PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R032-02

April 1, 2002

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

AUTHORITY: §1, NRS 639.070.

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

1. A pharmacy or pharmacist is not required to obtain a license as a manufacturer to compound drugs if:

(a) The compounded drugs are prepared in a quantity that is:

(1) Necessary to fill a prescription; or

(2) Reasonably necessary to fill future prescriptions based upon the previous history of practitioners and patients who regularly use the pharmacy;

(b) The compounded drugs are not sold or otherwise provided by the pharmacy or pharmacist to any person other than the ultimate user of the drugs, the agent of the ultimate user of the drugs or a practitioner who will be administering the drugs to a patient; and

(c) The ingredients used to compound the drugs meet or exceed the standards of the United States Pharmacopoeia - National Formulary. If a component of the compounded drug does not have a monograph in the United States Pharmacopoeia - National Formulary, the component may still be used if the component is in a list of approved substances developed by the Secretary of Health and Human Services.

2. A pharmacy or pharmacist shall not compound a drug that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective.

3. A pharmacy or pharmacist shall not sell or otherwise provide a compounded drug to:

(a) Another pharmacy; or

(b) A practitioner, except that a pharmacy or pharmacist may sell or otherwise provide a compounded drug to a practitioner who will be administering the drug to a patient.