PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R153-99

December 9, 1999

EXPLANATION - Matter in *italics* is new; matter in brackets formitted material is material to be omitted.

AUTHORITY: §§1 and 2, NRS 453.146.

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 on 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;

Ethylmorphine;

Etorphine hydrochloride;

Granulated opium;

Hydrocodone;

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).

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) : is 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;

3. Unless specifically excepted or unless listed in another schedule, any of the following

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; or

- 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;

Sufentanil.

(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; or

- (d) Methylphenidate.
- 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 [:

Synthetic Dronabinol in sesame oil encapsulated in a soft gelatin capsule in a drug product approved by the United States 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,dpyran 1 ol; () delta 9 (trans) tetrahydrocannabinol);

- 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.

FLUSH 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) Lysergic acid;
 - (d) Lysergic acid amide;
 - (e) Methyprylon;
 - (f) Sulfondiethylmethane;
 - (g) Sulfonethylmethane;
 - (h) Sulfonmethane;

- (i) 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;
- (j) Any suppository dosage form containing amobarbital, secobarbital, pentobarbital, or any salt of any of these drugs approved by the Food and Drug Administration for marketing only as a suppository; or
- (k) Tiletamine and zolazepam or any salt thereof. (Some trade or other names for a tiletamine-zolazepam combination product: Telzol. 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. Except as otherwise provided in subsections 7 to 10, inclusive, or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of:
 - (a) Ephedrine or N-methylephedrine, their optical isomers, salts and salts of optical isomers;
 - (b) Hydriodic acid; or
 - (c) Hydrogen iodide gas,

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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. Ephedrine sulfate injection, as a solution, in either single-dose or multiple-dose ampules or vials in the possession of a practitioner or other person licensed by the board to possess drugs is not a controlled substance.
- 8. The following products, listed by their brand names and their generic equivalents, which are prepared for over-the-counter sale in compliance with the Federal Food, Drug and Cosmetic Act and the applicable regulations adopted by the Food and Drug Administration and contain immediate precursors specified in subsection 6, are not controlled substances for the purposes of this section:
 - (a) Amesec Capsules;
 - (b) Asthmalixir Elixir;
 - (c) Azma Aid Tablets;
 - (d) Bronitin Tablets;
 - (e) Bronkotabs;
 - (f) Bronkolixir Elixir;
 - (g) Bronkaid Tablets;
 - (h) Delaval Softener;
 - (i) Efedron Nasal Jelly;
 - (j) Guaiphed Elixir;
 - (k) Lufyllin EPG Elixir;
 - (1) M2205 Sanitizer Cleaner;
 - (m) Mastiumen;
- (n) Mini Thin 2 Way Action, containing not more than 25 milligrams of ephedrine and not more than 100 milligrams of guaifenesin;

- (o) Pazo Hemorrhoid Ointment and Suppositories;
- (p) Phedral C.T. Tablets;
- (q) Primatene "M" Formula Tablets;
- (r) Primatene "P" Formula Tablets;
- (s) Primatene Tablets;
- (t) Quarter-mate Sanitizing Teat Dip;
- (u) Rynal;
- (v) Tedral Tablets, Suspension & Elixir;
- (w) Tedrigen Tablets;
- (x) Theodrine Tablets;
- (y) Vicks Inhaler; and
- (z) Vicks Vatronol Nose Drops.
- 9. Mahuang or other botanical products of genus ephedra used in their natural state as a preparation for human consumption are not controlled substances for the purposes of this section.
- 10. The board may deem a compound, mixture or preparation containing an immediate precursor specified in subsection 6 not to be a controlled substance for the purposes of this section, if:
- (a) The compound, mixture or preparation has been approved for its intended use by the appropriate local, state or federal agency; and
 - (b) The compound, mixture or preparation:
- (1) Is intended for prescription or over-the-counter use as a medication and contains one or more other active ingredients which are not listed in another schedule and which are included in a combination, quantity, proportion or concentration so that the compound, mixture or

preparation does not present any significant potential for use as an immediate precursor in the manufacture of the controlled substances methamphetamine or N, N-dimethylamphetamine; or

(2) Is not intended for use as a medication and is packaged in such form or concentration, or packaged with adulterants or denaturants, so that as packaged it does not present any significant potential for use as an immediate precursor in the manufacture of the controlled substances methamphetamine or N, N-dimethylamphetamine.

11. Except as otherwise provided in subsections 12 and 13, or specifically excepted or listed in another schedule, any material, compound, mixture or preparation containing any quantity of anabolic steroids, including their salts, isomers 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, (HGC);
(i) Dihydromesterone;
(j) Ethylestrenol;
(k) Fluoxymesterone;

(l) Formyldienolone;

(m) 4-Hydroxy-19-nortestosterone;
(n) Mesterolone;
(o) Methandrenone;
(p) Methandriol;
(q) Methandrostenolone;
(r) Methenolone;
(s) 17-Methyltestosterone;
(t) Methyltrienolone;
(u) Nandrolone;
(v) Norbolethone;
(w) Norethandrolone;
(x) Normethandrolone;
(y) Oxandrolone;
(z) Oxymesterone;
(aa) Oxymetholone;
(bb) Quinbolone;
(cc) Stanolone;
(dd) Stanozolol;
(ee) Stenbolone;
(ff) Testosterone; or
(gg) Trenbolone.

- 12. Any anabolic steroid described in subsection 11 which is used solely for implantation in cattle or any other nonhuman species and is approved by the Food and Drug Administration of the Department of Justice for that use is not a controlled substance.
- 13. 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.
 - 14. Ketamine HCL : is hereby enumerated on Schedule III.
- 15. Synthetic Dronabinol in sesame oil encapsulated in a soft gelatin capsule in a drug product approved by the United States 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.