

Neuada State Board of Pharmacy

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October 22, 2021

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, December 2, 2021, at 9:00 a.m. Public access for the meeting is:

Pursuant to Governor Steve Sisolak's Emergency Directive 044 and AB 253, the meeting can be listened to or viewed live over Zoom remotely or attend at the following location:

Hilton Garden Inn Las Vegas Strip South 7830 S. Las Vegas Blvd. Las Vegas, NV 89123

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

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Via Teleconference 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:

- A. Amendment of Nevada Administrative Code (NAC) 453.510: Schedule I. The proposed amendment to NAC 453.510 will add certain benzodiazepines and fentanyl related substances to the controlled substances listed in Schedule 1. (LCB File R023-21)
 - 1. The need for and the purpose of the proposed regulation or amendment.

The proposed amendment to NAC 453.510 will add Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine) and fentanyl related substances Fentanyl carbamate (Ethyl-(1-phenethylpiperidin-4-yl)(phenyl)carbamate); Fluoro furanyl fentanyl; Fluoroacryl fentanyl; Fluorobutyryl fentanyl;Methyl acetyl fentanyl; Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl); N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluorofentanyl); Phenyl

fentanyl (some trade or other names: benzoyl fentanyl); Phenylpropanoyl fentanyl; Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl); to the list of controlled substances listed in Schedule I 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 the regulated entities or on the public. The regulation amendment will have a beneficial effect on the regulated entities and on the public since the drugs proposed for addition to Schedule I have a high potential for abuse and no accepted medical use, and the regulation amendment will benefit public health, safety and welfare.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effects on regulated entities and on the public will be beneficial since the drugs proposed for addition to Schedule I have a high potential for abuse and no accepted medical use, and the regulation amendment will benefit public health, safety and welfare.

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.

This 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 does not provide a new or increase of fees.

- **B. Amendment of Nevada Administrative Code (NAC) 639:** The proposed amendments impose limitations concerning the dispensing, selling, supplying, furnishing and administration of certain compounded drugs; requiring outsourcing facilities to establish policies and procedures. (LCB File R002-21)
 - 1. The need for and the purpose of the proposed regulation or amendment.

The proposed amendments will add a new section providing that drugs compounded by a pharmacy, dispensing practitioner, or outsourcing facility cannot be dispensed, resold, supplied, or furnished by any entity other than the licensed entity that compounded the drug. Outsourcing facilities must have procedures to prohibit the dispensing of their compounded products by other entities. Drugs compounded by an outsourcing facility may be administered pursuant to an order of a practitioner. The regulation is necessary for the protection, health and safety of the public.

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 the regulated entities or on the public. This amendment will have a beneficial economic effect on regulated entities and the public by ensuring the delivery of safe and reliable pharmaceutical care. The regulation amendment will benefit public health, safety and welfare.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effect on regulated entities and on the public will be to improve the delivery of safe and reliable pharmaceutical care in Nevada. The regulation amendment will benefit public health, safety and welfare.

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.

This 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 does not provide a new or increase of fees.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments, in written form, to the Board at pharmacy.nv.gov or to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521. Written submissions must be received by the Board on or before December 2, 2021. 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 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.

Pursuant to NRS 233B.064(1), upon adoption of any regulation, the Board, 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.

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

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R023-21

September 28, 2021

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; revising the list of substances contained in schedule I; 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 regulations set forth the drugs and substances that are enumerated in schedule I. (NAC 453.510) This regulation revises the list of drugs and substances contained in schedule I.

