

**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 [H], 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 ***[H] and section 1 of this regulation.***



March 1, 2016

Dr. Ilisa Bernstein
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Re: DSCSA Required Guidances and Rules

Dear Dr. Bernstein:

As you know, the Pharmaceutical Distribution Security Alliance (PDSA) is a coalition of companies and organizations dedicated to the safety and integrity of the pharmaceutical distribution supply chain. As you also know, the Drug Supply Chain Security Act (DSCSA) requires the Agency to issue regulations and guidances on a number of topics to assist in the implementation of the DSCSA.

PDSA is concerned that the delayed release of the required guidances and rules does not lead to the most effective and efficient implementation of the DSCSA. For example, the identification and investigation of suspect and illegitimate product lies at the heart of the DSCSA. As explained in PDSA's August 11, 2014 comments on the Agency's draft guidance regarding suspect and illegitimate product, clear guidance is necessary for the effective implementation of the DSCSA and for achieving supply chain security.

Similarly, the delayed release of licensing standards for wholesale distributors and third-party logistics providers has impeded effective implementation. We are aware of at least one instance in which distribution of a product—product subject to a drug shortage, nonetheless—was ceased for multiple days due to confusion related to the application of the third-party logistics provider licensure provisions of the DSCSA. In other states, there is significant confusion related to non-resident licensure requirements. For example, Georgia has properly recognized the preemptive effect of the DSCSA and ceased licensing third-party logistics providers pending the release of the FDA standards. However, California, Missouri, and Idaho require licensure of non-resident third-party logistics providers, and as a condition of such licensure require home-state licensure. Therefore, a Georgia-based third-party logistics provider cannot meet the licensure requirements for multiple states because Georgia has properly recognized and complied with the DSCSA. This type of confusion can significantly impede the distribution of medications needed by patients and undermines the statutory construct set out in the DSCSA.

To prevent continued uncertainty, we urge the Agency to finalize and release the statutorily mandated DSCSA regulations and guidances—specifically its guidance on suspect and illegitimate product; its guidance on waivers, exceptions, and exemptions; its guidance on licensure reporting; and its regulations establishing uniform licensure standards for wholesale distributors and third-party logistics providers.¹

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PDSA appreciates the FDA's continued efforts in implementation of the DSCSA. We welcome the opportunity to discuss these important topics or provide any other assistance that would be valuable to the Agency.

Sincerely,

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¹ PDSA is separately providing comments related to the release of any guidance related to grandfathering. While the issue of grandfathering is important, release of guidance on that topic could significantly compromise compliance if inconsistent with the June 8, 2015 letter from PDSA regarding grandfathering.