ADOPTED REGULATION OF

THE STATE BOARD OF PHARMACY

LCB File No. R079-15

Effective April 4, 2016

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

AUTHORITY: §1, NRS 453.146, 453.2182 and 639.070.

A REGULATION relating to controlled substances; adding lorcaserin to the controlled substances listed in schedule IV in conformity with federal regulations; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

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. (NRS 453.2182) The Drug Enforcement Administration of the United States Department of Justice has added lorcaserin to the list of controlled substances in schedule IV of the federal Controlled Substances Act. (78 Fed. Reg. 26,701-26,705) This regulation brings the treatment of lorcaserin into conformity with federal regulations by adding it to the list of controlled substances in schedule IV of the Uniform Controlled Substances Act.

Section 1. NAC 453.540 is hereby amended to read as follows:

- 453.540 1. Schedule IV 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 containing any of the following narcotic drugs, including, without limitation, their salts, calculated as the free anhydrous base of alkaloid, is hereby enumerated on schedule IV, in quantities:

(a) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit; or

(b) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane).

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including, without limitation, their salts, isomers and salts of isomers, is hereby enumerated on schedule IV, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Alprazolam;
Barbital;
Bromazepam;
Butorphanol;
Camazepam;
Carisoprodol;
Chloral betaine;
Chloral hydrate;
Chlordiazepoxide;
Clobazam;
Clonazepam;
Clorazepate;
Clotiazepam;

Cloxazolam;
Delorazepam;
Diazepam;
Dichloralphenazone;
Estazolam;
Ethchlorvynol;
Ethinamate;
Ethyl loflazepate;
Fludiazepam;
Flunitrazepam;
Flurazepam;
Halazepam;
Haloxazolam;
Ketazolam;
Loprazolam;
Lorazepam;
Lorcaserin;
Lormetazepam;
Mebutamate;
Medazepam;
Meprobamate;
Methohexital;
Methylphenobarbital (mephobarbital);

Midazolam;
Nimetazepam;
Nitrazepam;
Nordiazepam;
Oxazepam;
Oxazolam;
Paraldehyde;
Petrichloral;
Phenobarbital;
Pinazepam;
Prazepam;
Quazepam;
Suvorexant;
Temazepam;
Tetrazepam;
Tramadol (2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol);
Triazolam;
Zaleplon;
Zolpidem; or
Zopiclone.

4. Any material, compound, mixture or preparation which contains any quantity of fenfluramine, including, without limitation, its salts, isomers and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible, is hereby enumerated on schedule IV. For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

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 stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, is hereby enumerated on schedule IV:

Cathine ((+)-norpseudoephedrine);
Diethylpropion;
Fencamfamin;
Fenproporex;
Mazindol;
Mefenorex;
Modafinil;
Pemoline (including organometallic complexes and chelates thereof);
Phentermine;
Pipradrol;
Sibutramine; or
SPA ((-)-dimethylamino-1,2,diphenylethane).

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of pentazocine, including, without limitation, its salts, is hereby enumerated on schedule IV.

R079-15 NAC Chapter 453.540 Schedule IV

January 27, 2016

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 will add the prescription drug *lorcaserin* to the controlled substances listed in Schedule IV, and provides for other matters properly related thereto. This change is needed, and is being made at the request and with the support of the major crime labs throughout the state, to respond to a documented increase in abuse and harm resulting from the misuse of this medication.

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 further provided time for public comment at the workshop(s) concerning the proposed amendment.

The Board received no comment or testimony regarding the proposed change, except for the initial request and support for the change from crime labs throughout the state.

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: 30 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: N/A

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. Further, the Board 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 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 legitimate businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

The Board anticipates that this regulation will have no immediate or long-term economic effects on legitimate 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.