

## Terminal Distributor Requirements for Prescribers Engaged in Drug Compounding

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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, administer, 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 handing 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 a drug that 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); or
3. Is intended for injection into the human body.

**Non-sterile compounded drug** means a drug preparation intended to be non-sterile or are administered in a way that does not have a high risk of infection. Non-sterile compounded drugs include, but are not limited to, the preparation of solutions, suspensions, ointments, creams, powders, suppositories, capsules, and tablets.

**Sterile compounded drug** means a drug preparation intended to be sterile in order to prevent contamination and risk of infection. "Sterile" means a dosage form free of living microorganisms (aseptic). Sterile compounded drugs include injectables, implants, infusions, and ophthalmic solutions.

There are some exemptions to this licensure requirement for prescriber practices that purchase, possess, administer, and/or distribute dangerous drugs. These exemptions can be found by visiting: [www.pharmacy.ohio.gov/prescriberTDDD](http://www.pharmacy.ohio.gov/prescriberTDDD)

### **Drug Compounding by Prescriber Practices and TDDD Licensure**

In general, the exemptions to Ohio's TDDD licensure requirements ([www.pharmacy.ohio.gov/prescriberTDDD](http://www.pharmacy.ohio.gov/prescriberTDDD)) do not apply if the prescriber practice is engaged in drug compounding.

Compounding is defined as the "preparation, mixing, assembling, packaging, and labeling of one or more drugs. Compounding includes the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a drug or bulk drug substance."

However, if a practice that possesses dangerous drugs is exempted from TDDD licensure ([www.pharmacy.ohio.gov/PrescriberTDDD](http://www.pharmacy.ohio.gov/PrescriberTDDD)) there are some additional exemptions in the Board's prescriber drug compounding rules that would apply practices engaged in lower-risk compounding activities.

Therefore, any practice that is generally exempted from TDDD licensure ([www.pharmacy.ohio.gov/PrescriberTDDD](http://www.pharmacy.ohio.gov/PrescriberTDDD)) that engages in the following lower-risk compounding activities is **NOT** required to obtain a TDDD license:

1. The preparation of a device, as defined in Title 21 U.S. Code section 321, containing dangerous drugs strictly in accordance with the manufacturer's labeling for administration and beyond-use dating. **(Example, preparing Restylane per manufacturer's instructions.)**
2. The preparation or reconstitution of non-hazardous\*, conventionally manufactured sterile dangerous drug products for direct administration with no intervening steps in accordance with the manufacturer's labeling for preparation, administration and beyond-use dating. **(Example, preparing Botox injections).**
3. The compounding, preparation, dilution or reconstitution of non-hazardous\*, non-sterile dangerous drug preparations. **(Example, amoxicillin oral suspension that**

**requires reconstitution).**

4. The possession of compounded drug preparations provided by an Ohio licensed [outsourcing facility](#). **(NOTE: If a prescriber compounds any sterile drug received from an outsourcing facility, the prescriber office is subject to licensure as a TDDD).**
  
5. The dilution of non-hazardous\*, conventionally manufactured sterile dangerous drug products (e.g., diluting or mixing into a syringe to administer directly to the patient). **(Example, diluting Kenalog or buffering lidocaine at the time of administration. NOTE: Preparation of such medications in advance of administration requires licensure and compliance with the Board's compounding rules).**

### **What is Considered a Non-Hazardous Drug?**

Ohio rules define a hazardous drug for the purpose of compounding as any antineoplastic drug listed in **table one** on the [National Institute for Occupational Safety and Health's List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings](#).

**REMINDER:** *If you are administering a hazardous drug from a single-use vial with no intervening steps, you are not engaged in drug compounding.*

**SPECIAL NOTE FOR VETERINARIANS:** The Board's compounding rules, and the requirements listed in this inspection guide, only apply to veterinarians that are engaged in hazardous drug compounding. Non-hazardous drug compounding for veterinary medicine is not regulated by the Board of Pharmacy. However, any compounding done in a veterinary clinic must comply with certain labeling requirements. For more information, please see page 32 of the Veterinary Clinic inspection guide ([www.pharmacy.ohio.gov/vetinspect](http://www.pharmacy.ohio.gov/vetinspect)).

For questions regarding this requirement, please review the following frequently asked questions. 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>.

## **Frequently Asked Questions**

### **Q1) What are the specific requirements for a prescriber who is engaged in drug compounding?**

To assist licensees in compliance with all Board of Pharmacy rules, the Board created an inspection guide. The guide can be accessed here: [www.pharmacy.ohio.gov/prescribercomp](http://www.pharmacy.ohio.gov/prescribercomp)

### **Q2) I am a prescriber practice that is licensed as a TDDD, am I required to comply with the Board's drug compounding rules?**

The Board has exempted the following **non-hazardous\*** devices and drugs **prepared by prescriber practice licensed as a TDDD** from the general compounding requirements of [Chapter 4729:7-3](#) of the Ohio Administrative Code:

- (1) The preparation of a device, as defined in Title 21 U.S. Code section 321, containing dangerous drugs strictly in accordance with the manufacturer's labeling for administration and beyond-use dating. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the device. If no such beyond-use date exists, the dangerous drug product may only be used for up to six hours following preparation. These devices shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. Unless administered immediately, the drug device described in this paragraph shall bear a label listing the name of the device (if not legible), date, and time prepared.*
  
- (2) The reconstitution of a conventionally manufactured sterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration, and the beyond-use dating indicated on the manufacturer's labeling. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the drug product. If no such beyond use date or timeframe exists, the dangerous drug product may only be used for up to six hours following preparation. These drug products shall be prepared using aseptic technique and procedures shall be in place to*

*minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible), date, and time prepared.*

*(3) The preparation, reconstitution or dilution of a conventionally manufactured nonsterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration and beyond-use dating. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the drug product. If no such beyond-use date exists, the dangerous drug product shall be assigned a beyond-use date in accordance with USP. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible), date, and time prepared.*

*(4) The dilution of a conventionally manufactured sterile dangerous drug product (e.g., diluting or mixing into a syringe to administer directly to the patient). The drug product shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. The dangerous drug product may only be used for up to six hours following preparation. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug, date, and time prepared.*

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