ADOPTED 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.)

Effective December 22, 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 hydrocodone 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 December 22, 2014, 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 December 22, 2014, if the product is dispensed before April 8, 2015.

INFORMATIONAL STATEMENT
LCB File No. R137-14

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. EXPLANATION OF THE NEED FOR THE ADOPTED REGULATION

NAC 453.520 currently lists products containing high percentages of hydrocodone as Schedule II controlled substances. However, NAC 453.530 contains certain provisions that allow products containing a small percentage of hydrocodone to be listed as Schedule III controlled substances. NAC 453.520 and .530 were consistent with similar federal controlled substance regulations until August 22, 2014, when the Federal Drug Enforcement Administration (DEA) amended its regulations, effective October 6, 2014, and placed all hydrocodone containing products on Schedule II. Consistent with the new and current DEA regulations, this proposed amendment to NAC 453.520 specifies that all hydrocodone containing products will now be listed as Schedule II controlled substances, and the exceptions in NRS 453.530 will be eliminated. This proposed amendment will bring Nevada's controlled substance regulations back in line with their federal counterparts.

2. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

The Board solicited comment on the proposed amendment by (1) posting notice, with links to the full text of the proposed amendment, to the LCB Administrative Regulation Notices webpage, (2) posting a copy of the full text of the proposed changes to the Board's website as part of the Board Meeting materials, (3) posting notice to the Nevada Public Notice website, operated by the Department of Administration, with a link back to a full text of the proposed amendment on the Board's website, and (4) posting notices and agendas in numerous public locations per NRS Chapter 233B.

The Board also solicited comment from Nevada dispensers, and from representatives of relevant industry associations that Board Staff deemed likely to have an interest in the proposed amendment. The Board also provided time for public comment at the workshop(s) concerning the proposed amendment.

Parties interested in obtaining a copy of the summary of the proposed amendment, or that wish to view the text of the proposed amendment, may access that information on the Board's website at bop.nv.gov, or by contacting the Board's office at (775) 850-1440.

3. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was __21___.
The number of persons who testified at the hearing was __-0-_.
The number of agency submitted statements was _-0-___.
The name of persons who testified at the hearing:

4. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

The Board solicited comment on the proposed amendment by (1) posting notice, with links to the full text of the proposed amendment, to the LCB Administrative Regulation Notices webpage, (2) posting a copy of the full text of the proposed changes to the Board's website as part of the Board Meeting materials, (3) posting notice to the Nevada Public Notice website, operated by the Department of Administration, with a link back to a full text of the proposed amendment on the Board's website, and (4) posting notices and agendas in numerous public locations per NRS Chapter 233B.

The Board also solicited comment from Nevada dispensers, and from representatives of relevant industry associations that Board Staff deemed likely to have an interest in the proposed amendment. The Board also provided time for public comment at the workshop(s) concerning the proposed amendment.

Parties interested in obtaining a copy of the summary of the proposed amendment, or that wish to view the text of the proposed amendment, may access that information on the Board's website at bop.nv.gov, or by contacting the Board's office at (775) 850-1440.

5. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted without changes because the amendments were drafted consistent with the language in the Federal Register the proposed amendments are designed to follow. Additionally, the Board received no comments from industry or the public requesting any changes.

6. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

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.

7. 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.

8. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, 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.

9. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH 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.

10. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

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