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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

04/21/2020 11:36 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Schedule I Controlled Substances Addition

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/27/2020 5:00 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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800 NE Oregon St, Suite 150
Portland, OR 97232

Filed By:
Fiona Karbowicz
Rules Coordinator

HEARING(S)

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

DATE: 05/27/2020

TIME: 9:30 AM

OFFICER: Rachel Melvin

ADDRESS: Portland State Office
Building

800 NE Oregon St. Suite 150

Portland, OR 97232

SPECIAL INSTRUCTIONS:

This hearing meeting will be held via telephonic conference call. To participate call 1-877-873-8017, participant code 139360#. Written comment may be submitted anytime prior to 4:30PM on 5/27/2020 to pharmacy.rulemaking@oregon.gov.

NEED FOR THE RULE(S):

Due to an increase of illicit benzodiazepine-type substances and non-fatal overdose reports, Oregon State Police petitioned for these substances to be added to the Schedule I Controlled Substance listing.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Oregon-Idaho HIDTA (High Intense Drug Trafficking Area) Investigative Support Center Clonazepam Identified in Overdose Incidents

https://www.oregon.gov/pharmacy/Imports/%28U%29_ORIDHIDTA_032019RFIClonazepamOverdosesV2.pdf

FISCAL AND ECONOMIC IMPACT:

It is estimated that this will have no fiscal impact.

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 Oregon Board of Pharmacy, small businesses or members of the public.

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

Small businesses were not involved in rule development; small businesses are not impacted by these regulations.

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

This is a result of a law enforcement directive.

AMEND: 855-080-0021

RULE SUMMARY: Schedule I controlled substances in Oregon

CHANGES TO RULE:

855-080-0021

Schedule I ¶¶

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21CFR part 1308.11, and unless specifically excepted 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).¶¶

(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) or is not an FDA approved drug.¶

(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) Marijuana and delta-9-tetrahydrocannabinol (THC).

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 475.035, 475.059, 475.065