



License Verification Requirements Prior to Sale

Updated 3/12/2024

This guidance applies to drug distributors conducting sales (even no-cost sales) of dangerous drugs and terminal distributors conducting occasional wholesale sales in accordance with OAC [4729:5-3-09](#).

A drug distributor* license authorizes an entity to sell dangerous drugs at wholesale if **the entity ensures that the purchaser is appropriately licensed** under ORC 4729.51. The requirement that you must verify Ohio Board of Pharmacy licensure or exempt status pursuant to ORC [4729.60](#) is detailed in OAC [4729:6-3-04](#).

**A distributor of dangerous drugs includes the following license types: manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs and wholesale distributor of dangerous drugs (includes broker and virtual wholesaler).*

Additionally, OAC [4729:5-3-09](#) permits terminal distributors of dangerous drugs to conduct occasional wholesale sales under certain circumstances.

It is most likely that a drug distributor or terminal distributor is selling dangerous drugs or medical gases **to an Ohio business** (i.e., physician's office, nursing home, etc.) rather than making a sale directly to a licensed prescriber. Therefore, the business must be appropriately licensed. If the purchaser is a terminal distributor of dangerous drugs (TDDD), you must verify the licensure is appropriate to your sales. Refer to OAC [4729:6-3-04](#).

REMINDER: Dangerous drugs are defined in the Ohio Revised Code as any 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);
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, local anesthetic injectable products, insulin, and botulinum toxin (Botox) as well as controlled substances. See ORC [4729.01](#)(F).

IMPORTANT: This also includes drug samples.

Licensure can be verified using the Ohio's [eLicense system](#) or by downloading a [licensing roster](#) in a Microsoft Excel spreadsheet. The Ohio Board of Pharmacy also allows [URL parameters](#) to be used on the Roster Request page to quickly download an active roster list. Using these links will automatically trigger the roster list of your choice to automatically download upon the page loading.

The TDDD license must be one of the following:

Category II License: This licensee may possess, have custody or control of, and distribute prescription drugs that are **not** controlled substances. The license will be in the name of the facility/business to which the sales are made. It should NOT be a contingency license for another provider (i.e., license for Pharmacy name with %Nursing Home name on second line).

Limited Category II License: This licensee may only possess, have custody or control of, and distribute prescription drugs that are **not** controlled substances approved by a Medical Director. To view a licensee's approved drug list, please visit: <http://www.pharmacy.ohio.gov/Licensing/PublicDocuments.aspx>

Category III License: This licensee may possess, have custody or control of, and distribute prescription drugs, including controlled substances contained in Schedules I, II, III, IV, or V. The license will be in the name of the facility/business to which the sales are made. It should NOT be a contingency license for another provider (i.e., license for Pharmacy name with %Nursing Home name on second line).

Limited Category III License: This licensee may only possess, have custody or control of, and distribute prescription drugs, including controlled substances approved by a Medical Director. To view a licensee's approved drug list, please visit:

<http://www.pharmacy.ohio.gov/Licensing/PublicDocuments.aspx>

NOTE: Prescribers and business types are not exempt from licensure if they possess controlled substances or dangerous drugs used for compounding. For more information, please refer to the following guidance documents:

- Exemptions for Prescriber Practices (www.pharmacy.ohio.gov/prescriberTDDD)
- Exemptions for Non-Prescriber Practices (www.pharmacy.ohio.gov/NppTDDD)

Licensure Verification Rules

The Board's licensure verification rules can be accessed here:

- [Drug Distributors: Rule 4729:6-3-04 - Verification of licensure prior to sale or purchase.](#)
- [Terminal Distributors: Rule 4729:5-3-04 - Verification of licensure prior to sale or purchase.](#)

Definition of Sales (OAC 4729.01)

"Sale" or "sell" includes any transaction made by any person, whether as principal proprietor, agent, or employee, to do or offer to do any of the following: deliver, distribute, broker, exchange, gift or otherwise give away, or transfer, whether the transfer is by passage of title, physical movement, or both.

"Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

Notice for Third-Party Logistics Providers

A third-party logistics provider is exempt from licensure verification requirements if the licensee has access to documentation indicating the entity responsible for directing the sale or disposition of the drugs (e.g., virtual wholesaler, manufacturer, etc.) has complied with the license verification requirements of OAC [4729:6-3-04](#).

Requirements Prior to Sales to Terminal Distributors of Dangerous Drugs

Before a drug distributor (or terminal distributor conducting an occasional wholesale sale pursuant to [OAC 4729:5-3-09](#)) may sell or distribute dangerous drugs to any person in this state, the distributor (or terminal) shall conduct a documented query of a roster maintained by the board to determine if the purchaser is:

- (1) A terminal distributor of dangerous drugs. For a limited terminal distributor of dangerous drugs license, a drug distributor shall also review a current version of the licensee's drug list to ensure the purchaser is authorized to possess the drugs ordered.
- (2) A distributor of dangerous drugs. (**REMINDER:** A distributor of dangerous drugs includes the following license types: manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs and wholesale distributor of dangerous drugs (includes broker and virtual wholesaler).
- (3) Exempted from licensure in accordance with ORC [4729.541](#) (see next section for requirements).

Except for exempted facilities and persons, licensure verification is required prior to every sale. Exempted facilities and persons require verification to be completed annually.

Requirements Prior to Sales to Exempted Facilities and Persons

Here are the steps every drug distributor (or terminal distributor making occasional wholesale sales) must take to prior to selling dangerous drugs to a facility or person claiming an exemption from the Board's TDDD licensing law:

For Prescribers:

To confirm a purchasing prescriber meets the exemption criteria pursuant to section [4729.541](#) of the Revised Code, the drug distributor shall comply **with all the following**:

- (a) Provide the prescriber the requirements in Ohio law of when a prescriber is required to hold a license as a terminal distributor of dangerous drugs. This document can be accessed here: www.pharmacy.ohio.gov/PrescriberTDDD.
- (b) Verify the prescriber is appropriately licensed in this state. Licensure can be verified using the Ohio's [eLicense system](#).
- (c) Require the prescriber who claims an exemption to the terminal distributor of dangerous drug licensing requirement to attest in writing, which may include an electronic signature, that the prescriber meets the licensing exemptions in section [4729.541](#) of the Revised Code on an annual basis. The Board developed a sample attestation form, which can be accessed here: www.pharmacy.ohio.gov/WSattest.
- (d) Ensure that all attestations are maintained by the drug distributor for a period of three years after the sale or distribution of the dangerous drug.

For Other Exempted Entities and Persons (i.e., non-prescribers):

To confirm any other person purchasing dangerous drugs meets the exemption criteria pursuant to section [4729.541](#) of the Revised Code, the drug distributor shall comply with all the following:

(a) Provide the person the requirements in Ohio law of when a person is required to hold a license as a terminal distributor of dangerous drugs. This can be achieved by providing the language directly from ORC [4729.541](#) (A)(4) thru (A)(17) or this document: www.pharmacy.ohio.gov/NppTDDD

(b) Require the person who claims an exemption to the terminal distributor of dangerous drug licensing requirement to attest in writing, which may include an electronic signature, that the person meets the licensing exemptions in section [4729.541](#) of the Revised Code on an annual basis. The Board developed a sample attestation form, which can be accessed here: www.pharmacy.ohio.gov/WSattest.

(c) Ensure that all attestations are maintained by the drug distributor for a period of three years after the sale or distribution of the dangerous drug.