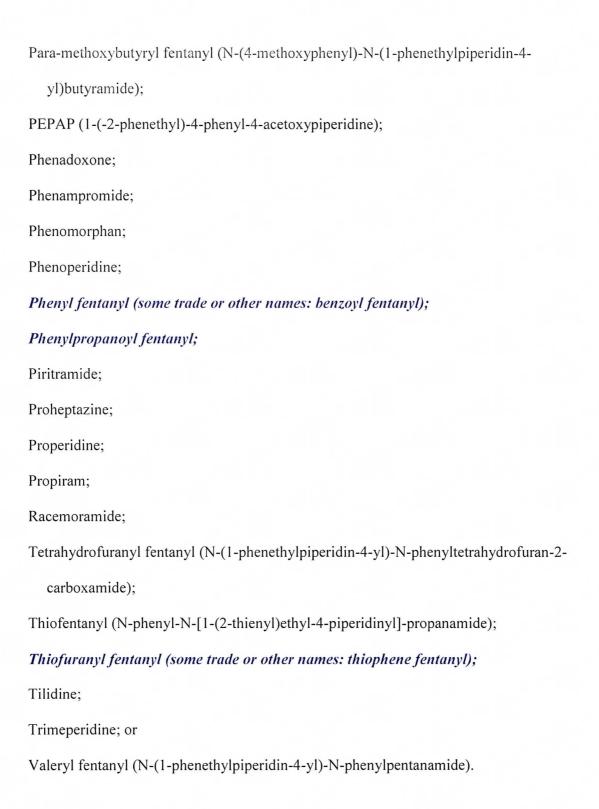
- **Section 1.** NAC 453.510 is hereby amended to read as follows:
- 453.510 1. Schedule I consists of the drugs and other substances listed in this section by whatever official, common, usual, chemical or trade name designated.
- 2. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including, without limitation, 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:

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Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-
  phenylacetamide);
Acetylmethadol;
Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other
  names: acryloylfentanyl);
Allylprodine;
Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-
  acetylmethadol, levomethadyl acetate or "LAAM");
Alphameprodine;
Alphamethadol;
Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide;
   1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);
Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-
  phenylpropanamide);
Benzethidine;
Betacetylmethadol;
Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-
  phenylpropanamide);
Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-
  piperidinyl]-N-phenylpropanamide);
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Beta-hydroxythiofentanyl (trade or other names: N-[1-[2-hydroxy-2-(thiophen-2-
  yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-
  piperidinyl]-N-phenylpropanamide);
Betameprodine;
Betamethadol;
Betaprodine;
Butyryl fentanyl (trade or other names: N-(1-phenethylpiperidin-4-yl)-N-
  phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);
Clonitazene;
Cyclopentyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);
Cyclopropyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);
Dextromoramide;
Diampromide;
Diethylthiambutene;
Difenoxin;
Dimenoxadol;
Dimepheptanol;
Dimethylthiambutene;
Dioxaphetyl butyrate;
Dipipanone;
Ethylmethylthiambutene;
Etonitazene;
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Etoxeridine;
Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-
   ethylbenzodioxolylbutanamine);
Fentanyl carbamate (Ethyl-(1-phenethylpiperidin-4-yl)(phenyl)carbamate);
Fluoro furanyl fentanyl;
Fluoroacryl fentanyl;
Fluorobutyryl fentanyl;
Fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);
[4-Fluoroisobutyryl] Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-
   phenethylpiperidin-4-yl)isobutyramide); {(some trade or other names: para-
  fluoroisobutyryl fentanyl);]
Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);
Furethidine;
Hydroxypethidine;
Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);
Ketobemidone;
Levomoramide;
Levophenacylmorphan;
[3-Methylfentanyl (N-3-methyl-1-(2-phenylethyl)-4-piperidyl-N-phenylpropanamide);
3-Methylthiofentanyl (N-(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl-N-
  phenylpropanamide);}
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Methoxyacetyl fentanyl; [(2 methoxy N (1-phenethylpiperidin 4 yl) N
  phenylacetamide);}
Methyl acetyl fentanyl;
Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-
  methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl
  methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl));
Methylfentanyl;
Methylthiofentanyl;
Morpheridine;
MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);
Noracymethadol;
Norlevorphanol;
Normethadone;
N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro
  ortho-fluorofentanyl; 2'-fluor 2'-fluorofentanyl);
Norpipanone;
Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;
Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-
  yl)isobutyramide);
Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-
  yl)butyramide);
[Para-fluorofentanyl (N (4 fluorophenyl) N-1 (2-phenethyl) 4-piperidinylpropanamide);]
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3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, 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: Acetorphine; Acetyl fentanyl; Acetyldihydrocodeine; Benzylmorphine; Codeine methylbromide; Codeine-N-Oxide; Cyprenorphine; Desomorphine; Dihydromorphine; Drotebanol; Etorphine (except hydrochloride salt); Heroin; Hydromorphinol; Methyldesorphine; Methyldihydromorphine; Morphine methylbromide; Morphine methylsulfonate;

