

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

LCB File No. R040-04

Effective July 13, 2004

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 drugs; adding carisoprodol to schedule IV; and providing other matters properly relating thereto.

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-propionoxy-butane).

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation ~~is~~ 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;

Triazolam;

Zaleplon; or

Zolpidem.

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;

Siputramine; 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.

**NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R040-04**

The State Board of Pharmacy adopted regulations assigned LCB File No. R040-04 which pertain to chapter 453 of the Nevada Administrative Code on June 3, 2004.

Notice date: 4/30/2004
Hearing date: 6/3/2004

Date of adoption by agency: 6/3/2004
Filing date: 7/13/2004

INFORMATIONAL STATEMENT

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. 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 on April 30, 2004 in county courthouses and through mailings to all libraries and interested parties.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 555 Double Eagle Court, Suite 1100, Reno, Nevada, 89521.

2. 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 6.
The number of persons who testified at the hearing was 6.
The number of agency submitted statements was 1.

3. 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.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all libraries and interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

There was one response from MedPointe Pharmaceuticals, the manufacturer of Soma (carisoprodol).

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 555 Double Eagle Court, Suite 1100, Reno, Nevada, 89521.

4. 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.

5. 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.

The regulation may slightly reduce sales of the drug carisoprodol which has been determined to be of potential abuse. The reduction may equate to those persons obtaining the drug inappropriately. The beneficial effect is realized by the public, wherein a drug of potential abuse is reduced from easy access.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

The immediate effect of this regulation enactment will necessitate computer program adjustment by retail pharmacies. The majority of pharmacies will accomplish this in central information technology departments. The long term effects dissipate within one year, wherein carisoprodol distribution will again adjust to appropriate patient utilization.

6. 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.

7. 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.

8. 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.

9. 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.