



**NOTICE OF PROPOSED RULEMAKING**  
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855  
BOARD OF PHARMACY

**FILED**  
06/16/2023 10:17 AM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Amends Schedule I; Adds Xylazine

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/26/2023 4:30 PM

*The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.*

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Filed By:  
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HEARING(S)

*Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.*

DATE: 07/26/2023

TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

ADDRESS: Oregon Board of Pharmacy - Virtual Meeting, 800 NE Oregon St., Suite 150, Portland, OR 97232

REMOTE MEETING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 503-446-4951

CONFERENCE ID: 627978258

SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony virtually during this hearing, sign up on our website at

[www.oregon.gov/pharmacy/pages/](http://www.oregon.gov/pharmacy/pages/)

rulemaking-information or email your first and last name, email address and phone number to

pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.

You must submit written comments before 4:30PM on July 26, 2023. Email written comments to

pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Amends Schedule I rule by adding language related to xylazine.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Scheduling Xylazine-

Federal Bill: Combating Illicit Xylazine Act – Discussion Draft

[https://www.cortezmasto.senate.gov/imo/media/doc/Combating Illicit Xylazine Act2.pdf](https://www.cortezmasto.senate.gov/imo/media/doc/Combating%20Illicit%20Xylazine%20Act2.pdf)

DEA Public Safety Alert 3/21/2023 <https://www.dea.gov/alert/dea-reports-widespread-threat-fentanyl-mixed-xylazine#:~:text=United%20States%20Drug%20Enforcement%20Administration,-Search&text=>

National Institute on Drug Abuse- Xylazine <https://nida.nih.gov/research-topics/xylazine#Reference>

OAR 875-015-0040 Minimum Standards for Veterinary Drugs

<https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=280560>

Xylazine: FDA Prescription Animal Drug Label

<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=991eae20-c3c2-4498-b166-a72b5927edb8&type=display>

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#### STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others.

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#### FISCAL AND ECONOMIC IMPACT:

None anticipated.

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#### COST OF COMPLIANCE:

*(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).*

There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

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#### DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved with the development of proposed amendments.

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#### WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

This is an urgent public health need that does not affect licensees and registrants.

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AMEND: 855-080-0021

RULE SUMMARY: Amends OAR 855-080-0021 by adding "Xylazine, unless in the form of a FDA-approved product" to Schedule I. Proposed amendments are necessary due to the widespread public health threat that xylazine poses. According to the DEA, xylazine and fentanyl drug mixtures place users at a higher risk of suffering a fatal drug poisoning. Because xylazine is not an opioid, naloxone (Narcan) does not reverse its effects. People who inject drug mixtures containing xylazine also can develop severe wounds, including necrosis—the rotting of human tissue—that may lead to amputation.

CHANGES TO RULE:

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.11 (04/01/2022), and unless specifically exempt or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:¶¶

(a) 1,4-butanediol;¶¶

(b) Gamma-butyrolactone¶¶

(c) Methamphetamine, except as listed in OAR 855-080-0022;¶¶

(d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)¶¶

(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.¶¶

(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,¶¶

(A) Methylmethcathinone (Mephedrone);¶¶

(B) Methylenedioxypropylvalerone (MDPV);¶¶

(C) Methylenedioxymethylcathinone (Methylone);¶¶

(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);¶¶

(E) Fluoromethcathinone (Flephedrone);¶¶

(F) 4-Methoxymethcathinone (Methedrone).¶¶

(g) Xylazine, unless in the form of a FDA-approved product.¶¶

(2) Schedule I also includes any compounds in the following structural classes (2a-2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:¶¶

(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;¶¶

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH-201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;¶¶

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;¶¶

(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);¶¶

(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;¶¶

(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;¶¶

(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl) indene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;¶¶

(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class

include but are not limited to: UR-144, XLR-11 and A-796,260;¶

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;¶

(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and¶

(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AKB48.¶

(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) is not an FDA approved drug or is exempted from the definition of controlled substance in ORS 475.005(6)(b)(A)-(E).¶

(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are derived from fentanyl by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the phenyl group, or any combination of the above.¶

(5) Schedule I also includes any compounds in the following structural classes (a - b), and their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:¶

(a) Benzodiazepine class: A fused 1,4-diazepine and benzene ring structure with a phenyl connected to the diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or benzene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Clonazolam, Flualprazolam¶

(b) Thienodiazepine class: A fused 1,4-diazepine and thiophene ring structure with a phenyl connected to the 1,-4-diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or thiophene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Etizolam¶

(6) Exceptions. The following are exceptions to subsection (1) of this rule:¶

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals;¶

(b) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products;¶

(c) The following substances per ORS 475.005(6)(b):¶

(A) The plant Cannabis family Cannabaceae;¶

(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;¶

(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;¶

(D) The seeds of the plant Cannabis family Cannabaceae; or¶

(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph. ¶

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055, ORS 475.065