



## Terminal Distributor Licensure Exemptions for Non-Prescriber Practices

Updated 8/24/2023

### **IMPORTANT UPDATE:**

- **Effective July 11, 2023, the following non-prescriber practices are exempt from licensure as a terminal distributor of dangerous drugs:**
  - A person who possesses nitrous oxide (including nitrogen) for use as a direct ingredient in food pursuant to 21 C.F.R. 184.1545 or for testing or maintaining a plumbing or heating, ventilation, and air conditioning system.
  - A person who possesses medical oxygen, sterile water, or sterile saline for direct administration to patients or for the purpose of installation or maintenance of home medical equipment, as defined in section 4752.01 of the Revised Code. **NOTE: This may apply to institutional facilities such as nursing homes and residential care facilities. This may also apply to non-emergent patient transport companies that possess oxygen, and no other drugs, for direct administration.**

### **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. Terminal distributors of dangerous drugs include, but are not limited to, hospitals, pharmacies, EMS organizations, laboratories, nursing homes, and prescriber practices (under certain conditions).

**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.

**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.

### **What are the requirements for prescriber practices?**

This guidance applies to all *non-prescriber practices* that may be exempted from licensure as a TDDD. For more information on prescriber practice requirements, visit:

[www.pharmacy.ohio.gov/prescriberTDDD](http://www.pharmacy.ohio.gov/prescriberTDDD).

### **What are the TDDD licensure exemptions for non-prescriber practices?**

***IMPORTANT: None of the exemptions that are starred (\*) apply if the entity possesses controlled substances or dangerous drugs used for compounding.***

The following are the licensure exemptions for non-prescriber practices [see OAC [4729.541](#)(A)(4)(17)]:

*\*(4) An individual who holds a current license, certificate, or registration issued under Title XLVII of the Revised Code and has been certified to conduct diabetes education by a national certifying body specified in rules adopted by the state board of pharmacy under section [4729.68](#) of the Revised Code, but only with respect to insulin that will be used for the purpose of diabetes education and only if diabetes education is within the*

*individual's scope of practice under statutes and rules regulating the individual's profession;*

*\*(5) An individual who holds a valid certificate issued by a nationally recognized S.C.U.B.A. diving certifying organization approved by the state board of pharmacy under rules adopted by the board, but only with respect to medical oxygen that will be used for the purpose of emergency care or treatment at the scene of a diving emergency;*

*\*(6) With respect to epinephrine autoinjectors that may be possessed under section [3313.7110](#), [3313.7111](#), [3314.143](#), [3326.28](#), or [3328.29](#) 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;*

*\*(7) With respect to epinephrine autoinjectors that may be possessed under section [5101.76](#) 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;*

*\*(8) With respect to epinephrine autoinjectors that may be possessed under Chapter 3728. of the Revised Code, a qualified entity, as defined in section [3728.01](#) of the Revised Code;*

*\*(9) With respect to inhalers that may be possessed under section [3313.7113](#), [3313.7114](#), [3314.144](#), [3326.30](#), or [3328.30](#) 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;*

*\*(10) With respect to inhalers that may be possessed under section 5101.77 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;*

*\*(11) With respect to naloxone that may be possessed under section 2925.61 of the Revised Code, a law enforcement agency and its peace officers;*

*\*(12) With respect to naloxone that may be possessed under section 4729.514 of the Revised Code for use in emergency situations or for personally furnishing supplies of naloxone, a service entity, as defined in that section;*

*\*(13) 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;*

*\*(14) 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;*

*\*(15) A person who possesses nitrous oxide for use as a direct ingredient in food pursuant to 21 C.F.R. 184.1545 or for testing or maintaining a plumbing or heating, ventilation, and air conditioning system; [NOTE: THIS PROVISION IS NOT IN EFFECT UNTIL 10/3/23, BUT THE BOARD HAS ISSUED A RESOLUTION HONORING SUCH EXEMPTIONS EFFECTIVE 7/11/23]*

*\*(16) A person who possesses medical oxygen, sterile water, or sterile saline for direct administration to patients or for the purpose of installation or maintenance of home medical equipment, as defined in section 4752.01 of the Revised Code; [NOTE: THIS PROVISION IS NOT IN EFFECT UNTIL 10/3/23, BUT THE BOARD HAS ISSUED A RESOLUTION HONORING SUCH EXEMPTIONS EFFECTIVE 7/11/23]*

*(17) A facility that is owned and operated by the United States department of defense, the United States department of veterans affairs, or any other federal agency.*

***IMPORTANT: None of the exemptions that are starred (\*) apply if the entity possesses controlled substances or dangerous drugs used for compounding.***

### **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](#).

### **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 an exemption listed above.

### **I obtained a license for my location, 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, but I am an exempted entity, 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](http://www.pharmacy.ohio.gov/WSattest). The Board does not certify an exemption status; therefore, exemption forms **should not be submitted to the Board**. 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>.