

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1661 Session of 2023

INTRODUCED BY METZGAR, GIRAL, PICKETT, KUZMA, MARCELL, HANBIDGE, PASHINSKI, ZIMMERMAN, R. MACKENZIE AND HEFFLEY, SEPTEMBER 7, 2023

AS AMENDED ON THIRD CONSIDERATION, IN SENATE, APRIL 30, 2024

AN ACT

1 Amending the act of April 14, 1972 (P.L.233, No.64), entitled
2 "An act relating to the manufacture, sale and possession of
3 controlled substances, other drugs, devices and cosmetics;
4 conferring powers on the courts and the secretary and
5 Department of Health, and a newly created Pennsylvania Drug,
6 Device and Cosmetic Board; establishing schedules of
7 controlled substances; providing penalties; requiring
8 registration of persons engaged in the drug trade and for the
9 revocation or suspension of certain licenses and
10 registrations; and repealing an act," further providing for <--
11 definitions and for prohibited acts and penalties; and <--
12 providing for secure storage of xylazine. FURTHER PROVIDING <--
13 FOR SCHEDULES OF CONTROLLED SUBSTANCES; AND PROVIDING FOR
14 SECURE STORAGE OF XYLAZINE.

15 The General Assembly of the Commonwealth of Pennsylvania
16 hereby enacts as follows:

17 Section 1. Section 2(b) of the act of April 14, 1972 <--
18 (P.L.233, No.64), known as The Controlled Substance, Drug,
19 Device and Cosmetic Act, is amended by adding definitions to
20 read:

21 Section 2. Definitions. * * *
22 (b) As used in this act:
23 * * *

1 ~~"Licit use of xylazine" means any of the following:~~

2 ~~(1) Dispensing or prescribing for, or administrating to, a~~
3 ~~nonhuman species of a drug containing xylazine that:~~

4 ~~(i) has been approved by the Secretary of Health and Human~~
5 ~~Services under 21 U.S.C. § 360b (relating to new animal drugs);~~

6 ~~or~~

7 ~~(ii) is authorized under 21 U.S.C. § 360b(a)(4)).~~

8 ~~(2) The manufacturing, distribution or use of xylazine as an~~
9 ~~active pharmaceutical ingredient for manufacturing an animal~~
10 ~~drug approved under 21 U.S.C. 360b or an animal drug that has~~
11 ~~been issued an investigation use exemption under 21 U.S.C. §~~
12 ~~360b(j).~~

13 ~~(3) The manufacturing, distribution or use of a xylazine~~
14 ~~bulk chemical for pharmaceutical compounding by a licensed~~
15 ~~pharmacist or veterinarians.~~

16 ~~(4) Any other use approved or authorized under 21 U.S.C. Ch.~~
17 ~~9 (relating to Federal Food, Drug, and Cosmetic Act).~~

18 * * *

19 ~~"Xylazine" means any of the following substances, including~~
20 ~~the salts, isomers and salts of isomers of the substances when~~
21 ~~the existence of the salts, isomers and salts of isomers is~~
22 ~~possible within the specific chemical designation:~~

23 ~~(1) Xylazine.~~

24 ~~(2) Xylazine M (2,6-Meth dimethylaniline).~~

25 ~~(3) Xylazine M (N-thiourea 2,6 dimethylaniline).~~

26 ~~(4) Xylazine M (Sulfone HO-) isomer 2.~~

27 ~~(5) Xylazine M (HO-2,6 dimethylalaline isomer 1).~~

28 ~~(6) Xylazine M (HO-2,6 dimethylalaline isomer 2).~~

29 ~~(7) Xylazine M (oxo-).~~

30 ~~(8) Xylazine M (HO-) isomer 1.~~

- 1 ~~(9) Xylazine M (HO) isomer 1 glucuronide.~~
2 ~~(10) Xylazine M (HO) isomer 2.~~
3 ~~(11) Xylazine M (HO) isomer 2 glucuronide.~~
4 ~~(12) Xylazine M (HO oxo) isomer 1.~~
5 ~~(13) Xylazine M (HO oxo) isomer 1 glucuronide.~~
6 ~~(14) Xylazine M (HO oxo) isomer 2.~~
7 ~~(15) Xylazine M (HO oxo) isomer 2 glucuronide.~~
8 ~~(16) Xylazine M (sulfone).~~
9 ~~(17) Xylazine M (sulfone HO) isomer 1.~~
10 ~~(18) Any compound, mixture or preparation which contains any~~
11 ~~quantity of the substances specified under this definition.~~

12 Section 2. Section 13(a) (12), (14), (16), (30), (32), (33),
13 and (f) (2) of the act are amended to read:

14 Section 13. Prohibited Acts; Penalties. (a) The following
15 acts and the causing thereof within the Commonwealth are hereby
16 prohibited:

