Nevada State Board of Pharmacy

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March 9, 2016

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 Thursday, April 14, 2016, at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, 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/or 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) 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. 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.***