

**ADOPTED REGULATION OF THE  
STATE BOARD OF PHARMACY**

**LCB File No. R133-14**

Effective June 26, 2015

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; designating tramadol as a schedule IV controlled substance; and providing other matters properly relating thereto.

**Legislative Counsel's Digest:**

Existing law establishes five schedules of controlled substances. Substances are categorized based on: (1) the potential for abuse of the substance; (2) whether there is an accepted medical use for the substance; and (3) the potential for physical and psychological dependence on the substance. (NRS 453.166-453.206) Under existing law, the State Board of Pharmacy is authorized to add, delete or reschedule substances listed as controlled substances in each schedule. (NRS 453.146) The Board is required to place a substance in schedule IV if it finds that: (1) the substance has a low potential for abuse relative to substances in schedule III; (2) the substance has currently accepted medical use in treatment in the United States; and (3) abuse of the substance may lead to limited physical or psychological dependence relative to the substances in schedule III. (NRS 453.196) This regulation adds tramadol to the list of substances in schedule IV.

**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;  
Lormetazepam;  
Mebutamate;  
Medazepam;  
Meprobamate;  
Methohexital;  
Methylphenobarbital (mephobarbital);  
Midazolam;

Nimetazepam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

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.

R133-14  
NAC 453.540  
Tramadol Rescheduled to Schedule IV

March 3, 2015

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

On July 2, 2014, the Federal Drug Enforcement Agency (DEA) published a final ruling in the Federal Register placing tramadol into Schedule IV of the Controlled Substances Act. The rule became effective August 18, 2014. The proposed amendment to NAC 453.540 will add tramadol to Nevada's Schedule IV, consistent with the new federal regulation.

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.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

There was no public response expressed relative to this proposed regulation.

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 16.  
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:

There was no public response expressed relative to this proposed regulation.

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 posting a summary of the proposed amendment on the Board's website (bop.nv.gov), and by posting hard copies of its agenda at

various public locations. The Board also provided time for public comment at the workshop(s) concerning the proposed amendment.

There was no response from affected businesses relative to this proposed regulation.

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 change as no testimony was offered.

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 economic impact on affected 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.

Enforcement of the regulation will be performed during annual inspections of all pharmacies. There will be no additional cost incurred by the board.

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.

In 21 CFR § 1308.14, the DEA placed Tramadol on its Schedule IV. The Board of Pharmacy is likewise scheduling Tramadol on Nevada's Schedule IV.

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.