



MIKE DEWINE
GOVERNOR
STATE OF OHIO

Executive Order 2023-08D

The Emergency Adoption of Rule 4729:9-1-03 of the Ohio Administrative Code by the State of Ohio Board of Pharmacy

WHEREAS, my first action as Governor was to sign Executive Order 2019-01D creating RecoveryOhio in order to combat the worst drug epidemic in my lifetime. Just this month, Administrator Milgram of the Drug Enforcement Administration (DEA) issued a public safety alert stating, “[x]ylazine is making the deadliest drug threat our country has ever faced, fentanyl, even deadlier”; and

WHEREAS, although approved only for veterinary use, xylazine (also known as “Tranq” or “Tranq Dope”) is a non-opioid with an increasing presence as an adulterant, often in combination with opioids, in the illicit drug supply. Adulterants are frequently added to clandestine drugs to (1) increase or decrease a drug’s effects; or (2) increase a drug’s resale value. Following these trends, the earliest reports of xylazine indicate that it was being used to enhance the effects of heroin; and

WHEREAS, both isolated and in combination with other drugs, xylazine is implicated as a cause or contributing cause of death in the United States. According to the DEA: (1) the emergence of xylazine across the United States appears to be following the same path as fentanyl, beginning in the Northeast before spreading to the South and then working its way into drug markets westward; and (2) its low cost contributes, in part, to xylazine’s expanded presence in the nation’s illegal drug supply; and

WHEREAS, the presence of xylazine has been frequently found by crime labs in Ohio with some estimating that 25 to 30 percent of drug evidence containing fentanyl also contain xylazine; and

WHEREAS, the Ohio Department of Health reports that there have been 248 unintentional drug overdoses involving Xylazine since 2019, however not all jurisdictions conduct routine testing for xylazine in toxicology. Therefore, the prevalence of xylazine misuse is likely underreported; and

WHEREAS, when xylazine is used in combination with an opioid (e.g., heroin or fentanyl), xylazine may worsen respiratory depression in the event of a drug overdose. Because

xylazine is not an opioid, naloxone is not known to be effective at reversing overdoses caused by xylazine and there is no known antidote, or reversal agent, for xylazine overdose in humans; and

WHEREAS, xylazine may be accompanied by skin ulcers with wounds that excrete pus, have decaying tissue and bacterial infections, which can lead to amputation at higher rates than those who inject other drugs. See Figures 1 and 2. Heroin and xylazine have some similar pharmacological effects including bradycardia, hypotension, central nervous system depression, and respiratory depression; and



Figures 1 and 2. Skin ulcers caused by xylazine. Malayala SV, Papudesi BN, Bobb R, Wimbush A. Xylazine-Induced Skin Ulcers in a Person Who Injects Drugs in Philadelphia, Pennsylvania, USA. *Cureus*. 2022 Aug 19;14(8):e28160. doi: 10.7759/cureus.28160. PMID: 36148197; PMCID: PMC9482722.

WHEREAS, the State of Ohio Board of Pharmacy (“Board of Pharmacy”) has considered the eight factors in Section 3719.44 of the Ohio Revised Code to add a previously unscheduled substance to schedule III. The eight factors include: (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) risk to public health; (7) potential of the substance to produce psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor; and

WHEREAS, in accordance with the previous finding, the Board of Pharmacy has determined pursuant to Section 3719.44 that xylazine should be added to schedule III as a controlled substance depressant; and

WHEREAS, Section 119.03(G) of the Ohio Revised Code authorizes the Governor, on the request of a State agency, to suspend the normal rule making procedures with respect to specific rules when an emergency exists necessitating the immediate adoption, amendment, or rescission of such rules. When such a determination is made, the agency may immediately adopt, amend, or rescind such rules, but the rules are only valid for one hundred eighty (180) days; and

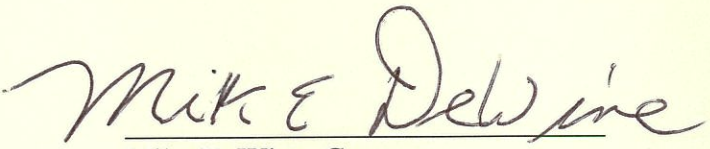
WHEREAS, the Board of Pharmacy has requested a determination whether an emergency exists that requires 4729:9-1-03 on an emergency basis and that would therefore permit the Board of Pharmacy, pursuant to Sections 119.03(G) and 3719.44 of the Ohio Revised Code, to immediately adopt this rule.

NOW THEREFORE, I, Mike DeWine, Governor of the State of Ohio, have determined, upon the request of the Board of Pharmacy, that an emergency exists requiring the immediate adoption of rule 4729:9-1-03 of the Ohio Administrative Code.

Further, I hereby order that the procedures prescribed by Section 119.03 of the Ohio Revised Code with respect to the adoption or amendment of the specified rule be suspended and that the Board of Pharmacy be permitted to adopt the rule immediately by filing it electronically with the Secretary of State, the Director of the Legislative Service Commission, and the Joint Committee on Agency Rule Review ("JCARR").

Furthermore, I hereby order that this Executive Order be filed in electronic form with the Board of Pharmacy, the Secretary of State, the Director of the Legislative Service Commission, and JCARR.

I signed this Executive Order on March 28th, 2023, in BOWLING GREEN, Ohio, and it will expire one hundred and eighty (180) days from the effective date of the emergency rule, or upon the adoption of the rule through the normal JCARR process, whichever is sooner.


Mike DeWine, Governor

ATTEST:

Frank LaRose, Secretary of State

