Nevada State Board of Pharmacy

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July 31, 2020

AMENDED NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of
Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will conduct a Public Hearing on Thursday September 3, 2020 at 9:00 a.m. at the following location:

Pursuant to Governor Steve Sisolak's Emergency Directive 006, there will be no physical location for this meeting. The meeting can be listened to or viewed live over Zoom.

Via Videoconference at Zoom: https://zoom.us/j/5886256671

or

Via Teconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to Chapters 453 and/or 639 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

Amendment of Nevada Administrative Code (NAC) 453.520: Schedule II. The proposed amendment adds such drug products to the list of controlled substances in schedule II in conformity with federal regulations of the Uniform Controlled Substances Act. (LCB File No. R084-20)

1. The need for and the purpose of the proposed regulation or amendment.

The proposed amendment to NAC 453.520 will add a precursor to fentanyl, 4-Anilino-N-Phenethyl-4-Piperidine (ANPP) (some trade or other names: 4-ANPP; despropionyl fentanyl), to the list of controlled substances listed in Schedule II in conformity with federal regulations of the Uniform Controlled Substances Act.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the

public:

(a) Both adverse and beneficial effects.

There should be no adverse economic impact from this regulation amendment on regulated businesses or the public. Drugs classified as schedule II are abused and can be addictive and the regulation amendment in scheduling this drug will benefit public health, safety and welfare.

(b) Both immediate and long-term effects.

The Board anticipates that there will be no immediate or long-term economic effect on regulated businesses or the public, or that any such effects will be negligible.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation amendment.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation amendments of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation amendment does not provide a new or increase of fees.

Public comment is welcomed by the Board, but will be heard during the public comment item and may be limited to three minutes per person. You may call into the videoconference by following the link or calling the phone number listed above. The president may allow additional time to a given speaker as time allows and in his or her sole discretion.

Public comment may also be submitted in written form to the Board at pharmacy@pharmacy.nv.gov or to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521.

If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

This notice has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to Governor's Declaration of Emergency Directive 006.

The text of each regulation will include the entire text of any section of the Nevada Administrative Code which is proposed for amendment or repeal. This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary.

Upon adoption of any regulation, the agency, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R084-20

July 20, 2020

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

AUTHORITY: §1. NRS 453.146, 453.2182 and 639.070.

A REGULATION relating to controlled substances; adding certain immediate precursors to fentanyl to the list of controlled substances set forth in schedule II of the Uniform Controlled Substances Act; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to add, delete or reschedule substances listed as controlled substances in schedules I, II, III, IV and V of the Uniform Controlled Substances Act by regulation. (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 exception, to similarly treat the substance under the Uniform Controlled Substances Act. (NRS 453.2182) This regulation adds certain immediate precursors to fentanyl to the list of controlled substances set forth in schedule II of the Uniform Controlled Substances Act, consistent with federal regulations. (21 C.F.R. § 1308.12)

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).

(c) Immediate precursors to fentanyl:

4-anilino-N-phenethylpiperidine (some trade or other names: 4-ANPP; ANPP; 4-anilino-N-phenethyl-4-piperidine; despropionyl fentanyl; 4-Aminophenyl-1-phenethylpiperidine; N-phenyl-1-(2-phenylethyl)-4-piperidinamine)

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.