Nevada State Board of Pharmacy

431 W. PLUMB LANE • RENO, NEVADA 89509
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
E-mail: pharmacy@pharmacy.nv.gov • Website: bop.nv.gov

October 28, 2015

AMENDED NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of
Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will hold a public hearing at 9:00 a.m., on Wednesday, December 2, 2015, at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada. The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to chapters 453 and 639 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

Amendment of Nevada Administrative Code (NAC) 453.540 Schedule IV

1. The need for and the purpose of the proposed regulation or amendment.

The proposed amendment will add lorcaserin to the controlled substances listed in Schedule IV, and provides for other matters properly related thereto.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no adverse or beneficial economic effect of this regulation on legitimate business or the public.

(b) Both immediate and long-term effects.

There will be no immediate or long-term economic effect on legitimate business or the public.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no significant new costs incurred by the board for enforcement of this regulation.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement

explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The Board of Pharmacy is not aware of this regulation being required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Amendment of Nevada Administrative Code (NAC) 639.926 Transmission of information regarding dispensing of controlled substances to certain persons.

1. The need for and the purpose of the proposed regulation or amendment.

Amends the rule that presently establishes frequency of the controlled substance information transmitted to the Board. The amendment will improve the timeliness of the date to improve the quality of the data provided to practitioners and pharmacies pursuant to NRS 453.1545 and SB459.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no significant adverse or beneficial economic effect of this regulation on the business or the public.

(b) Both immediate and long-term effects.

There will be no immediate or long-term economic effect on businesses or the public.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no cost incurred by the board for enforcement of this regulation.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include 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.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The Board of Pharmacy is not aware of this regulation being required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulations of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Amendment of Nevada Administrative Code (NAC) 639.620, NAC 639.6282, NAC 639.6305 – Third-Party Logistics Providers

1. The need for and the purpose of the proposed regulation or amendment.

The regulation amends the definition of third-party logistics providers (3PLs) to be consistent with the Federal Drug Quality and Security Act (DQSA). The amendment requires that a 3PL obtain a license as an authorized warehouse, rather than being licensed as a wholesaler as they have historically been licensed.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no adverse or beneficial economic effect of this regulation on the business or the public. The Board is amending the regulation to create a sub-category of license for 3PLs, rather than continuing to license them as wholesalers.

(b) Both immediate and long-term effects.

There will be no immediate or long-term economic effect on businesses or the public.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no significant new costs incurred by the board for enforcement of this regulation.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The Drug Quality and Security Act (DQSA) was signed into law by President Obama on November 27, 2013. Title II of DQSA, The Drug Supply Chain Security Act, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. One of those steps is to require third-party logistics providers, or 3PLs, to be licensed by their respective states as 3PLs, and not as wholesalers, as they have historically been licensed.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation of the same activity in which the state regulation is more stringent. The amendment is intended to bring Nevada law in line with federal law to ease compliance concerns within the industry.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments in written form to the Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada 89509, or at e-mail address: shunting@pharmacy.nv.gov. Written submissions must be received by the Board at least fourteen days before the scheduled public hearing. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

A copy of this notice and the regulation to be adopted and amended will be on file at the State Library, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be

adopted and amended will be available in all counties in which an office of the agency is not maintained, at the main public library, for inspection and copying by members of the public during business hours. The text of each regulation will include the entire text of any section of the Nevada Administrative Code which is proposed for amendment or repeal. This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary.

Upon adoption of any regulation, the agency, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at the following locations:

Nevada State Board of Pharmacy
Reno, Nevada

Nevada State Board of Pharmacy
Las Vegas, Nevada

Mineral County Courthouse
Hawthorne, Nevada

Elko County Courthouse
Elko, Nevada

Washoe County Courthouse
Reno, Nevada

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.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R001-15

July 29, 2015

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

AUTHORITY: §§1-4, NRS 639.070 and 639.233.

A REGULATION relating to pharmacy; revising provisions governing the licensure of a third-party logistics provider; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

The federal Drug Supply Chain Security Act defines a "third-party logistics provider" as an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor or disperser of a product, but does not take ownership of the product nor have the responsibility to direct the sale or disposition of the product. (21 U.S.C. § 360eee(22)) UPS and DHL are examples of companies that provide those services. **Section 1** of this regulation amends the definition of "third-party logistics provider" in existing regulations to include the provision of such services on behalf of wholesalers to more closely align that definition with the federal definition of that term. (NAC 639.6282)

Existing regulations require a third-party logistics provider in this State to obtain a license to engage in business as an authorized warehouse. (NAC 639.6305) Existing regulations define an "authorized warehouse" as a warehouse or other business in the State that receives, stores or ships prescription drugs and goods pursuant to a written contract with a manufacturer, wholesaler, pharmacy or chain warehouse under which the authorized warehouse acts solely as the agent or bailee of the manufacturer, wholesaler, pharmacy or chain warehouse. (NAC 639.622) **Section 2** of this regulation expressly provides that a third-party logistics provider that is located in the State or that ships certain poisons, drugs, chemicals, devices or appliances into this State is required to: (1) obtain a license to engage in business as an authorized warehouse; and (2) comply with the provisions of existing regulations governing warehouses.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

"Poisons, drugs, chemicals, devices or appliances" mean poisons, drugs, chemicals, devices or appliances that are subject to the provisions of chapters 453, 454 or 639 of NRS.

Sec. 2. NAC 639.620 is hereby amended to read as follows:

639.620 As used in NAC 639.620 to 639.644, inclusive, ***and section 1 of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 639.621 to 639.629, inclusive, ***and section 1 of this regulation*** have the meanings ascribed to them in those sections.

Sec. 3. NAC 639.6282 is hereby amended to read as follows:

639.6282 "Third-party logistics provider" means a business that contracts with a manufacturer ***or wholesaler*** to provide or coordinate warehousing, distribution or other services ***for poisons, drugs, chemicals, devices or appliances*** on behalf of the manufacturer ***or wholesaler*** without taking title to or ownership of the ~~[prescription]~~ ***poisons,*** drugs ***, chemicals, devices or appliances*** and without authority to direct the sale or disposition of the ~~[prescription]~~ ***poisons,*** drugs ~~[.]~~ ***, chemicals, devices or appliances.***

Sec. 4. NAC 639.6305 is hereby amended to read as follows:

639.6305 A third-party logistics provider ***that is located*** in this State ***or that ships poisons, drugs, chemicals, devices or appliances into this State*** shall obtain a license to engage in business as an authorized warehouse pursuant to, and shall otherwise comply with, the provisions of NAC 639.620 to 639.644, inclusive ~~[.]~~ ***and section 1 of this regulation.***