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 (TDDD) license allows a business entity to purchase, possess, and/or distribute dangerous drugs at a specific location. A terminal distributor of dangerous drugs includes hospitals, pharmacies, EMS organizations, laboratories, nursing homes, and prescriber practices.

Distribution includes the administration of drugs on-site to patients as well as providing medications to patients 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 the meets any of the following:

1. Requires a prescription;
2. Bears on the label a Federal Legend (Rx Only or Caution: Federal law prohibits dispensing without a prescription);
3. Is intended for injection into the human body; or
4. Any drug that is a biological product, as defined in section 3715.01 of the Revised Code.

In general, this includes antibiotics, vaccines, sterile saline, local anesthetic injectable products, insulin, botulinum toxin (Botox), and medical oxygen as well as controlled substances. See ORC 4729.01 (F). **IMPORTANT:** This also includes drug samples.

When does a prescriber need to obtain a TDDD 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 dangerous drugs to anyone other than the following:

(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 that are covered on the next page of this document];

(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 is a prescriber exempt from Board of Pharmacy licensure?

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).

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

Exemption #2: A prescriber owned facility 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. A separate license is required for each separate location where dangerous drugs are received, stored, used, or distributed.

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

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.

NOTE: A previous legal interpretation by the Board had limited this exemption to dental practices. However, an updated analysis no longer limits exemption #3 to dental practices.

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

IMPORTANT: The exemptions listed above DO NOT apply to the following:

- Any prescriber practice that engages in drug compounding, including hazardous drug compounding. For more information on TDDD licensing relating to dangerous drugs that are compounded, visit: www.pharmacy.ohio.gov/prescribercompound
- Any prescriber practice that purchases and possesses 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:** 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 meet the definition of a pain management clinic are required to obtain a category III terminal distributor license (ORC 4731.054 and 4729.552). **This applies even if drugs are not on-site.** For more information on this requirement, please visit: www.pharmacy.ohio.gov/PMCinspect.
- Prescriber practices treating more than thirty individuals for opioid dependence or addiction using a controlled substance are required 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/OBOTinspect.

How do I apply for a TDDD license?

Applications are submitted using Ohio's eLicense system. For more information on adding a new license, please refer to this guide.

What rules apply to prescriber practices licensed as a TDDD?

To assist prescribers licensed as TDDDs, the Board has developed the following guidance documents based upon a prescriber's practice setting:

- Pain Management Clinics – 4729:5-11
- First Aid Departments – 4729:5-13
- Office-Based Opioid Treatment Facilities – 4729:5-18
- Clinic and Prescriber Offices – 4729:5-19
- Veterinary Clinics – 4729:5-20
- Opioid Treatment Programs – 4729:5-21
- Non-limited Facilities – 4729:5-22

- Limited Facilities – 4729:5-23

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

According to the DEA, a registration is required for 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 controlled substances are kept 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 controlled substances or if only one office stores controlled substances. The address registered with DEA must be the location where the controlled substances are located.

DEA on-line forms are available here: www.deadiversion.usdoj.gov. 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. Per ORC 4729.541 (A)(13), 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.

How should I determine if I meet one of the exemptions listed above?

Prospective licensees are encouraged to consult with their legal counsel to determine if they meet the exemptions listed above.

I obtained a license for my prescriber practice, but I am exempt, how do I inactivate my license?

Persons no longer requiring a TDDD license must submit a discontinuation of business form to the Board.

I obtained a license for my prescriber practice, but I am exempt, can I still apply or maintain a TDDD license?

Yes. Exempted entities may still obtain/maintain a TDDD license even if they are still exempt.

Is there a form I can use to document my exemption status?

Yes. The Board created a sample form that can be accessed here: www.pharmacy.ohio.gov/WSattest. Please be advised that this is a sample form and that sellers

may have their own forms or process to verify exemption status.

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.