



Minutes of the March 28, 2023
Emergency Meeting of the State of Ohio Board of Pharmacy

Tuesday March 28, 2023

2:00 p.m. Pursuant to the Emergency Meeting Notice issued on Monday, March 27, 2023, the State of Ohio Board of Pharmacy convened an Emergency Board Meeting in the Hearing Room, 17th Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio. The State of Ohio Board of Pharmacy convened for the purpose of considering the placement of Xylazine as a Schedule III Substance, with the following members present:

Trina Buettner, RPh, *Vice President/Presiding*; Victor Goodman, *Public Member*; Mindy Ferris, RPh; Jason George, RPh; TJ Grimm, RPh; Jeff Huston, RPh; and Christine Pfaff, RPh.

Also present were Steven Schierholt, *Executive Director*; Sharon Maerten-Moore, *Chief Legal Counsel*; and Kathryn Lewis, *Legal Administrator*.

2:00 p.m. Pursuant to section 3719.44 of the Ohio Revised Code, Mr. McNamee led a discussion on the placement of Xylazine as a Schedule III Controlled Substance, including the consideration of the following eight (8) criteria: (1) The actual or relative potential for abuse; (2) The scientific evidence of the pharmacological effect of the substance; (3) The state of current scientific knowledge regarding the substance; (4) The history and current pattern of abuse; (5) The scope, duration, and significance of abuse; (6) The risk to the public health; (7) The potential of the substance to produce psychic or physiological dependence liability; and (8) Whether the substance is an immediate precursor.

R-2023-0329 Ms. Ferris moved that the Board request that Governor DeWine issue an order in accordance with division (G)(1) of section 119.03 for the immediate adoption of an amendment to rule 4729:9-1-03 of the Administrative Code to classify any material, compound, mixture, or preparation that contains xylazine as a schedule III depressant. Ms. Ferris further moved that the Board authorize the filing of an amendment to rule 4729:9-1-03 of the Administrative Code with the Common Sense Initiative and the Joint Committee on Agency Rule Review to classify as a schedule III depressant any material, compound, mixture, or preparation that contains xylazine. The motion was seconded by Mr. Huston and approved by the Board: Yes-6, No-0.

2:17 p.m. To ensure that licensees remain in compliance with Ohio Law upon the classification of Xylazine as a Schedule III Controlled Substance, Mr. McNamee presented temporary enforcement waivers for Terminal Distributors of Dangerous Drugs to the Board for approval.



R-2023-0330 Mr. Huston moved that the Board approve the temporary enforcement waivers for Terminal Distributors of Dangerous Drugs. The motion was seconded by Ms. Ferris and approved by the Board: Yes-6, No-0. The following temporary enforcement waivers for Terminal Distributors of Dangerous Drugs were approved by the Board:

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 <u>June 30, 2023</u>, 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 <u>June 30, 2023</u>.	Veterinary clinics have until <u>June 30, 2023</u>, 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</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

<i>schedule. (OAC 4729:5-3-07 [E])</i>		
All Other Controlled Substance Requirements	Terminal distributors, such as 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

2:20 p.m.

To ensure that licensees remain in compliance with Ohio Law upon the classification of Xylazine as a Schedule III Controlled Substance, Mr. McNamee presented temporary enforcement waivers for Drug Distributors to the Board for approval.

R-2023-0331

Mr. Grimm moved that the Board approve the temporary enforcement waivers for Drug Distributors. The motion was seconded by Mr. George and approved by the Board: Yes-6, No-0. The following temporary enforcement waivers for Drug Distributors were approved by the Board:

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	Drug distributors (wholesaler, manufacturer, 3PL, outsourcing facility, repackager) that sell or facilitate the sale	Drug distributors with a Category 2 Drug Distributor License may continue to sell xylazine into the state until <u>June 30, 2023</u> .

<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>	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 requirements for any drug distributor updating their license by <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/WSapplyX
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</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.

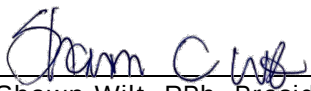
<i>is added to the schedule. (OAC 4729:6-3-06 [D])</i>		
Suspicious Order and Customer Reporting <i>Drug distributors shall design and operate a system to identify and report suspicious orders by customers for reported drugs. (OAC 4729:6-3-05 [C])</i>	All drug distributors shall begin reporting suspicious 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 (OAC 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 30, 2023</u> . 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> .	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 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	This applies to requirements relating to record keeping, security, and drug disposal.

	come into compliance with all other controlled substance requirements.	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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R-2023-0332

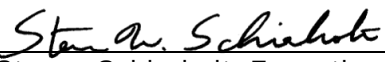
Ms. Ferris moved to adjourn the March 28, 2023, State of Ohio Board of Pharmacy Emergency Meeting. The motion was seconded by Mr. Grimm and approved by the Board: Yes-6, No-0.

2:24 a.m. The Emergency Board Meeting Adjourned.



Shawn Wilt, RPh, President

Date: 04/04/2023



Steven Schierholt, Executive Director

Date: 04/04/2023