REVISED PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R061-05

April 5, 2006

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

AUTHORITY: §§1-4, NRS 639.070.

A REGULATION relating to pharmacies; authorizing a pharmacy, under certain circumstances, to repackage a controlled substance or dangerous drug that was previously dispensed by another pharmacy; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2, 3 and 4 of this regulation.

Sec. 2. ***As used in sections 2, 3 and 4 of this regulation:***

1. "Original label" means the label affixed by an original pharmacy to the container of a controlled substance or dangerous drug.

2. "Original pharmacy" means a pharmacy that dispenses a controlled substance or dangerous drug which is subsequently delivered to another pharmacy for repackaging.

3. "Patient" means the ultimate user, patient or subject of research to whom a controlled substance or dangerous drug is dispensed by an original pharmacy. The term includes an agent of the patient.

4. "Repackaging pharmacy" means a pharmacy that repackages a controlled substance or dangerous drug that was previously dispensed by another pharmacy.

5. "Unit of use" has the meaning ascribed to it in NAC 639.460.

Sec. 3. ***Except as otherwise provided in section 4 of this regulation, a pharmacy may repackage a controlled substance or dangerous drug that was previously dispensed by an original pharmacy if the repackaging pharmacy:***

1. Makes a record of the:

(a) Name of the patient as given on the original label;

(b) Name of the controlled substance or dangerous drug;

(c) Name and address of the original pharmacy;

(d) Original prescription number;

(e) Date the controlled substance or dangerous drug is delivered to the repackaging pharmacy;

(f) Identity of the person who delivers the controlled substance or dangerous drug to the repackaging pharmacy, including, without limitation, the person's relationship to the patient;

(g) Quantity of the controlled substance or dangerous drug:

(1) Dispensed by the original pharmacy;

(2) Delivered by the patient to the repackaging pharmacy; and

(3) Delivered to the patient by the repackaging pharmacy; and

(h) Date on which the repackaged controlled substance or dangerous drug is delivered to the patient.

2. Does not intermingle the controlled substance or dangerous drug with the repackaging pharmacy's regular inventory or filled prescriptions.

3. Repackages the controlled substance or dangerous drug in a unit-of-use container that holds each dose in a secure and sanitary manner.

4. Completes the repackaging of the controlled substance or dangerous drug not later than the end of the first business day after the day the controlled substance or dangerous drug is delivered to the repackaging pharmacy.

5. Affixes to the container of the repackaged controlled substance or dangerous drug a label that includes:

(a) All information included on the original label;

(b) The name and address of the repackaging pharmacy;

(c) The date on which the controlled substance or dangerous drug is repackaged; and

(d) A disclaimer which indicates that the only activity performed by the repackaging pharmacy has been the repackaging of the controlled substance or dangerous drug. This requirement is satisfied if the label includes the words "repackaged by," or their equivalent, followed by the name of the repackaging pharmacy.

6. Inspects the controlled substance or dangerous drug and determines that it is:

(a) The controlled substance or dangerous drug named on the original label;

(b) Not damaged; and

(c) Not adulterated.

Sec. 4. *A repackaging pharmacy shall not:*

1. Repackage more than one controlled substance or dangerous drug in each unit-of-use container.

2. Repackage a controlled substance or dangerous drug that has been previously repackaged. The pharmacy may accept delivery of such a controlled substance or dangerous drug only for the purpose of destroying it.

3. Deliver a repackaged controlled substance or dangerous drug to a person other than the patient named on the original label.