

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

LCB File No. R079-15

September 16, 2015

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-propionoxy-butane).

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.

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

LCB File No. R047-15

September 15, 2015

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

AUTHORITY: §1, NRS 639.070.

A REGULATION relating to pharmacy; revising provisions relating to the transmission of information regarding the dispensing of controlled substances to certain persons; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Under existing regulations, the State Board of Pharmacy requires each pharmacy that uses a computerized system to record information concerning prescriptions and that dispenses to certain persons a controlled substance that is listed in schedule II, III or IV to transmit certain information concerning the controlled substance to the Board or its agent on a weekly basis. (NAC 639.926) Certain practitioners who dispense controlled substances are also subject to those requirements. (NAC 639.745) This regulation requires such a pharmacy or practitioner to transmit that information not later than the next business day after dispensing the controlled substance. This regulation also requires such a pharmacy or practitioner that does not dispense such a controlled substance to transmit to the Board or its agent a zero report stating that the pharmacy or practitioner did not dispense such a controlled substance on the immediately preceding business day. Finally, this regulation revises the methods that a pharmacy or practitioner is required to use to transmit the information or zero report.

Section 1. NAC 639.926 is hereby amended to read as follows:

639.926 1. Each pharmacy that uses a computerized system to record information concerning prescriptions and that dispenses a controlled substance that is listed in schedule II, III or IV to a person who is not an inpatient of a hospital, correctional institution or nursing facility shall transmit to the Board or its agent the following information, as applicable, set forth in the

2011 ASAP Version 4.2 Standard for Prescription Monitoring Programs published by the American Society for Automation in Pharmacy. The following Segments and the accompanying Data Elements of the Implementation Guide for the *2011 ASAP Version 4.2 Standard for Prescription Monitoring Programs* are hereby adopted by reference:

(a) The Segment entitled “TH Transaction Header” and the following Data Elements:

- (1) Version/Release Number;
- (2) Transaction Control Number;
- (3) Transaction Type;
- (4) Response ID;
- (5) Creation Date;
- (6) Creation Time;
- (7) File Type; and
- (8) Segment Terminator Character;

(b) The Segment entitled “IS Information Source” and the following Data Elements:

- (1) Unique Information Source ID;
- (2) Information Source Entity Name; and
- (3) Message;

(c) The Segment entitled “PHA Pharmacy Header” and the following Data Elements:

- (1) National Provider Identifier (NPI);
- (2) DEA Number;
- (3) Pharmacy or Dispensing Prescriber Name;
- (4) Phone Number;

(5) Contact Name; and

(6) Chain Site ID;

(d) The Segment entitled “PAT Patient Information” and the following Data Elements:

(1) Last Name;

(2) First Name;

(3) Address Information - 1;

(4) City Address;

(5) State Address;

(6) ZIP Code Address;

(7) Phone Number;

(8) Date of Birth; and

(9) Gender Code;

(e) The Segment entitled “DSP Dispensing Record” and the following Data Elements:

(1) Reporting Status;

(2) Prescription Number;

(3) Date Written;

(4) Refills Authorized;

(5) Date Filled;

(6) Refill Number;

(7) Product ID Qualifier;

(8) Product ID;

(9) Quantity Dispensed;

- (10) Days Supply;
- (11) Transmission Form of Rx Origin Code;
- (12) Classification Code for Payment Type; and
- (13) Date Sold;

(f) The Segment entitled “PRE Prescriber Information” and the following Data Elements:

- (1) National Provider Identifier (NPI);
- (2) DEA Number;
- (3) DEA Number Suffix;
- (4) Last Name;
- (5) First Name; and
- (6) Phone Number;

(g) The Segment entitled “CDI Compound Drug Ingredient Detail” and the following Data Elements:

- (1) Compound Drug Ingredient Sequence Number;
- (2) Product ID Qualifier;
- (3) Product ID;
- (4) Component Ingredient Quantity; and
- (5) Compound Drug Dosage Units Code;

(h) The Segment entitled “TP Pharmacy Trailer” and the Data Element Detail Segment Count; and

(i) The Segment entitled “TT Transaction Trailer” and the following Data Elements:

- (1) Transaction Control Number; and

(2) Segment Count.

2. A copy of the publication may be obtained from the American Society for Automation in Pharmacy at the Internet address <http://www.asapnet.org>, or by telephone at (610) 825-7783, for the price of \$175 for members and \$770 for nonmembers.

3. ~~{The}~~ A pharmacy *that dispenses a controlled substance and is required to transmit information to the Board or its agent pursuant to subsection 1* shall transmit the information ~~{required pursuant to this section}~~ not later than ~~{each Wednesday for the prescriptions filled from the immediately preceding Sunday through Saturday. If a Wednesday falls on a legal holiday, then the information must be reported on the next business day that is not a legal holiday.}~~ *the end of the next business day after dispensing the controlled substance. A pharmacy that does not dispense a controlled substance as specified in subsection 1 shall transmit to the Board or its agent a zero report stating that the pharmacy did not dispense such a controlled substance on the immediately preceding business day.*

4. The information *required pursuant to this section or a zero report* must be transmitted by means of ~~{a form of electronic data transmission approved by the Board, including, without limitation, a computer modem that can transmit information at the rate of 2400 baud or more.}~~ :

- (a) *A secure file transfer protocol;*
- (b) *An upload from an Internet web portal; or*
- (c) *A manual entry.*

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This agenda item has been tabled until the FDA can continue looking into the licensure process.

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