LCB File No. R032-02

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Compounding Regulations

(Ver. 1/14/02)

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

1. A pharmacy or pharmacist shall not be required to obtain a manufacturer's permit to compound drugs where:

(a) The compounded drug is prepared in a quantity that is:

(i) Necessary to fill a prescription; or

(ii) Reasonable to fill future prescriptions based upon the prescribing habits of practitioners or patients who regularly use the pharmacy.

(b) The drugs prepared are not sold or otherwise provided to any person other than the ultimate user of the drug or his agent

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

2. A pharmacy or pharmacist may not compound a drug that has been withdrawn or removed from the market because it was unsafe or ineffective.

3. A pharmacy or pharmacist may not sell or otherwise provide a compounded drug to another pharmacy or to a practitioner except that a pharmacy or pharmacist may sell or otherwise provide a compounded drug to a practitioner who will be administering the compounded drug to a patient.

Workshop 3/7/02