# PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

### **LCB File No. R140-14**

Workshop October 16, 2014

#### NAC 639.6625 "Compound" and "compounding" defined. (NRS 639.070)

- 1. Except as otherwise provided in subsection 2, "compound" and "compounding" mean:
- (a) The preparation, mixing or assembling of a drug product of which at least one component is a prescription drug; and
- (b) The packaging and labeling incident to the preparation, mixing or assembling of a drug product for the purpose of selling or dispensing the drug product pursuant to a prescription or chart order.
- 2. The terms "compound" and "compounding" do not include the mixing or reconstituting of a nonsterile drug product that is performed in accordance with:
- (a) The directions contained in the labeling of the drug product that have been approved by the Food and Drug Administration and provided by the manufacturer of the drug product; or
- (b) Any other directions provided by the manufacturer of the drug product that are consistent with the labeling of the drug product that have been approved by the Food and Drug Administration.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

#### NRS 639.007 "Drug" and "medicine" defined. "Drug" and "medicine" mean:

- 1. Articles recognized in the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;
- 2. Articles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals;
- 3. Articles, other than food, aspirin and effervescent saline analgesics, intended to affect the structure or any function of the body of humans or other animals;
- 4. Articles intended for use as a component of any article specified in subsection 1, 2 or 3; and
  - 5. Any controlled substance.

(Added to NRS by 1967, 1651; A 1971, 2039; 1983, 1505; 1987, 1566)

## NAC 639.67\*\*\* Compounding of nasal medications. (NRS 639.070)

- 1. For products intended to be delivered into the nasal cavity the pharmacy engaged in the practice of compounding nasal irrigation, nasal solution, powder for delivery into the nasal sinus, or nasal spray products shall:
  - (a) Label the compound with the statement; "Not for use in the lungs" and
    - (1) Compound the drug to the Standards for Compounding and Dispensing Sterile Products NAC 639.6705 to NAC 639.67079. or

(2) Compound the drug to the Standards for Compounding and Dispensing Nonsterile Products NAC 639.6703 to NAC 639.67037 and perform objectionable microorganisms testing per USP 1111 to validate the pharmacy's compounding procedure of each product type.