Morphine-N-Oxide;
Myrophine;
Nicocodeine;
Nicomorphine;
Normorphine;
Pholcodine; or
Thebacon.
4. Unless specifically excepted or unless listed in another schedule, any material,
compound, mixture or preparation which contains any quantity of the following hallucinogeni
substances, including, without limitation, 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:
Adinazolam (some trade or other names: 8-chloro-1-((dimethylamino)methyl)-6-phenyl
4H-s-triazlo(4,3-a)(1,4)benzodiazepine; adinazolamum; Deracyn);
Alpha-ethyltryptamine (some trade or other names: ET, Trip);
Alpha-methyltryptamine (some trade or other names: AMT);

- Bromazolam (some trade or other names: 8-bromo-1-methyl-6-phenyl-4H[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; XLI-268);
- 1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);
- 4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);
- 4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);
- 1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);
- 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);
- 4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine (some trade or other names: Etizolam);
- Clonazolam (some trade or other names: 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; clonitrazolam);

- 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18; BTM-8; RCS-8);
- Diclazepam (some trade or other names: 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepine-2-one; 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one; 2'-chlorodiazepam; Chlorodiazepam; Ro 5-3448);
- 2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alphamethylphenethylamine; 2,5-DMA);
- 2,5-dimethoxy-4-ethylamphet-amine (some trade or other names: DOET);
- 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);
- 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);
- 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);
- 2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivative thereof (some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N-o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-NBOMe; 25D-

NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe);

- 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);
- 2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);
- 2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);
- 3-[(2-Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy-N, N-dimethyltryptamine;4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT);
- 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or other names: CP-47,497);
- 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other names: cannabicyclohexanol; CP-47,497 C8 homologue);
- Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

- 4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4-ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);
- 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);
- Flualprazolam (some trade or other names: 8-chloro-6-(2-fluorophenyl)-1-methyl-4H[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4Hbenzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; 2'-fluoro alprazolam; ortho-fluoro
 alprazolam);
- Flubromazepam (some trade or other names: 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-Bromo-5-(2-fluorophenyl)-1H-benzo[e][1,4]diazepin-2(3H)-one; 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one);
- Flubromazolam (some trade or other names: 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine);
- Flunitrazolam (some trade or other names: 6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);
- (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

- 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);
- [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluorpentyl JWH-018 indazole);
- [1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);
- [1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophyenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);
- (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);
- 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);
- 1-(5-fluoropentyl)-N-(tricyclo[3.3.1.13,7]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-

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carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA;
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1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22);

Flutoprazepam (some trade or other names: 7-chloro-1-(cyclopropylmethyl)-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

Meclonazepam (some trade or other names: (3S)-5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one; Ro 11-3128);

4-methoxyamphetamine (some trade or other names: 4-methoxy-alphamethylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine (some trade or other names: MMDA);

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; "STP");

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-122);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-ADB; 5F-MDMB-PINACA);

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine (MDMA);

Methylenedioxy-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-200);

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other names: ADB-CHMINACA; MAB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (trade or other name: ADB-PINACA);

- N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: AB-PINACA);
- N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trade or other name: AB-FUBINACA);
- N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other name: AB-CHMINACA);
- N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alphamethyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);
- 2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);
- Nifoxipam (some trade or other names: 5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7-nitro-2H-1,4-benzodiazepin-2-one; 1,3-Dihydro-5-(2-fluorophenyl)-3-hydroxy-7-nitro-2H-1,4-benzodiazepin-2-one; 3-hydroxydesmethylflunitrazepam; DP 370);
- Nitrazolam (some trade or other names: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

- Norflurazepam (some trade or other names: 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; nor-Flurazepam; N-Desalkylflurazepam; Desalkylflurazepam; Ro 5-3367);
- 1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);
- 1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);
- 1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);
- 1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);
- (1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: UR-144);
- 1-pentyl-N-(tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);
- 1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC);

Phenazepam (some trade or other names: 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-bromo-5-(2-chlorophenyl)-1,2-dihydro-3H-1,4-benzodiazepin-2-one; BD 98; Fenazepam; Elzepam; Phezipam; Phenorelaxan; Phenzitat);

Pyrazolam (some trade or other names: 8-bromo-1-methyl-6-(2-pyridinyl)-4H- (1,2,4)triazolo(4,3-a)(1,4)benzodiazepine; 8-bromo-1-methyl-6-(pyridin-2-yl)-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; Pirazolam);

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-
butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);
Gamma hydroxy butyric acid (some trade or other names: GHB);
Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-
methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; Tabernanthe
iboga);
Lysergic acid diethylamide;
Marijuana;
Mescaline;
Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP,
3-MeOPP, 4-MeOPP);
Developed (some trade or other nemes) 2 Heavil 1 hadrony 7 9 0 10 total-like 6 6 0
Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-
trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as *Lophophora* williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzofisochromene-7-carboxylate);

Ethylamine analog of phencyclidine (some trade or other names: N-ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidine (some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine; TFMPP).

