



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.

- *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. See ORC 4729.01(Q)
- *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)

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

ORC 4729.51(B) states that no registered Wholesale Distributor of Dangerous Drugs shall sell to anyone other than an *individual* health care professional authorized by law to prescribe drugs or dangerous drugs in the course of the individual's professional practice (also called a prescriber – note: not a prescriber's practice/business), a Terminal Distributor of Dangerous Drugs (most prescribers' practices/businesses), another Wholesale Distributor of Dangerous Drugs, or a manufacturer.

A prescriber or healthcare professional authorized by law to prescribe drugs or dangerous drugs 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. See ORC 4729.01(I)

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

Exemption #1: A health care professional authorized by law to prescribe drugs or dangerous drugs who practices as a sole proprietor under their medical license does not need a license as a terminal distributor of dangerous drugs (TDDD).

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 4729.51(B)(1)(j).

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/TDDD/General.aspx>). A separate license is required for each separate location where dangerous drugs are received, stored, used, or distributed.

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 4729.51(1)(k).

Currently, the ONLY GROUP affected by this exemption are dentists licensed by the Ohio Dental Board. Therefore, dentist owned businesses are not required to have a Terminal Distributor of Dangerous Drugs license.

THE EXEMPTIONS LISTED ABOVE DO NOT APPLY FOR PRESCRIBER PRACTICES THAT PURCHASE AND POSSESS DANGEROUS DRUGS THAT ARE COMPOUNDED OR USED FOR THE PURPOSE OF COMPOUNDING OR CONTROLLED SUBSTANCES CONTAINING BUPRENORPHINE THAT ARE USED FOR THE PURPOSE OF TREATING DRUG DEPENDENCE OR ADDICTION.

ALL PRESCRIBER PRACTICES THAT ARE PAIN MANAGEMENT CLINICS ARE REQUIRED TO OBTAIN A CATEGORY III TERMINAL DISTRIBUTOR LICENSE.

For more information regarding the TDDD licensing exemptions relating to dangerous drugs that are compounded or used for the purpose of compounding, please visit: www.pharmacy.ohio.gov/CompoundingTDDD

For more information regarding the TDDD licensing exemptions relating to controlled substances containing buprenorphine that are used for the purpose of treating drug dependence or addiction, please visit: www.pharmacy.ohio.gov/BuprenorphineTDDD

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>.