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

CHAPTER 855  
BOARD OF PHARMACY

**FILED**

02/23/2022 3:00 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Amends Schedule I rule by adding exceptions to Marijuana and delta-9-tetrahydrocannabinol (THC)

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 03/29/2022 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:  
Rachel Melvin  
Rules Coordinator

HEARING(S)

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

DATE: 03/29/2022

TIME: 9:30 AM

OFFICER: Rachel Melvin

ADDRESS: Oregon Board of Pharmacy

800 NE Oregon St., Suite 150

Portland, OR 97232

SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony during this hearing, sign up on our website at [www.oregon.gov/pharmacy/pages/rulemaking-information](http://www.oregon.gov/pharmacy/pages/rulemaking-information) or email your contact information to [pharmacy.rulemaking@bop.oregon.gov](mailto:pharmacy.rulemaking@bop.oregon.gov) to receive the link to join the virtual meeting. Please indicate which rule(s) you would like to comment on.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 414 724 81# for audio only.

You may file written comments before 4:30PM on March 29, 2022 by emailing your comments to [pharmacy.rulemaking@bop.oregon.gov](mailto:pharmacy.rulemaking@bop.oregon.gov).

NEED FOR THE RULE(S)

The proposed amendments resolve a discrepancy between ORS 475.005(6)(b)(A)-(E) and OAR 855-080-0021 by adding the following exceptions to schedule I- Marijuana and delta-9-tetrahydrocannabinol (THC): The plant Cannabis family Cannabaceae; any part of the plant Cannabis family Cannabaceae, whether growing or not; resin extracted from any part of the plant Cannabis family Cannabaceae; the seeds of the plant Cannabis family Cannabaceae; or any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed. ORS 475.005(6) was adopted as a result of impacts of the Federal 2018 Farm Bill legalizing cultivation of hemp and marketing of hemp-

derived products.

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DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

ORS 475.005(6)

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

The proposed rule amendments provide clarity for licensees, registrants and the public by listing exceptions to Schedule I (OAR 855-080-0021) related to Marijuana and delta-9-tetrahydrocannabinol (THC) consistent with ORS 475.005(b)(A)-(E). It is anticipated that these amendments will not impact any group of people differently than others.

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FISCAL AND ECONOMIC IMPACT:

It is not possible to assess the fiscal impact of this rule as there are too many unknowns regarding the hemp products industry.

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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).*

OBOP/Other State Agencies/Units of Local Government/Public: Minimal fiscal impact.

Cost of Compliance (including small businesses): Unknown, but likely minimal.

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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 the proposed rule amendment.

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

A RAC was not consulted, board staff proposed rule amendments to ensure clarity.

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AMEND: 855-080-0021

RULE SUMMARY: Amends Schedule I rule by adding exceptions to Marijuana and delta-9-tetrahydrocannabinol (THC) which were exempted from Schedule I under the Federal 2018 Farm Bill.

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 21 CFR 1308.11 (04/01/2020), 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).¶¶

(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~~ 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: Clonazepam, 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) 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.

Statutory/Other Authority: ORS 689.205

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