17 * * *

18 ~~(12) The acquisition or obtaining of possession of a~~
19 ~~controlled substance or xylazine, except for the licit use of~~
20 ~~xylazine, by misrepresentation, fraud, forgery, deception or~~
21 ~~subterfuge.~~

22 * * *

23 ~~(14) The administration, dispensing, delivery, gift or~~
24 ~~prescription of any controlled substance or xylazine, except for~~
25 ~~the licit use of xylazine, by any practitioner or professional~~
26 ~~assistant under the practitioner's direction and supervision~~
27 ~~unless done (i) in good faith in the course of his professional~~
28 ~~practice; (ii) within the scope of the patient relationship;~~
29 ~~(iii) in accordance with treatment principles accepted by a~~
30 ~~responsible segment of the medical profession.~~

1 ~~***~~

2 ~~(16) Knowingly or intentionally possessing a controlled or~~
3 ~~counterfeit substance or xylazine, except for the licit use of~~
4 ~~xylazine, by a person not registered under this act, or a~~
5 ~~practitioner not registered or licensed by the appropriate State~~
6 ~~board, unless the substance was obtained directly from, or~~
7 ~~pursuant to, a valid prescription order or order of a~~
8 ~~practitioner, or except as otherwise authorized by this act.~~

9 ~~***~~

10 ~~(30) Except as authorized by this act, the manufacture,~~
11 ~~delivery, or possession with intent to manufacture or deliver, a~~
12 ~~controlled substance or xylazine, except for the licit use of~~
13 ~~xylazine, by a person not registered under this act, or a~~
14 ~~practitioner not registered or licensed by the appropriate State~~
15 ~~board, or knowingly creating, delivering or possessing with~~
16 ~~intent to deliver, a counterfeit controlled substance.~~

17 ~~***~~

18 ~~(32) The use of, or possession with intent to use, drug~~
19 ~~paraphernalia for the purpose of planting, propagating,~~
20 ~~cultivating, growing, harvesting, manufacturing, compounding,~~
21 ~~converting, producing, processing, preparing, testing,~~
22 ~~analyzing, packing, repacking, storing, containing, concealing,~~
23 ~~injecting, ingesting, inhaling or otherwise introducing into the~~
24 ~~human body a controlled substance or xylazine, except for the~~
25 ~~licit use of xylazine, in violation of this act.~~

26 ~~(33) The delivery of, possession with intent to deliver, or~~
27 ~~manufacture with intent to deliver, drug paraphernalia, knowing,~~
28 ~~or under circumstances where one reasonably should know, that it~~
29 ~~would be used to plant, propagate, cultivate, grow, harvest,~~
30 ~~manufacture, compound, convert, produce, process, prepare, test,~~

1 ~~analyze, pack, repack, store, contain, conceal, inject, ingest,~~
2 ~~inhale or otherwise introduce into the human body a controlled-~~
3 ~~substance or xylazine, except for the licit use of xylazine, in~~
4 ~~violation of this act.~~

5 * * *

6 ~~(f) Any person who violates clause (12), (14) or (30) of~~
7 ~~subsection (a) with respect to:~~

8 * * *

9 ~~(2) Any other controlled substance or counterfeit substance~~
10 ~~classified in Schedule I, II, or III, or xylazine, except for~~
11 ~~the licit use of xylazine, is guilty of a felony and upon~~
12 ~~conviction thereof shall be sentenced to imprisonment not~~
13 ~~exceeding five years, or to pay a fine not exceeding fifteen~~
14 ~~thousand dollars (\$15,000), or both.~~

15 * * *

16 SECTION 1. SECTION 4(3) OF THE ACT OF APRIL 14, 1972
17 (P.L.233, NO.64), KNOWN AS THE CONTROLLED SUBSTANCE, DRUG,
18 DEVICE AND COSMETIC ACT, IS AMENDED BY ADDING SUBCLAUSES TO
19 READ:

<--

20 SECTION 4. SCHEDULES OF CONTROLLED SUBSTANCES.--THE
21 FOLLOWING SCHEDULES INCLUDE THE CONTROLLED SUBSTANCES LISTED OR
22 TO BE LISTED BY WHATEVER OFFICIAL NAME, COMMON OR USUAL NAME,
23 CHEMICAL NAME, OR TRADE NAME DESIGNATED.

