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PERMANENT ADMINISTRATIVE ORDER

BP 8-2020

CHAPTER 855 BOARD OF PHARMACY **FILED**

06/22/2020 4:20 PM ARCHIVES DIVISION SECRETARY OF STATE & LEGISLATIVE COUNSEL

FILING CAPTION: Schedule I Controlled Substances Addition; and required Prescription Reader Accessibility Services.

EFFECTIVE DATE: 06/23/2020

AGENCY APPROVED DATE: 06/18/2020

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RULES:

855-041-1131, 855-080-0021

ADOPT: 855-041-1131

REPEAL: Temporary 855-041-1131 from BP 8-2019

RULE TITLE: Prescription Reader Accessibility

NOTICE FILED DATE: 04/23/2020

RULE SUMMARY: Pharmacy accessibility services required by 2019 HB 2935

RULE TEXT:

A pharmacy shall notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request; a prescription reader is a device designed to audibly convey labeling information. A pharmacy that provides a prescription reader shall make it available to the person for at least the duration of the prescription, shall confirm it is appropriate to address the person's visual impairment, and shall ensure that prescription labels are compatible with the prescription reader. This requirement does not apply to an institutional drug outlet, dispensing a drug intended for administration by a healthcare provider.

STATUTORY/OTHER AUTHORITY: ORS 689.205 STATUTES/OTHER IMPLEMENTED: ORS 689.561 AMEND: 855-080-0021

RULE TITLE: Schedule I

NOTICE FILED DATE: 04/21/2020

RULE SUMMARY: Schedule I controlled substances in Oregon

RULE TEXT:

(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) Methylenedioxypyrovalerone (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