For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

- 5. All parts of the plant presently classified botanically as Datura, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound, manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.
- 6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone

or methaqualone having a depressant effect on the central nervous system, including, without limitation, 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.

7. 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, including, without limitation, their salts, isomers and salts of isomers:

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one, alpha-pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha-pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: alpha-PHP);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one, β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alphaaminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,Ndimethylcathinone;

N,N-dimethyl MDCATH; N,N-dimethyl-3,4- methylenedioxycathinone; N,N-dimethyl-

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β-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one; bk-MDDMA);
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N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA);

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade or other names: ephylone);

Fenethylline;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4-FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-2(methylamino)propan-1-one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-methylcathinone, 1-(2-fluorophenyl)-2-(methylamino)propan-1-one, 2-FMC);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone, 4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N-Methylcathinone, cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-

Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

- 4'-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);
- 4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-

Methylenedioxy pyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethylbenzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2(pyrrolidin-1-yl)pentan-1-one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482);

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one, α methylaminovalerophenone); or

Pentylone (trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolylpentanamine; bk-MBDP; bk-methyl-K).

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or

identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule, Tetrahydrocannabinols (natural or synthetic equivalents of substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances, derivatives and their isomers with a similar chemical structure; and Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

- 10. Unless specifically listed in another schedule and except as otherwise provided in subsection 11, any material, compound, mixture or preparation which contains any quantity of CBD (natural or synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity).
 - 11. A drug product which:
 - (a) Has been approved by the United States Food and Drug Administration;
- (b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and
 - (c) Contains not more than 0.1 percent residual THC by weight,
- ⇒ is not a controlled substance.

REVISED PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R002-21

September 1, 2021

EXPLANATION - Matter in *italics* is new, matter in brackets [omitted material] is material to be omitted.

AUTHORITY: §§ 1 and 2, NRS 639.070 and 639.100, as amended by section 4 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1017.

A REGULATION relating to pharmacy; imposing limitations concerning the dispensing, selling, supplying, furnishing and administration of certain compounded drugs; requiring an outsourcing facility to establish certain procedures; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law prohibits a person who does not hold the proper certificate, license or permit from compounding a drug. (NRS 639.100, as amended by section 4 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1017) Existing regulations define "outsourcing facility" to mean a facility that: (1) is engaged in the compounding of sterile drugs; and (2) is registered with the federal government as an outsourcing facility. (NAC 639.6912) **Section 1** of this regulation prohibits the dispensing, reselling, supplying or furnishing of a drug compounded by a pharmacy, dispensing practitioner or outsourcing facility by any entity other than the pharmacy, dispensing practitioner or outsourcing facility, as applicable, that compounded the drug. **Section 2** of this regulation: (1) requires an outsourcing facility to establish procedures to ensure compliance with **section 1**; and (2) provides that a drug compounded by an outsourcing facility may be administered pursuant to the order of a practitioner.

- **Section 1.** Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:
- 1. A drug compounded by a pharmacy, a dispensing practitioner or an outsourcing facility must not be dispensed, resold, supplied or furnished by any person or entity other than the pharmacy, dispensing practitioner or outsourcing facility, as applicable, that compounded the drug.

- 2. As used in this section, "outsourcing facility" has the meaning ascribed to it in NAC 639.6912.
 - **Sec. 2.** NAC 639.6915 is hereby amended to read as follows:
- 639.6915 *1.* An outsourcing facility that is engaged in the compounding of sterile drugs in this State or for shipment into this State shall:
- [H.] (a) Obtain a license from the Board as a manufacturer in accordance with NRS 639.100 and 639.233;
 - [2.] (b) Comply with the provisions of NAC 639.609 to 639.619, inclusive; [and
 - 3.] (c) Comply with all the requirements of 21 U.S.C. § 353b [.]; and
- (d) Establish and implement procedures to prohibit other persons and entities from dispensing, reselling, supplying or furnishing drugs compounded by the outsourcing facility in violation of section 1 of this regulation.
- 2. A drug compounded by an outsourcing facility may be administered pursuant to the order of a practitioner.