24 * * *

25 (3) SCHEDULE III--IN DETERMINING THAT A SUBSTANCE COMES
26 WITHIN THIS SCHEDULE, THE SECRETARY SHALL FIND: A POTENTIAL FOR
27 ABUSE LESS THAN THE SUBSTANCES LISTED IN SCHEDULES I AND II;
28 WELL DOCUMENTED AND CURRENTLY ACCEPTED MEDICAL USE IN THE UNITED
29 STATES; AND ABUSE MAY LEAD TO MODERATE OR LOW PHYSICAL
30 DEPENDENCE OR HIGH PSYCHOLOGICAL DEPENDENCE. THE FOLLOWING

1 CLASSES OF CONTROLLED SUBSTANCES ARE INCLUDED IN THIS SCHEDULE:

2 * * *

3 (X) XYLAZINE, INCLUDING ANY OF THE FOLLOWING SUBSTANCES,
4 THEIR SALTS, ISOMERS AND SALTS OF ISOMERS WHENEVER THE EXISTENCE
5 OF THE SALTS, ISOMERS AND SALTS OF ISOMERS IS POSSIBLE WITHIN
6 THE SPECIFIC CHEMICAL DESIGNATION:

7 1. XYLAZINE.

8 2. XYLAZINE-M (2,6MICH DIMETHYLANILINE).

9 3. XYLAZINE-M (N-THIOUREA-2,6-DIMETHYLANILINE).

10 4. XYLAZINE-M (SULFONE-HO-) ISOMER 2.

11 5. XYLAZINE-M (HO-2,6-DIMETHYLALINE ISOMER 1).

12 6. XYLAZINE-M (HO-2,6-DIMETHYLALINE ISOMER 2).

13 7. XYLAZINE M (OXO-).

14 8. XYLAZINE-M (HO-) ISOMER 1.

15 9. XYLAZINE-M (HO-) ISOMER 1 GLUCURONIDE.

16 10. XYLAZINE-M (HO-) ISOMER 2.

17 11. XYLAZINE-M (HO-) ISOMER 2 GLUCURONIDE.

18 12. XYLAZINE-M (HO-OXO-) ISOMER 1.

19 13. XYLAZINE-M (HO-OXO-) ISOMER 1 GLUCURONIDE.

20 14. XYLAZINE-M (HO-OXO-) ISOMER 2.

21 15. XYLAZINE-M (HO-OXO-) ISOMER 2 GLUCURONIDE.

22 16. XYLAZINE-M (SULFONE).

23 17. XYLAZINE-M (SULFONE-HO-) ISOMER 1.

24 18. A COMPOUND, MIXTURE OR PREPARATION WHICH CONTAINS ANY
25 QUANTITY OF THE SUBSTANCES REFERRED TO IN THIS CLAUSE.

26 (XI) XYLAZINE AS DESCRIBED IN SUBCLAUSE (X) IS NOT A
27 CONTROLLED SUBSTANCE WHEN USED IN ANY OF THE FOLLOWING MANNERS:

28 1. DISPENSING OR PRESCRIBING FOR, OR ADMINISTERING TO, A
29 NONHUMAN SPECIES OF A DRUG CONTAINING XYLAZINE THAT:

30 (A) HAS BEEN APPROVED BY THE UNITED STATES SECRETARY OF

1 HEALTH AND HUMAN SERVICES UNDER 21 U.S.C. § 360B (RELATING TO
2 NEW ANIMAL DRUGS); OR

3 (B) IS AUTHORIZED UNDER 21 U.S.C. § 360B(A) (4).

4 2. THE MANUFACTURING, DISTRIBUTION OR USE OF XYLAZINE AS AN
5 ACTIVE PHARMACEUTICAL INGREDIENT FOR MANUFACTURING AN ANIMAL
6 DRUG APPROVED UNDER 21 U.S.C. § 360B OR AN ANIMAL DRUG THAT HAS
7 BEEN ISSUED AN INVESTIGATION USE EXEMPTION UNDER 21 U.S.C. §
8 360B(J).

9 3. THE MANUFACTURING, DISTRIBUTION OR USE OF A XYLAZINE BULK
10 CHEMICAL FOR PHARMACEUTICAL COMPOUNDING BY A LICENSED PHARMACIST
11 OR VETERINARIANS.

12 4. ANY OTHER USE APPROVED OR AUTHORIZED UNDER 21 U.S.C. CH.
13 9 (RELATING TO FEDERAL FOOD, DRUG, AND COSMETIC ACT).

14 5. ANOTHER USE APPROVED OR PERMISSIBLE UNDER FEDERAL OR
15 STATE LAW.

16 * * *

17 Section 3 2. The act is amended by adding a section to read: <--

18 Section 13.9. Secure Storage of Xylazine.--A practitioner
19 who is a veterinarian shall comply with the provisions of
20 section 4(5) of the act of September 27, 1961 (P.L.1700,
21 No.699), known as the "Pharmacy Act," for the storage and
22 protection of xylazine.

23 ~~Section 4. This act shall take effect in 60 days.~~ <--

24 SECTION 3. THIS ACT SHALL TAKE EFFECT IMMEDIATELY. <--