drugs at a specific address for distribution to patients. It also includes entities, such as laboratories, that purchase and possess dangerous drugs for research purposes.

Distribution includes administration of drugs on-site to patients as well as handing the drugs to the patient to take away from the facility for later use (commonly known as personally furnishing).

Dangerous drugs are defined in the Ohio Revised Code as any drug requiring a prescription, bears on the label a Federal Legend (Rx Only or Caution: Federal law prohibits dispensing without a prescription), or is intended for injection into the human body. This includes antibiotics, vaccines, sterile saline, local anesthetic injectable products, insulin, and medical oxygen as well as controlled substances. See ORC 4729.01(F). **NOTE: This includes drug samples.**

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

ORC 4729.51(B) states that no licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor shall sell to anyone other than

- (1) A licensed terminal distributor of dangerous drugs;
- (2) Any person exempt from licensure as a terminal distributor of dangerous drugs under section [4729.541](#) of the Revised Code [includes exemptions for prescribers];
- (3) A licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor; or
- (4) A terminal distributor, manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor that is located in another state, is not engaged in the sale of dangerous drugs within this state, and is actively licensed to engage in the sale of dangerous drugs by the state in which the distributor conducts business.

When does a prescriber not need to obtain a license from the Board of Pharmacy?

ORC [4729.541](#) includes the following exemptions:

Exemption #1: A health care professional authorized by law to prescribe drugs or dangerous drugs who



practices as a sole proprietor under their professional license does not need a license as a terminal distributor of dangerous drugs (TDDD).

NOTE: There are certain situations where this exemption does not apply (see next page).

Exemption #2: Prescribers' businesses that do not need to be licensed as a TDDD are a business practice that is a corporation (including an S-corporation), limited liability company, or professional association **IF** the business practice has a **SOLE SHAREHOLDER** who is a licensed health professional authorized to prescribe drugs (prescriber) and is authorized to provide the professional services being offered by the practice. See ORC 4729.541.

This means that if the business practice has a single prescriber (MD, DO, DVM, DPM, etc.) who **is the sole shareholder, member, or owner** of the practice, then this business practice is not required to be licensed as a Terminal Distributor of Dangerous Drugs with the Ohio Board of Pharmacy.

However, if the business practice is a group practice **AND** there are **multiple owners, shareholders, or members** then the business practice (corporation, professional association, LLC, or partnership) is required to be licensed as a Terminal Distributor of Dangerous Drugs with the Board of Pharmacy. There is an application available from the Board office (<http://www.pharmacy.ohio.gov/Licensing/TDDD.aspx>). A separate license is required for each separate location where dangerous drugs are received, stored, used, or distributed.

NOTE: There are certain situations where this exemption does not apply (see below).

Exemption #3: A corporation (including an S-corporation), limited liability company, partnership, limited partnership, or professional association if, to be a shareholder, member, or partner, an individual is required to be licensed, certified, or otherwise legally authorized under Title XLVII of the Revised Code to perform the professional service provided by the entity and each such individual is a licensed health professional authorized to prescribe drugs. See ORC 4729.541.

Currently, the ONLY GROUP affected by this exemption are dentists licensed by the Ohio Dental Board.

NOTE: There are certain situations where this exemption does not apply (see below).

The exemptions listed above DO NOT apply to any of the following:

- **Effective April 1, 2017**, prescriber practices that purchase and possess dangerous drugs that are compounded or used for the purpose of compounding. For more information on TDDD licensing relating to dangerous drugs that are compounded or used for the purpose of compounding, visit: www.pharmacy.ohio.gov/prescribercompound
- **Effective June 1, 2017**, prescriber practices that purchase and possess controlled substances. Drugs that are considered controlled substances under the Federal Controlled Substances Act are divided into five schedules (I-V). Schedule I & II controlled substance drugs require a DEA Form 222 to purchase. For more information, including a complete list, visit: <https://www.dea.gov/drug-scheduling>. **NOTE:** Be advised that this licensure requirement applies to any location storing controlled substances. This includes: emergency packs, samples or any other stock of controlled substance medications.
- Prescriber practices that purchase and possess hazardous dangerous drugs that are compounded or used for the purpose of compounding. For more information on TDDD licensing relating to dangerous drugs that are compounded or used for the purpose of compounding, visit: www.pharmacy.ohio.gov/hazardous

- Prescriber practices that meet the definition of a pain management clinic are required to obtain a category III terminal distributor license ([ORC 4731.054](#) and [4729.552](#)).
- **Effective October 31, 2017**, prescriber practices treating more than thirty individuals for opioid dependence or addiction using a controlled substance to obtain a license as a terminal distributor of dangerous drugs with an office-based opioid treatment classification. **This applies even if drugs are not on-site.** For more information on this requirement, please visit: www.pharmacy.ohio.gov/OBOT.

Do I need to register with the U.S. Drug Enforcement Administration (DEA)?

According to the DEA, a registration is required of all practitioners who possess, distribute, or prescribe controlled substances. One registration is required for every address where controlled substances are located.

- A prescriber who has multiple offices will need a separate registration for each office where he/she keeps a controlled substance on site.
- A prescriber who has multiple offices within the same state, may use one DEA registration for all the offices if none of them store a controlled substance or if only one office stores a controlled substance. The address registered with DEA must be the location where the controlled substances are located.
- A prescriber who has multiple offices in different states must have a DEA registration for each state, even if he/she does not possess any controlled substance in any of the offices.

DEA on-line forms are available on the Internet at www.deadiversion.usdoj.gov Look for On- Line Forms. Federal rules and regulations are also available on this site.

I am a federal military facility or United States Veteran's Administration health care facility, do I need to obtain a terminal distributor of dangerous drugs license to purchase and possess dangerous drugs?

No. Federal military facilities and U.S. Veteran's Administration health care facilities are not subject to Ohio law and are not required to obtain a terminal distributor of dangerous drugs license to purchase and possess dangerous drugs.

What is the best way to contact the Board if I need additional information?

If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.