



Special Notice: Xylazine Scheduling & Licensee Compliance

Issued 4/17/2023

On March 29, 2023, the Ohio Board of Pharmacy classified xylazine as a Schedule III Controlled Substance via [emergency rule](#). To ensure that licensees remain in compliance with Ohio Law, the Board is issuing temporary enforcement waivers for veterinary clinics, terminal distributors, and drug distributors starting on page 3 of this document.

The Board also put together a set of [frequently asked questions](#), which start on page 9 of this document.

For questions regarding the emergency scheduling of xylazine, please review this document. 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>.

Important Terms:

Terminal Distributor of Dangerous Drug: A Terminal Distributor of Dangerous Drugs (TDDD) license allows a business entity to purchase, possess, administer, and/or distribute dangerous drugs to patients at a specific location. A terminal distributor of dangerous drugs includes hospitals, pharmacies, EMS organizations, veterinary clinics, animal shelters, laboratories, nursing homes, and prescriber practices. While not every veterinary clinic is required to be licensed by the Board (see [exemptions](#)), a TDDD license is required for controlled substance medications.

Drug Distributor: A Distributor of Dangerous Drugs license allows a business entity to purchase, possess, and/or distribute dangerous drugs at wholesale. A drug distributor includes manufacturers of dangerous drugs, outsourcing facilities, third-party logistics

providers, repackagers of dangerous drugs and wholesale distributors of dangerous drugs (including brokers and virtual wholesalers).

Category “2”: A category of TDDD or drug distributor license that allows the licensee to possess, have custody or control of, and distribute prescription drugs (including medical oxygen and other medical grade gases) that are not controlled substances.

Category “3”: A category of TDDD or drug distributor license that allows the licensee to possess, have custody or control of, and distribute prescription drugs, including controlled substances contained in Schedules I, II, III, IV, or V.

Waivers for Terminal Distributors of Dangerous Drugs

Ohio Requirement	Enforcement Waiver	Guidance
Category 3 - Terminal Distributor Licensure to Possess Controlled Substances <i>Any veterinary clinic in the State of Ohio that possesses controlled substances must obtain a Category 3 license as a Terminal Distributor of Dangerous Drugs (ORC 4729.541[D][2]).</i>	Veterinary clinics that possess xylazine who were previously exempted from licensure as a terminal distributor of dangerous drugs have until June 30, 2023, to obtain a Category 3 Terminal Distributor License (Terminal - Facility - Veterinary Medicine - Category 3). To not disrupt patient care, those veterinarians without an existing terminal distributor license may continue to purchase xylazine in this state until June 30, 2023.	Veterinary clinics have until June 30, 2023, to obtain a Category 3 Veterinary Facility License. Veterinary clinics that do not obtain a terminal distributor license by June 30, 2023, will not be permitted to continue possessing and using xylazine. The cost of a 2-year license is \$120.00. For more information on applying for a license, visit: www.pharmacy.ohio.gov/VetApplyX

Controlled Substance Inventory Requirements <i>When a drug is added to the schedule of controlled substances by state or federal law, rule or regulation, a terminal distributor shall complete an inventory pursuant to this rule of all stocks of such drug or compound no later than ten days of the drug or compound being added to the schedule. (OAC 4729:53-07 [E])</i>	Terminal distributors, such as veterinary facilities and animal shelters, that possess xylazine have <u>thirty days (4/28/23)</u> to complete the required inventory.	For more information on the requirements for conducting a controlled substance inventory, please see: -Page 22 of the Veterinary Facility Inspection Guide: www.pharmacy.ohio.gov/vetinspect -Page 27 of the Animal Shelter Inspection Guide: www.pharmacy.ohio.gov/ASinspect
All Other Controlled Substance Requirements	Terminal distributors, such as pharmacies, veterinary facilities, and animal shelters, that possess xylazine have <u>thirty days (4/28/23)</u> to come into compliance with all other controlled substance requirements.	This applies to requirements relating to record keeping, security, and drug disposal. For more information on the requirements for controlled substances, please see: -The Veterinary Facility Inspection Guide: www.pharmacy.ohio.gov/vetinspect -The Animal Shelter Inspection Guide: www.pharmacy.ohio.gov/ASinspect

Waivers for Drug Distributors*

**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).*

Ohio Requirement Waiver		Guidance
Category 3 - Drug Distributor Licensure to Sell Controlled Substances <i>Any entity engaged in the wholesale distributor of controlled substances must obtain a Category 3 license as a Drug Distributor (ORC 4729.52).</i>	Drug distributors (wholesaler, manufacturer, 3PL, outsourcing facility, repackager) that sell or facilitate the sale of xylazine in this state and currently possess a Category 2 Drug Distributor License, have until <u>June 30, 2023</u>, to obtain a Category 3 Drug Distributor License. To not disrupt patient care, those with an existing Category 2 license may continue to sell xylazine in this state until <u>June 30, 2023</u>. Additionally, the Board hereby waives the criminal records check	Drug distributors with a Category 2 Drug Distributor License may continue to sell xylazine into the state until <u>June 30, 2023</u>. This allows drug distributors to upgrade their license during the renewal period that begins in May 2023 and only pay one fee. Distributors who seek to continue distribution of xylazine into Ohio must obtain a Category 3 Drug Distributor license by <u>June 30, 2023</u>. For more information on changing your category of license, the Board developed the following guidance for drug distributors: www.pharmacy.ohio.gov/WSupplyX

	requirements for any drug distributor updating their license by <u>June 30, 2023.</u>	
Controlled Substance Inventory Requirements <i>When a drug is added to the schedule of controlled substances by state or federal law, rule or regulation, a drug distributor shall complete an inventory pursuant to paragraph (A) of this rule of all stocks of such substance no later than ten days after the drug is added to the schedule. (OAC 4729:6-3-06 [D])</i>	Drug distributors that possess xylazine have <u>thirty days (4/28/23)</u> to complete the required inventory.	For additional information on controlled substance inventories conducted by drug distributors, see OAC 4729:6-3-06.

