ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R061-05

Effective May 4, 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;

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

(i) Initials of the registered pharmacist or intern pharmacist who provides the verification required by subsection 7.

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

3. Repackages the entire quantity of the controlled substance or dangerous drug delivered by the patient to the repackaging pharmacy or adds to the record required by subsection 1 an explanation of the difference between the quantity repackaged and the quantity delivered to the repackaging pharmacy.

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

5. 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.

6. 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.

7. Causes a registered pharmacist or intern pharmacist to inspect the repackaged controlled substance or dangerous drug and verify 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.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R061-05

The State Board of Pharmacy adopted regulations pertaining to Chapter 639 of the Nevada Administrative Code on April 20, 2006.

Notice date: 3/15/2006 **Date of adoption by agency:** 4/10/2006
Hearing date: 4/20/2006 **Filing date:** 5/4/2006

INFORMATIONAL STATEMENT

1. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

There was no public response expressed relative to this proposed regulation.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

There was no public response expressed relative to this proposed regulation.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

There was no response from affected businesses relative to this proposed regulation.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted with minor changes.

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

This regulation should have no economic impact on affected businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation will have no immediate or long-term economic effects on business or the public.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

Enforcement of the regulation will be performed during annual inspections of all pharmacies. There will be no additional cost incurred by the board.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

8. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

9. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.