Nevada State Board of Pharmacy

431 W. PLUMB LANE • RENO, NEVADA 89509
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
E-mail: pharmacy@pharmacy.nv.gov • Website: bop.nv.gov

October 24, 2014

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 hold a public hearing at 1:30 p.m., on Wednesday, December 3, 2014, at the Hyatt Place, 1790 E. Plumb Lane, Reno, NV. 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 639 of the Nevada Administrative Code.

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

Amendment of Nevada Administrative Code 453.520 and 453.530

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

   On August 22, 2014, the Federal Drug Enforcement Agency (DEA) published a final ruling in the Federal Register rescheduling hydrocodone combination products from Schedule III to Schedule II of the Controlled Substances Act. The rule became effective October 6, 2014.

   The proposed amendment will bring the treatment of hydrocodone in Nevada's controlled substance regulations, whether produced as a single-entity product or in combination with any other active ingredient, into conformity with current federal regulations, with which Nevada pharmacists are required to comply.

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.

   This regulation should have no adverse or beneficial economic effect on businesses or on the public. Businesses and the public

may feel some short-term adverse impact in the process of obtaining hydrocodone containing products due to the heightened level of regulation and additional rules associated with Schedule II controlled substances. That impact is primarily due, however, to the already effective change in DEA regulations, which preceded these proposed amendments.

(b) Both immediate and long-term effects.

The Board anticipates that this regulation will have no immediate or long-term economic effects on business or the public.

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 for enforcement of this regulation.

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.

These proposed regulations overlap or duplicate 21 C.F.R. § 1308, the DEA's regulation that now lists all hydrocodone containing products to Schedule II.

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

21 C.F.R. § 1308, the DEA's regulation that now lists all hydrocodone containing products to Schedule II.

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 regulations of the same activity in which the federal 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 Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada 89509, or at e-mail address: shunting@pharmacy.nv.gov. Written submissions must be received by the Board at least fourteen days before the scheduled public hearing. 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.

A copy of this notice and the regulation to be adopted and amended will be on file at the State Library, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be adopted and amended will be available in all counties in which an office of the agency is not maintained, at the main public library, for inspection and copying by members of the public during business hours. 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.

This notice of hearing has been posted at the following locations:

Nevada State Board of Pharmacy
Reno, Nevada

Nevada State Board of Pharmacy
Las Vegas, Nevada

Mineral County Courthouse
Hawthorne, Nevada

Elko County Courthouse
Elko, Nevada

Washoe County Courthouse
Reno, Nevada

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R137-14

(The provisions of LCB File No. R138-14 are included in this regulation.)

October 20, 2014

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

AUTHORITY: §§1-3, NRS 453.146, 453.2182 and 639.070.

A REGULATION relating to controlled substances; rescheduling certain controlled substances that contain hydrocodone from schedule III of the Uniform Controlled Substances Act to schedule II in conformity with federal regulations; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing federal and state regulations list hydrocodone as a controlled substance in schedule II of the federal Controlled Substances Act and of the state Uniform Controlled Substances Act respectively. (21 U.S.C. §§ 801 et seq.; 21 C.F.R. § 1308.12; NRS 453.166-453.219; NAC 453.520) Before August 22, 2014, both federal and state regulations also listed certain hydrocodone combination products as controlled substances in schedule III of those acts respectively. Those products contain specified doses of hydrocodone in combination with specified amounts of certain other drugs. (21 C.F.R. § 1308.13; NAC 453.530)

On August 22, 2014, the Drug Enforcement Administration of the United States Department of Justice deleted all hydrocodone combination products from schedule III. Accordingly, under federal regulations, all products that contain hydrocodone, whether produced as a single-entity product or in combination with any other active ingredient, are listed as controlled substances in schedule II of the Controlled Substances Act. (79 Fed.Reg. 49,661, 49,682)

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 within 60 days after the publication in the Federal Register of the final order concerning the federal action. (NRS 453.2182)

This regulation brings the treatment of hydrocodone, whether produced as a single-entity product or in combination with any other active ingredient, into conformity with federal regulations. **Section 1** of this regulation specifies that all hydrocodone combination products are controlled substances listed in schedule II. **Section 2** of this regulation deletes the specified hydrogen combination products from schedule III. **Section 3** of this regulation provides that the reclassification of hydrocodone combination products from schedule III to schedule II does not apply to a prescription for a schedule III hydrocodone combination product that is issued before the effective date of this regulation if the product is dispensed before April 8, 2015.

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.

Sec. 2. NAC 453.530 is hereby amended to read as follows:

453.530 1. Schedule III 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 material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation, is hereby enumerated on schedule III, including:

(a) Those compounds, mixtures or preparations in dosage unit form containing any substance listed in schedule II which has a stimulant effect on the central nervous system, which compounds, mixtures or preparations were listed on August 25, 1971, as excepted compounds under the regulations of the Drug Enforcement Administration of the Department of Justice, and any other drug of the same quantitative composition as a drug shown on the list or which is the same except that it contains a lesser quantity of controlled substances;

(b) Benzphetamine;

(c) Chlorphentermine;

(d) Clortermine; or

(e) Phendimetrazine.