Suspicious Order and Customer Reporting <i>Drug distributors shall design and operate a system to identify and report suspicious orders by customers for reported drugs.</i> (OAC 4729:6-3-05 [C])	All drug distributors shall begin reporting suspicious orders and customers no later than <u>June 30, 2023.</u>	For more information on reporting suspicious order and customer due diligence, visit: www.pharmacy.ohio.gov/suspicious.
Reporting Wholesale Sales to the Ohio Automated Rx Reporting System (ORC 4729.78)	All drug distributors shall begin reporting the wholesale sales of xylazine no later than <u>June 30, 2023.</u>	For more information on the reporting of wholesale sales to the Ohio Automated Rx Reporting System, visit: www.pharmacy.ohio.gov/wholesalereport.
License Verification and Sales	Drug distributors may engage in the sale of xylazine to veterinarians who had been previously exempted from licensure <u>until June</u>	The Board is hereby waiving the verification requirements for previously exempted veterinary practices who seek to purchase xylazine until <u>June 30, 2023.</u> To sell to a previously exempted veterinary practice (or practice holding a Category 2

	30, 2023. Distributors must notify the veterinary facility of the requirements that they obtain a Category 3 Terminal Distributor of Drugs prior to <u>June 30, 2023.</u>	license), the distributor must notify the veterinary practice in writing (may be an electronic notification) of the requirement to obtain a Category 3 Terminal Distributor of Dangerous Drugs license by the <u>June 30, 2023,</u> deadline. While not required, a copy of this notice meets the notification requirement of this wavier.
All Other Controlled Substance Requirements	Drug distributors that possess xylazine have <u>thirty days (4/28/23)</u> to come into compliance with all other controlled substance requirements.	This applies to requirements relating to record keeping, security, and drug disposal. For more information on the requirements for controlled substances, please review the following rule chapters: ▪ OAC 4729:6-3 (Applicable to all drug distributors) ▪ OAC 4729:6-5 (Applicable to wholesale distributors) ▪ OAC 4729:6-6 (Applicable to virtual wholesale distributors) ▪ OAC 4729:6-7 (Applicable to brokers) ▪ OAC 4729:6-7 (Applicable to brokers) ▪ OAC 4729:6-8 (Applicable to manufacturers)

		▪ OAC 4729:6-9 (Applicable to repackagers) ▪ OAC 4729:6-10 (Applicable to outsourcing facilities) ▪ OAC 4729:6-11 (Applicable to third party logistics providers)
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Frequently Asked Questions

Q1) Do I need a DEA registration to maintain a supply of xylazine in my practice?

A1) No. Currently, the scheduling of xylazine is a state action that does not require a veterinarian to obtain a federal controlled substance registration from the U.S. Drug Enforcement Administration. In order to be able to order xylazine from a licensed wholesaler, the veterinary practice will need to obtain a Category 3 Terminal Distributor of Dangerous Drugs license by **June 30, 2023**. For more information on obtaining a TDDD license can be accessed here: www.pharmacy.ohio.gov/VetApplyX.

Q2) Do I need a DEA registration to engage in the wholesale distribution of xylazine in Ohio?

A2) No. Currently, the scheduling of xylazine is a state action that does not require a wholesaler or other drug distributor to obtain a federal controlled substance registration from the U.S. Drug Enforcement Administration. In order to be able to sell xylazine at wholesale,

the facility will need to obtain a Category 3 Drug Distributor license. For more information on changing your category of license, the Board developed the following guidance:

www.pharmacy.ohio.gov/WSupplyX.

REMINDER: Drug distributors upgrading their licenses due to the recent scheduling of xylazine, may wait until the license renewal period that begins in May 2023.

Q3) Is a veterinarian able to personally furnish xylazine to clients for administration to animals?

Yes. A veterinarian may personally furnish (a legal term for prescriber dispensing) a supply of xylazine for client administration. To personally furnish xylazine, a veterinarian must affix a container to drug that contains all of the following:

- (1) The name and address of the veterinarian;
- (2) The name of the patient for whom the drug is intended, which shall include the name of the owner and identification of the animal or animals;
- (3) Name and strength of the dangerous drug;
- (4) Directions for use; and
- (5) Date furnished.

NOTE: Once Xylazine is personally furnished by a veterinarian to a patient (owner), it is not subject to Board of Pharmacy licensure requirements.

REMINDER: A veterinarian shall be required to document the final association of a controlled substance dangerous drug with a patient/client using positive identification.

For more information on personally furnishing, see the Personally Furnishing section of the Board's [Veterinary Clinic Inspection Guide](#) (starting on Page 35).