PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R163-01

November 28, 2001

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

AUTHORITY: §1, NRS 453.146 and 639.070.

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 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;

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- (d) Clortermine; or
- (e) Phendimetrazine.

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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 of the Department of Health and Human Services 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,] and 8, or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of:
- (a) Ephedrine [or N-methylephedrine,], pseudoephedrine or phenylpropanolamine, their optical isomers, salts and salts of optical isomers [;], other than an over-the-counter ephedrine, pseudoephedrine or phenylpropanolamine drug product;
 - (b) N-methylephedrine, its optical isomers, salts and salts of optical isomers;
 - (c) Hydriodic acid; or
 - (d) 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, who	i cl
are prepared for over-the-counter sale in compliance with the Federal Food, Drug and Cosmet	ie
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 no	ot
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. 9. Except as otherwise provided in subsections [12 and 13,] 10 and 11, 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 (HGC); (i) Dihydrochlormethyltestosterone; (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.
- [12.] 10. Any anabolic steroid described in subsection [11] 9 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 Health and Human Services] for that use is not a controlled substance.
- [13.] 11. 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.] 12. Ketamine HCL is hereby enumerated on Schedule III.
- [15.] 13. 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.
- 14. As used in this section, "over-the-counter ephedrine, pseudoephedrine or phenylpropanolamine drug product" means a drug product that is sold in packages which contain not more than 3.0 grams of ephedrine base, pseudoephedrine base or phenylpropanolamine base and, if the drug product is not a liquid, packaged:
 - (a) In blister packs in which each blister contains not more than two dosage units; or
- (b) If the use of blister packs is technically infeasible, in packets or pouches that contain not more one dosage unit per packet or pouch.