

ODA Guide: Terminal Distributor of Dangerous Drugs (TDDD) License Refresher and FAQ

ODA has received a number of questions from members concerning TDDDs, when they are required, and what to expect concerning inspections. The below refresher and frequently asked question document was compiled to assist our members with these questions, and to learn when to reach out if they need additional assistance.

Please review this document and related links [here](#) on the Pharmacy Board's website. You will find guidance on TDDD licensure, exemptions, and compounding. You can also find Pharmacy Board inspection information and guidance [here](#).

Should you have additional questions about TDDD requirements or how they affect your practice, please reach out directly to ODA staff for assistance.

What is a TDDD?

TDDD licenses are required by Ohio law for pharmacies and other various medical facilities that purchase/possess/or distribute dangerous drugs including controlled substances.¹ Although the law applies to hospitals, pharmacies, EMS organizations, laboratories and nursing homes, physician practices may also be required to maintain a TDDD for more specific circumstances, in particular for compounding dangerous drugs, or for distribution of controlled substances.

Dangerous drugs are defined in the Ohio Revised Code as any drug that (1) requires a prescription, (2) bears on the label a Federal Legend, (3) is intended for injection into the human body, (4) is a biological product. This includes antibiotics, vaccines, local anesthetic injectable products, insulin, botulinum toxin and controlled substances.²

When does a prescriber need to obtain a TDDD license? Are there exemptions?

Ohio law generally prohibits manufacturers and distributors of dangerous drugs from distributing to any entity that does not hold a TDDD.³ Although prescribers are generally exempt, prescribers are required

¹ [R.C. 4729.51](#)

² [R.C. 4729.01](#)

³ [R.C. 4729.51](#)

to obtain a license if they are (1) compounding drugs, OR (2) distributing controlled substances.⁴ If you are a prescriber owned practice that does not conduct either of the above, Ohio law does not require your practice to obtain a TDDD.

To the extent that your practice may be exempt, you may wish to review the Pharmacy Board TDDD guidance page linked at the top of this guide. If you have additional questions about exemptions, please contact ODA staff for assistance.

I understand that maintaining a TDDD subjects my practice to inspections. What should I expect?

By obtaining a TDDD, prescriber practices are subject to inspections by the Pharmacy Board to ensure that TDDD license holders are complying with all tangential requirements of Ohio law (e.g. drug storage, record keeping requirements, etc.).⁵ The law also provides that these inspections can be conducted without notice.⁶ To better understand Pharmacy Board inspections for TDDD licensees, please review the guide on the Board's website [here](#), or linked above at the top of this document.

It should be noted that unannounced inspections apply to all pharmacy board licensees, not only physicians. ODA has received concerns from its members as to instances of unannounced inspections by Board inspectors that created unreasonable burdens on prescriber practices with TDDDs. Certainly a pharmacy inspection with no patients can accommodate an unannounced inspection far more appropriately than a physician practice that has active patients on location when the inspector arrives. We continue to work with regulators to ensure the inspection process is reasonable for prescriber practices, and that inspectors are mindful of the responsibilities of practicing physicians.

Practical FAQs for Dermatology Practices:

Q: Our prescriber-owned practice is eligible for exemption. Can we still receive samples of non-controlled medications that are helpful to our patients? (Other questions with same answer: Can we still order lidocaine? Can we still stock antibiotics in our office? Can we still dispense compounded prescriptions that are NOT compounded or packaged inside my office? Can we still order gases like oxygen or nitrous oxide? Can we still order liquid nitrogen?)

A: Yes, however, you may want to check with your vendors / distributors to make sure they will accept an exemption attestation. Further, according to the state board of pharmacy guide, some drug distributors (manufacturers, wholesalers, etc.) may only sell to licensed terminal distributors, even if the

⁴ [R.C. 4729.541](#)

⁵ [R.C. 3719.13](#)

⁶ [O.A.C 4729:5-3-03](#)

prescriber-owned entity is exempt. State and Federal laws provide definitions of what constitutes controlled substances.⁷

Q: I'm exempt from maintaining a TDDD, how do I let vendors know about my exempt status?

The state board of pharmacy has provided an exemption attestation form that may be used. You can find that form [here](#), or under "Forms" in the Board webpage link at the beginning of this guide.

Many vendors also have their own forms that they will have prescriber-owned practices sign annually to verify the practice's exemption status. (e.g. the vendor representative with drug samples may have an exemption attestation form on their iPad they will need you to sign). Some vendors such as medical suppliers may have their own process to document a prescriber owned practice's exempt status, see below for an example of Henry Schein.

Q: I buffer my lidocaine with sodium bicarbonate. Do I need to maintain a TDDD?

Yes, if you buffer your lidocaine, you need a TDDD license as long as the Pharmacy Board defines buffering of lidocaine as office-based compounding. Compounding medications in your office requires a TDDD license, and is an exception to the TDDD exemption list. (Note, you can still dispense products that are compounded off-site by a vendor, such as SKNV as one example).

Q: Medical supplier as an example: I order non-controlled prescription products from Henry Schein (example). How can I make sure I can still order from my medical supplier?

Your medical supplier may have a documentation process to attest to your exemption status. For example, Henry Schein may request:

Example of documentation and action needed for Henry Schein (see below for letter template):

- Document the reason for exemption from the Ohio TDDD license (e.g. "prescriber owned practice", and exemption number from 2023 guide linked at the top of this guide).
- The prescriber's name on the account (Name and Ohio medical license number)
- The shipping address and Henry Schein location account number of the exempt prescriber office location
- The billing address and Henry Schein billing account number of the exempt prescriber office location.
- Sign and date the letter
- Email the letter to Ohio.TDDD@henryschein.com

Additionally, for Henry Schein:

You will also need to complete the OH Attestation online on the Henry Schein website for all accounts. To complete the Ohio attestation online, you must be logged into your Henry Schein account and go to

⁷ [R.C. 3719.01](#); [US Drug Enforcement Agency Controlled Substance Schedules](#)

My Account, Verifications, then Ohio TDDD Attestation Forms. The system will automatically prompt you to complete the form if you are purchasing online.

Sample Henry Schein Letter for put on Practice Letterhead:

MM/DD/2024

To Whom It May Concern (Ohio.TDDD@henryschein.com),

PracticeName has prescriber-owned practice location(s) that is/are exempt from requiring a Terminal Distributor of Dangerous Drugs (TDDD) License from the state board of pharmacy in Ohio.

This practice falls under exemptions listed in Ohio Revised Code Section 4729.541 | Exemption from licensure as terminal distributor of dangerous drugs.

<https://codes.ohio.gov/ohio-revised-code/section-4729.541>

For clarity, the prescriber owned practice location(s) also fall under Exemption #2 in latest update (8/2023) of the pharmacy board's guide for Terminal Distributor Licensure of Prescriber Practices: <https://www.pharmacy.ohio.gov/documents/licensing/tddd/general/terminal%20distributor%20licensure%20of%20prescriber%20practices.pdf>

Exempt location(s) include:

- **PracticeAddress1** (Henry Schein account: #####, Billing Account: #####)

The prescriber affiliated with these exemptions is Dr. **PrescriberFirst PrescriberLast, MD/DO** (Ohio License number: **35.#####**)

We have also attached exemption forms from the state board of pharmacy template available here: <https://www.pharmacy.ohio.gov/documents/licensing/tddd/forms/general/tddd%20exemption%20attestation%20form.pdf>

Our exempt practice has also filled out the form on the Henry Schein portal under "Ohio TDDD Attestation Form" for each exempt practice location listed above.

Thank you,

Dr. PrescriberFirst PrescriberLast, MD/DO