

LCB FILE NO. R163-01

**PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY**

**REGULATIONS REGARDING PRODUCTS CONTAINING
EPHEDRINE, PSEUDOEPHEDRINE, OR PHENLYPROPANOLAMINE**

NAC 453.010 shall be amended to add the following new language:

As used in this chapter, unless the context otherwise requires:

1. "Board" means the state board of pharmacy.
2. "Emergency situation," within the meaning of subsection 2 of NRS 453.256 and these regulations, means a situation in which a prescribing practitioner determines that:
 - (a) Immediate administration of the controlled substance is necessary for the proper treatment of the patient;
 - (b) No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Uniform Controlled Substances Act; and
 - (c) It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance before he dispenses it.
3. *"Ordinary over-the-counter ephedrine, pseudoephedrine, or phenlypropanolamine product" means any product containing ephedrine, pseudoephedrine, or phenlypropanolamine that is:*
 - (a) *Except for liquids, sold in package sizes of not more than 3.0 grams of ephedrine base, 3.0 grams of pseudoephedrine base, or 3.0 grams of phenlypropanolamine base, and that is packaged in blister packs, each blister containing not more than two dosage units, or where the use of blister packs is technically infeasible, that is packaged in unit dose packets or pouches; and*
 - (b) *For liquids, sold in package sizes of not more than 3.0 grams of ephedrine base, 3.0 grams of pseudoephedrine base, or 3.0 grams of phenlypropanolamine base.*

NAC 453.530 shall be amended as follows:

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) 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, *pseudoephedrine*, *phenylpropanolamine* ~~[or *N-methylephedrine*]~~, their optical isomers, salts and salts of optical isomers *that are not ordinary over-the-counter ephedrine, pseudoephedrine, or phenylpropanolamine products;*

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

~~[(b)]~~ (c) Hydriodic acid; or

~~[(e)]~~ (d) 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. 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;~~

~~—(l) 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.]~~ 8. 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, 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.]~~ **10.** 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.]~~ **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.

Workshop 7/26/01

Public Hearing 10/17/01