

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

LCB File No. R003-15

January 21, 2015

Explanation – Language in *blue italics* is new; language in red ~~omitted material~~ is language to be omitted.

AUTHORITY: §1, NRS 639.070, NRS 639.100 and NRS 639.233.

Amendment of Nevada Administrative Code Chapter 639; NEW LANGUAGE regarding Outsourcing Facilities; Updating law in response to Federal Drug Quality and Security Act (DQSA).

Section 1. NAC Chapter 639 is hereby amended to read as follows:

NAC 639.____ "Outsourcing facility" defined. "Outsourcing facility" means a facility at one geographic location or address that:

- 1. Is a manufacturer as that term is defined in NRS 639.009;*
- 2. Is engaged in the compounding of sterile drugs; and*
- 3. Has elected to register with the Food and Drug Administration as an outsourcing facility pursuant to 21 U.S.C. § 503B.*

Section 2. NAC Chapter 639 is hereby amended to read as follows:

NAC 639.____ "Sterile drug" defined. "Sterile drug" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.

Section 3. NAC Chapter 639 is hereby amended to read as follows:

NAC 639.____ Any person who is registered with the Food and Drug Administration as an outsourcing facility pursuant to 21 U.S.C. § 503B and engages in the compounding of a sterile drug in this State, or engages in the compounding of a sterile drug for shipment into this State, shall obtain an outsourcing facility license from the Board.

Section 4. NAC Chapter 639 is hereby amended to read as follows:

NAC 639.____ Except as otherwise provided in this chapter, any person who is licensed by the Board as an outsourcing facility shall comply with all requirements of 21 U.S.C. § 503B and NAC 639.610 through 639.619.

Section 5. NAC Chapter 639 is hereby amended to read as follows:

NAC 639.____ An outsourcing facility (a) is not required to be a licensed pharmacy, and (b) may dispense dangerous drugs or controlled substances for identified individual patients pursuant to a prescription only if it is also licensed by the Board as a pharmacy.