➥ For the purposes of this subsection, "isomer" includes the optical, position or geometric isomer.

3. 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 is hereby enumerated on schedule III:

(a) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof;

(b) Chlorhexadol;

(c) Embutramide;

(d) Lysergic acid;

(e) Lysergic acid amide;

(f) Methyprylon;

(g) Sulfondiethylmethane;

(h) Sulfonethylmethane;

(i) Sulfonmethane;

(j) Any compound, mixture or preparation containing amobarbital, secobarbital, pentobarbital or any salt thereof and one or more other active medicinal ingredients, which are not listed in any schedule;

(k) Any suppository dosage form containing amobarbital, secobarbital, pentobarbital, or any salt of any of these drugs approved by the Food and Drug Administration of the United States Department of Health and Human Services for marketing only as a suppository; or

(l) Tiletamine and zolazepam or any salt thereof. (Some trade or other names for a tiletamine-zolazepam combination product: Telazol. Some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone. Some trade or other names for zolazepam: 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-[3,4-e][1,4]-diazepin-7(1H)-one, flupyrazapon).

4. Nalorphine is hereby enumerated on schedule III.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any of the following narcotic drugs or their salts, calculated as the free anhydrous base or alkaloid, in quantities is hereby enumerated on schedule III:

(a) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(b) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(c) ~~[Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;~~

~~(d) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;~~

~~(e)]~~ Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

~~[(f)]~~ *(d)* Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

~~[(g)]~~ *(e)* Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts; or

~~[(h)]~~ *(f)* Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

6. Unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of:

(a) N-methylephedrine, its optical isomers, salts and salts of optical isomers;

(b) Hydriodic acid; or

(c) Hydrogen iodide gas,

↪ are, as immediate precursors, controlled, the control of which is necessary to prevent, curtail or limit the manufacture of the controlled substances methamphetamine and N, N-dimethylamphetamine.

7. Except as otherwise provided in subsections 8 and 9, or specifically excepted or listed in another schedule, any material, compound, mixture or preparation containing any quantity of anabolic steroids, including their salts, isomers, esters and salts of isomers, whenever the existence of such salts of isomers is possible within the specific chemical designation, is hereby enumerated on schedule III:

(a) Androisoxazole;

(b) Androstenediol;

(c) Bolandiol;

(d) Bolasterone;

(e) Boldenone;

(f) Chlormethandienone;

(g) Clostebol;

(h) Chorionic gonadotropin (HCG);

(i) Dehydrochlormethyltestosterone;

(j) Dihydromesterone;

(k) Drostanolone;

(l) Ethylestrenol;

(m) Fluoxymesterone;

(n) Formebolone;

(o) Formyldienolone;

(p) 4-Hydroxy-19-nortestosterone;

(q) Mesterolone;

(r) Methandrenone;

(s) Methandriol;

(t) Methandrostenolone;

(u) Methenolone;

(v) 17-Methyltestosterone;

(w) Methyltrienolone;

(x) Mibolerone;

(y) Nandrolone;

(z) Norbolethone;

(aa) Norethandrolone;

(bb) Normethandrolone;

(cc) Oxandrolone;

(dd) Oxymesterone;

(ee) Oxymetholone;

(ff) Quinbolone;

(gg) Stanolone;

(hh) Stanozolol;

(ii) Stenbolone;

(jj) Testolactone;

(kk) Testosterone; or

(ll) Trenbolone.

8. Any anabolic steroid described in subsection 7 which is used solely for implantation in cattle or any other nonhuman species and is approved by the Food and Drug Administration for that use is not a controlled substance.

9. The following classifications are not controlled substances for the purposes of this section:

(a) Oral combinations containing therapeutic doses of estrogen and androgen;

(b) Parenteral preparations containing therapeutic doses of estrogen and androgen;

(c) Topical preparations containing androgens or combinations of androgen and estrogen; and

(d) Vaginal preparations.

10. Ketamine HCL is hereby enumerated on schedule III.

11. Synthetic Dronabinol in sesame oil encapsulated in a soft gelatin capsule in a drug product approved by the Food and Drug Administration (some trade or other names: (6aR-trans)-6a,7,8,10a-tetrahydro-6; 6,9-trimethyl-3-pentyl-6H-dibenzo [b,d]pyran- 1-ol; (-)-delta-9-(trans)-tetrahydrocannabinol; Marinol) is hereby enumerated on schedule III.

12. Gamma-hydroxybutyrate prepared by a registered pharmaceutical manufacturer of the Food and Drug Administration which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Food and Drug Administration is hereby enumerated on schedule III.

13. Human growth hormone (HGH) is hereby enumerated on schedule III.

14. Any material, compound, mixture or preparation containing buprenorphine, including its salts, is hereby enumerated on schedule III.

Sec. 3. The amendatory provisions of this regulation do not apply to a prescription for a product that contains hydrocodone in combination with any other active ingredient that is issued before the effective date of this regulation if the product is dispensed before April 8, 2015.