

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

LCB File No. R002-21

September 1, 2021

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

AUTHORITY: §§ 1 and 2, NRS 639.070 and 639.100, as amended by section 4 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1017.

A REGULATION relating to pharmacy; imposing limitations concerning the dispensing, selling, supplying, furnishing and administration of certain compounded drugs; requiring an outsourcing facility to establish certain procedures; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Existing law prohibits a person who does not hold the proper certificate, license or permit from compounding a drug. (NRS 639.100, as amended by section 4 of Senate Bill No. 408, chapter 218, Statutes of Nevada 2021, at page 1017) Existing regulations define “outsourcing facility” to mean a facility that: (1) is engaged in the compounding of sterile drugs; and (2) is registered with the federal government as an outsourcing facility. (NAC 639.6912) **Section 1** of this regulation prohibits the dispensing, reselling, supplying or furnishing of a drug compounded by a pharmacy, dispensing practitioner or outsourcing facility by any entity other than the pharmacy, dispensing practitioner or outsourcing facility, as applicable, that compounded the drug. **Section 2** of this regulation: (1) requires an outsourcing facility to establish procedures to ensure compliance with **section 1**; and (2) provides that a drug compounded by an outsourcing facility may be administered pursuant to the order of a practitioner.

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

1. A drug compounded by a pharmacy, a dispensing practitioner or an outsourcing facility must not be dispensed, resold, supplied or furnished by any person or entity other than the pharmacy, dispensing practitioner or outsourcing facility, as applicable, that compounded the drug.

2. As used in this section, “outsourcing facility” has the meaning ascribed to it in NAC 639.6912.

Sec. 2. NAC 639.6915 is hereby amended to read as follows:

639.6915 *1.* An outsourcing facility that is engaged in the compounding of sterile drugs in this State or for shipment into this State shall:

~~1-1~~ *(a)* Obtain a license from the Board as a manufacturer in accordance with NRS 639.100 and 639.233;

~~1-2~~ *(b)* Comply with the provisions of NAC 639.609 to 639.619, inclusive; ~~and~~

~~3-1~~ *(c)* Comply with all the requirements of 21 U.S.C. § 353b ~~1-1~~; *and*

(d) Establish and implement procedures to prohibit other persons and entities from dispensing, reselling, supplying or furnishing drugs compounded by the outsourcing facility in violation of section 1 of this regulation.

2. A drug compounded by an outsourcing facility may be administered pursuant to the order of a practitioner.