APPROVED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R001-19

Filed October 30, 2019

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §1, NRS 453.146 and 639.070.

A REGULATION relating to controlled substances; adding certain substances to the controlled substances listed in schedule II; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations to add, delete or reschedule substances listed as controlled substances in schedules I, II, III, IV and V of the Uniform Controlled Substances Act. (NRS 453.146) Existing law also provides that if a substance is designated, rescheduled or deleted as a controlled substance pursuant to federal law, the Board is required, with certain limited exceptions, to similarly treat the substance under the Uniform Controlled Substances Act. (NRS 453.2182) The Drug Enforcement Administration of the United States Department of Justice has added dronabinol in an oral solution in a drug product approved for marketing by the United States Food and Drug Administration to the list of controlled substances in schedule II of the federal Controlled Substances Act. (21 C.F.R. § 1308.12) This regulation brings the treatment of dronabinol oral solution in a drug product into conformity with federal regulations by adding dronabinol oral solution in a drug product, approved by the United States Food and Drug Administration, to the list of controlled substances in schedule II of the Uniform Controlled Substances Act.

Section 1. NAC 453.520 is hereby amended to read as follows:

453.520 1. Schedule II consists of the drugs listed in this section, by whatever official, common, usual, chemical or trade name designated.

2. Unless specifically excepted or unless listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable

origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis, is hereby enumerated in schedule II:

(a) Opium and opiate, and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone and naltrexone, and their respective salts, but including:

Codeine;

Diprenorphine;

Ethylmorphine;

Etorphine hydrochloride;

Granulated opium;

Hydrocodone;

Hydrocodone combination product (meaning any product that contains hydrocodone in combination with any other active ingredient);

Hydromorphone;

Metopon;

Morphine;

Opium extracts;

Opium fluid;

Powdered opium;

Raw opium;

Oxycodone;

Oxymorphone;

Thebaine; and

Tincture of opium.

(b) Any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (a) if they do not include the isoquinoline alkaloids of opium.

(c) Opium poppy and poppy straw.

(d) Cocaine hydrochloride salt prepared by a registered chemical or pharmaceutical manufacturer of the Drug Enforcement Administration of the Department of Justice which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Drug Enforcement Administration.

(e) Benzolyecgonine or ecgonine.

(f) Concentrate of poppy straw (meaning the crude extract of poppy straw in either liquid, solid or powder form and containing the phenanthrene alkaloids of the opium poppy).

3. Unless specifically excepted or unless listed in another schedule, any of the following opiates, 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 (dextrorphan and levopropoxyphene excepted), are hereby enumerated on schedule II:

Alfentanil;

Alphaprodine;

Anileridine;

Bezitramide;

Bulk dextropropoxyphene (in nondosage forms);

Carfentanil;

Dihydrocodeine;

Diphenoxylate;

Fentanyl;

Isomethadone;

Levo-alphacetylmethadol (some trade or other names: levo-alpha-acetylmethadol;

levomethadyl acetate; LAAM);

Levomethorphan;

Levorphanol;

Metazocine;

Methadone;

Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenylbutane;

Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;

Pethidine (meperidine);

Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;

Pethidine-Intermediate-B, ethyl-4-phenylpiperdine-4-carboxylate;

Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

Phenazocine;

Piminodine;

Racemethorphan;

Racemorphan;

Ramifentanil;

Sufentanil; or

Tapentadol.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system is hereby enumerated on schedule II:

(a) Amphetamine, its salts, optical isomers and salts of optical isomers;

(b) Phenmetrazine and its salts;

(c) Unless specifically excepted, any preparation which contains any quantity of methamphetamine, including its salts, isomers and salts of isomers, prepared by a registered chemical or pharmaceutical manufacturer of the Drug Enforcement Administration of the Department of Justice, which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Drug Enforcement Administration;

(d) Methylphenidate; or

(e) Lisdexamfetamine.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation, is hereby enumerated on schedule II:

Amobarbital;

Glutethimide;

Pentobarbital; or

Secobarbital.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances is hereby enumerated on schedule II:

(a) Immediate precursors to phencyclidine (PCP):

1-Phenylcyclohexylamine; or

1-piperidinocyclohexanecarbonitrile (PCC).

(b) Immediate precursors to amphetamine and methamphetamine:

Phenylacetone (some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone).

7. Any material, compound, mixture or preparation which contains any quantity of Nabilone (commonly referred to as: (+)-trans-3-(1,1-dimethylheptyl)-6, 6a, 7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H- dibenzol[b,d]pyran-9-one) is hereby enumerated on schedule II.

8. Dronabinol oral solution in a drug product approved by the United States Food and Drug Administration (some trade or other names: (6aR,10aR)-6a,7,8,10a-Tetrahydro-6,6,9-

trimethyl-3-penthyl-6H-dibenzo[b,d]-pyran-1-ol; (-)-delta-9-trans-tetrahydrocannabinol; Syndros) is hereby enumerated on schedule II.