ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R040-06

Effective May 4, 2006

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

AUTHORITY: §§ 1-5, NRS 639.070, 639.0725, 639.2328 and 639.23284.

A REGULATION relating to prescription drugs; providing for the regulation of certain pharmacies located in Canada that are licensed to provide mail order service to residents of this State; setting forth the drugs such pharmacies may and may not dispense; requiring such pharmacies to transmit and record certain information; 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 to 5, inclusive, of this regulation.

Sec. 2. ***1. A pharmacy located in Canada shall not dispense, sell or otherwise provide prescription drugs to a resident of this State unless the pharmacy holds a valid license issued by the Board pursuant to NRS 639.2328.***

2. A pharmacy located in Canada that wishes to obtain a license pursuant to NRS 639.2328 must submit an application to the Board on a form provided by the Board. The application must be signed by the owner or chief executive officer of the pharmacy, who must certify that the contents of the application are true and correct to the best of his knowledge, information and belief.

3. The staff of the Board shall not forward to the Board for the Board's consideration an application for licensure submitted by a Canadian pharmacy until the staff determines that the application is complete.

Sec. 3. ***1. A Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.2328 may dispense under those provisions only a drug that:***

(a) Appears in:

(1) The Orange Book; and

(2) The HC-DPD;

(b) Has been manufactured in accordance with standards established by:

(1) The Food and Drug Administration of the United States Department of Health and Human Services; or

(2) The Therapeutic Products Directorate of Health Canada;

(c) Is in a strength that appears in both the Orange Book and the HC-DPD; and

(d) Is drawn from the inventory of the pharmacy that is maintained at the pharmacy.

2. A Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.2328 may not dispense under those provisions:

(a) A drug that is in any of the following forms:

(1) A liquid form, except for ophthalmic solutions;

(2) An intravenous form; or

(3) A form that requires refrigeration or other special handling for shipment;

(b) A generic version of a drug, unless the generic version of the drug is "A-rated" in the Orange Book; or

(c) A drug that has been approved for sale without a prescription in Canada but for which a prescription is required in the United States, unless the patient has provided a prescription for the drug to the pharmacy.

3. As used in this section:

(a) "HC-DPD" means the Drug Product Database, copyright Her Majesty the Queen in Right of Canada, as amended, that is managed by Health Canada. Access to the database may be obtained on the Internet at the Internet address http://www.hc-sc.qc.ca/dhp-mps/prodpharma/databasdon/index_e.html.

(b) "Orange Book" means the list of "Approved Drug Products with Therapeutic Equivalence Evaluations," as amended, that is published by the Center for Drug Evaluation and Research of the Food and Drug Administration of the United States Department of Health and Human Services. A copy of the list may be obtained on the Internet at the Internet address http://www.fda.gov/cder/orange/obannual.pdf.

Sec. 4. *1. A Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.2328 shall:*

(a) Maintain a toll-free telephone number and an e-mail address at which a patient may contact and communicate with a pharmacist employed by the pharmacy;

(b) Ensure that a pharmacist employed by the pharmacy contacts a patient's prescribing practitioner in the United States regarding a prescription for the patient:

(1) If the prescription was electronically transmitted to the pharmacy in any manner other than directly from the office of the prescribing practitioner in the United States, to verify the authenticity and contents of the prescription; and

(2) Before making any change to the prescription that deviates from the prescription as written by the prescribing practitioner in the United States;

(c) Ensure that, before a prescription from a prescribing practitioner in the United States is transmitted to a prescribing practitioner in Canada for approval, a pharmacist employed by the pharmacy:

(1) Personally enters the data regarding the prescription into the pharmacy's computer system; or

(2) Verifies that the data regarding the prescription was entered correctly into the pharmacy's computer system by another employee of the pharmacy; and

(d) Ensure that the pharmacists employed by the pharmacy make and maintain a record, either on paper or in the pharmacy's computer system, that readily identifies the pharmacist who, with respect to a prescription:

(1) Entered or verified the data regarding the prescription pursuant to paragraph (c); and

(2) Filled the prescription or verified the correctness of the prescription, if the prescription was filled by an employee other than a pharmacist.

➥ The records required pursuant to this paragraph must be maintained by the pharmacy for at least 2 years and be made available, upon request, for inspection by the staff of the Board.

2. A Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.2328 shall not direct or otherwise allow a patient to have his prescription dispensed by or to otherwise use the services of a pharmacy that is not licensed by the Board.

3. If a Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.2328 does not have in stock a drug with which to dispense a patient's prescription and is unable to transfer the prescription to another pharmacy licensed pursuant to NRS 639.2328 that is able to dispense the prescription, the Canadian pharmacy shall:

(a) Ensure that a pharmacist employed by the pharmacy contacts the patient's prescribing practitioner in the United States to obtain authorization to change the prescription to a drug that the pharmacy has in stock; or

(b) Within sufficient time to ensure that the drug therapy of the patient will not be interrupted or disturbed, contact the patient to inform him that the pharmacy cannot dispense the prescription.

Sec. 5. *1. In addition to complying with the requirements of NRS 639.23286 and NAC 639.708, a Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.2328 shall ensure that each of the following are published on the Internet website, if any, of the pharmacy and printed upon any written materials provided by the pharmacy to a patient:*

(a) The normal business hours of the pharmacy;

(b) The toll-free telephone number of the pharmacy; and

(c) The e-mail address of the pharmacy.

2. In addition to complying with the requirements of NRS 639.2801, a Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.2328 shall ensure that each of the following is printed on the label of a prescription:

(a) The name of the prescribing practitioner in the United States with a designator proximate to the name such as "US" or "USA" or a similar designator indicating that the practitioner is from the United States; and

(b) The name of the prescribing practitioner in Canada with a designator proximate to the name such as "CAN" or "CANADA" or a similar designator indicating that the practitioner is from Canada.

➥ If the pharmacy is unable to print one or both of the names of the prescribing practitioners or their proximate national designators directly upon the label of the prescription, the

pharmacy may include such information on auxiliary labels affixed to the container in which the prescription is dispensed.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R040-06

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.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 555 Double Eagle Court, Suite 1100, Reno, Nevada, 89521.

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

The number of persons who attended the hearing was ___14__.
The number of persons who testified at the hearing was __14___.
The number of agency submitted statements was __0___.

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.

The Board received no testimony or evidence that the regulation would have adverse business effects. The Board received testimony that there will be a beneficial effect to the public, namely that the public may be able to save money on their prescription drugs.

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 licensed pharmacies and through consumer complaints. These regulations have not been implemented yet, however, the Board's costs to meet with prospective pharmacies and inspection of seven pharmacies has already cost the Board of Pharmacy over $9,000. The Board anticipates that the annual costs may be as much as or more than the present $9,000 per year.

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.