ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R016-14

Effective October 24, 2014

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 controlled substances listed on schedule III; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to add substances to or delete or reschedule all substances enumerated in schedules I, II, III, IV and V by regulation. (NRS 453.146) Existing regulations enumerate the drugs and substances that are included in schedule III and include ketamine HCL (ketamine hydrochloride) as one such drug. (NAC 453.530) This regulation removes the reference to HCL and includes the salts, isomers and salts of isomers of ketamine on the list of substances included in schedule III.

Section 1. 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 ***United States*** 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) 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) 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) 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]~~ ***, including its salts, isomers and salts of isomers,*** 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.

R016-14
NAC Chapter 453.510
Schedule III

June 20, 2014

INFORMATIONAL STATEMENT

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

The proposed amendment to NAC 453.530 will revise the definition of ketamine HCL to include its salts, isomers and salts of isomers to the controlled substances listed in Schedule III.

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 a summary of the proposed amendment on the Board's website (bop.nv.gov) with a link to the full text of the proposed amendment, (2) soliciting comment from Nevada dispensers who receive Board of Pharmacy notifications using a facsimile notice directed to each, and (3) contacting a representative of each relevant industry association 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, and opened the floor for public comment at the public hearing on the proposed amendment.

The Board received positive public comment on R016-14 from a representative of the Las Vegas Metro Forensics Controlled Substance Unit and the Clark County Crime Lab. Per AB 39, there is no cost to pharmacies.

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 __19___.
The number of persons who testified at the hearing was __1_.
The number of agency submitted statements was _-0-___.
The name of persons who testified at the hearing:

-David Goldthorpe, Las Vegas Metro Forensics Controlled Substance Unit and the Clark County Crime Lab - 5605 W. Badura 120B, Las Vegas, NV. 702-828-3945 – d13317g@lvmpd.com.

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 a summary of the proposed amendment on the Board's website (bop.nv.gov) with a link to the full text of the proposed amendment, (2) soliciting comment from Nevada dispensers who receive Board of Pharmacy notifications using a facsimile notice directed to each, and (3) contacting a representative of each relevant industry association 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, and opened the floor for public comment at the public hearing on the proposed amendment.

Board Staff received positive public comment on R016-14 from a representative of the Las Vegas Metro Forensics Controlled Substance Unit and the Clark County Crime Lab.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada, 89509.

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 regulation was drafted to comply with AB 39 and the Board received only positive comments from industry and the public.

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.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

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.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

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.