

NOTICES

DEPARTMENT OF HEALTH

Temporary Scheduling of Substance; Xylazine as a Schedule III Controlled Substance

[53 Pa.B. 3031]

[Saturday, June 3, 2023]

The Acting Secretary of Health (Secretary) of the Department of Health (Department) is issuing this final order temporarily scheduling Xylazine which is not currently listed in any schedule of The Controlled Substance, Drug, Device and Cosmetic Act (act) (35 P.S. §§ 780-101—780-144). This final order will place Xylazine in Schedule III subject to the limitations outlined as follows. The Secretary is taking this action because the scheduling of Xylazine in this Commonwealth on a temporary basis is necessary to avoid an imminent hazard to public safety.

On April 12, 2023, under section 3(d)(4) of the act (35 P.S. § 780-103(d)(4)), the Secretary transmitted to the Attorney General for review, a copy of the notice of intent to issue a final order. The Attorney General's Office agreed in writing that the temporary scheduling of Xylazine as a Schedule III controlled substance under the act was appropriate. The Secretary's notice of intent was published at 53 Pa.B. 2270 (April 22, 2023).

Under the act, a formal order may not be issued before the expiration of 14 days after both:

- (i) The date of publication in the *Pennsylvania Bulletin* of the proposed notice of the intention to issue a final notice and the grounds upon which the order is to be issued.
- (ii) The date the Secretary transmitted the notice to the Attorney General.

This formal order temporarily scheduling Xylazine as a Schedule III controlled substance is effective for 1 year from the date of publication of this final order in the *Pennsylvania Bulletin*. The Secretary may, during proceedings to permanently control Xylazine under section 3(d)(2) of the act, extend the temporary scheduling for up to 1 additional year.

Background

Although approved only for veterinary use, Xylazine is a nonopioid 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. 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 United States Drug Enforcement Administration: (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.

Xylazine use may be accompanied by skin ulcers with wounds that excrete puss, have decaying tissue and bacterial infections, which can lead to amputation at higher rates than those who inject other drugs. Heroin and Xylazine have some similar pharmacological effects including bradycardia, hypotension, central nervous system depression and respiratory depression. When used in combination with an opioid, 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.

Xylazine is not currently scheduled in the Commonwealth. In 2021, 30 counties across this Commonwealth saw cases where Xylazine contributed to individual deaths. In 2021, Xylazine contributed to 575 overdose deaths in this Commonwealth, a significant increase from 377 in 2020. Further, Philadelphia reported that 90% of street opioid samples in 2021 contained Xylazine. Because Xylazine poses a substantial risk to the residents of this Commonwealth, the Secretary has determined to schedule it as a Schedule III controlled substance on a temporary basis under section 4(3) of the act (35 P.S. § 780-104(3)). In doing so, the Secretary is acting to protect the residents of this Commonwealth. Substances in Schedule III are those that have a potential for abuse less than those listed in Schedules I and II; a well-documented and currently accepted medical use in the United States; and abuse may lead to moderate or low physical dependence or high psychological dependence.

Legal Authority and Action

Under section 3 of the act, the Secretary shall control all substances listed in Schedules I—V of the act. Under section 3(d) of the act, the Secretary is authorized to schedule any substance on a temporary basis to avoid an imminent hazard to public safety. When determining whether a substance poses an imminent hazard to public safety, the Secretary is required to consider: (1) the substance's history and current pattern of abuse; (2) the substance's scope, duration and significance of its abuse; (3) the risk to the public health; and (4) whether the substance is controlled under Federal law. When a substance is already controlled under Federal law, the Secretary is not required to take the remaining factors into consideration.

In addition, the Secretary is authorized under section 3(d) of the act to schedule on a temporary basis a substance under one of the schedules in section 4 of the act or 28 Pa. Code §§ 25.72 and 25.75 (relating to schedules of controlled substances; and paregoric) and if no exception or approval is in effect for the substance under section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. § 355).

In taking this action, the Secretary has considered: (1) that Xylazine has a documented, acceptable and important use in veterinary medicine, however, it currently is not approved for legitimate use by humans in the United States; (2) that Xylazine, both isolated and in combination with other drugs, is a cause or contributing cause of an increasing number of deaths in this Commonwealth; (3) the rise of Xylazine as a common adulterant in the drug supply; and (4) Naloxone and other reversal agents' lack of effectiveness in the event of an overdose involving Xylazine. Accordingly, although not currently scheduled at the Federal level, the Secretary has determined that Xylazine is a dangerous hazard to public safety in this Commonwealth.

Accordingly, the Secretary controls Xylazine as a Schedule III substance except when it is used in any of the following manners:

1. Dispensing or prescribing for, or administration to, a nonhuman species of a drug containing Xylazine that has been approved by the Secretary of Health and Human Services under section 512 of The Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 360b).
2. Dispensing or prescribing for, or administration to, a nonhuman species that is permissible under section 512(a)(4) of The Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 360b(a)(4)).
3. The manufacturing, distribution or use of Xylazine as an active pharmaceutical ingredient for manufacturing an animal drug approved under section 512 of The Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 360b or issued an investigation use exemption under subsection (j) of § 512.)
4. The manufacturing, distribution or use of a Xylazine bulk chemical for pharmaceutical compounding by licensed pharmacists or veterinarians.
5. Another use approved or permissible under The Federal Food, Drug, and Cosmetic Act.

For purposes of this temporary scheduling, Xylazine means any of the following substances, including their salts, isomers and salts of isomers whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

- (1) Xylazine.
- (2) Xylazine-M (2,6-Mich dimethylaniline).
- (3) Xylazine-M (N-thiourea-2,6-dimethylaniline).
- (4) Xylazine-M (Sulfone-HO-) isomer 2.
- (5) Xylazine-M (HO-2,6-dimethylaline isomer 1).
- (6) Xylazine-M (HO-2,6-dimethylaline isomer 2).
- (7) Xylazine M (oxo-).
- (8) Xylazine-M (HO-) isomer 1.
- (9) Xylazine-M (HO-) isomer 1 glucuronide.
- (10) Xylazine-M (HO-) isomer 2.
- (11) Xylazine-M (HO-) isomer 2 glucuronide.
- (12) Xylazine-M (HO-oxo-) isomer 1.
- (13) Xylazine-M (HO-oxo-) isomer 1 glucuronide.
- (14) Xylazine-M (HO-oxo-) isomer 2.
- (15) Xylazine-M (HO-oxo-) isomer 2 glucuronide.
- (16) Xylazine-M (sulfone).
- (17) Xylazine-M (sulfone-HO-) isomer 1.

(18) A compound, mixture or preparation which contains any quantity of the substances referred to in subparagraphs (1)—(17).

To revise 28 Pa. Code § 25.72 to conform to this final notice issued by the Secretary under section 3(c) of the act to temporarily schedule Xylazine, subject to the limitations previously outlined, as a Schedule III controlled substance, the Department plans to promulgate a conforming amendment to 28 Pa. Code § 25.72 through final-form rulemaking with proposed rulemaking omitted.

Accessibility

For additional information, or persons with a disability who require an alternative format of this notice (for example, large print, audiotope, Braille) should contact the Department of Health, Melissa Myers, Policy Office, 625 Forster Street, 8th Floor, Health and Welfare Building, Harrisburg, PA 17120, (717) 547-3104, or for speech and/or hearing impaired persons, call the Pennsylvania Hamilton Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

DR. DEBRA L. BOGEN,
Acting Secretary

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