License Verification for Drug Distributors

Updated 3/29/2022

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 State of 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).

It is most likely that a drug 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 requires 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 Ohio Revised Code (ORC) 4729.01(F). NOTE: This 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 TDDD license must be one of the following:

**Category II License:** This licensee may possess, have custody or control of, and distribute prescription drugs (including medical oxygen and other medical grade gases) 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 (including medical grade gases) 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](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
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 document: www.pharmacy.ohio.gov/prescribertddd.

Sales to Exempted Facilities and Persons

OAC 4729:6-3-04 includes exemptions to the requirements that a facility or person possess a terminal distributor of dangerous drugs license. Here are the steps every drug distributor must take to confirm they are complying with the rule:

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 to prescribe dangerous drugs or drug therapy related devices in the course of the individual's professional practice.

(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; and

(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)(15).
(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; and

(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.

Please be advised that additional licensure exemptions in ORC 4729.541 for the following entities are set to take effect on April 12, 2021:

(14) With respect to injectable or nasally administered glucagon that may be possessed under sections 3313.7115, 3313.7116, 3314.147, 3326.60, and 3328.38 of the Revised Code, any of the following: the board of education of a city, local, exempted village, or joint vocational school district; a chartered or nonchartered nonpublic school; a community school established under Chapter 3314. of the Revised Code; a STEM school established under Chapter 3326. of the Revised Code; or a college-preparatory boarding school established under Chapter 3328. of the Revised Code;

(15) With respect to injectable or nasally administered glucagon that may be possessed under section 5101.78 of the Revised Code, any of the following: a residential camp, as defined in section 2151.011 of the Revised Code; a child day camp, as defined in section 5104.01 of the Revised Code; or a child day camp operated by any county, township, municipal corporation, township park district created under section 511.18 of the Revised Code, park district created under section 1545.04 of the Revised Code, or joint recreation district established under section 755.14 of the Revised Code.