

LCB File No. R040-06

PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY

REGULATIONS FOR THE LICENSING OF CANADIAN PHARMACIES

Section 1. NAC chapter 639 shall be amended to add the following new language:

1. For the purposes of this regulation, “Orange Book” shall mean the List of Approved Drug Products produced by the United States Department of Health and Human Services, Food and Drug Administration, including all updates and supplements.

2. For the purposes of this regulation, “HC-DPD” shall mean the Drug Product Database made and maintained by Health Canada, access to which database can be made at www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/dpd_index_e.html.

3. A Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.23284 may only dispense a drug that:

(a) Appears in:

(1) The Orange Book; and

(2) The HC-DPD

(b) Has been manufactured in accordance with its approval by either:

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

(2) The Therapeutic Products Directorate of Health Canada;

(c) Is not in a liquid form except for ophthalmic solutions, an injectable form ~~except for Depo-Provera~~ that does not require refrigeration or other special handling for shipment, an intravenous form, or in a form that requires refrigeration or special handling for shipment by mail;

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

(e) Comes only from the pharmacy’s inventory maintained at the pharmacy.

4. A Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.23284 may not dispense:

(a) A generic version of a drug unless the generic version of the drug is “A-rated” in the Orange Book; or

(b) 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.

Section 2. NAC chapter 639 shall be amended to add the following new language:

1. No pharmacy resident in Canada may dispense, sell, or otherwise provide prescription drugs into Nevada unless the Canadian pharmacy is first licensed pursuant to NRS 639.23284.

2. A Canadian pharmacy seeking licensure pursuant to NRS 639.23284 shall submit an application to the Board on a form provided by the Board. The form shall be signed by the owner or chief executive officer of the corporation who shall certify that the contents of the application are true and correct. The Board’s staff shall not provide an application to the Board for approval until the application is complete.

Section 3. NAC chapter 639 shall be amended to add the following new language:

1. A Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.23284 shall:

(a) Maintain a toll-free telephone number and an e-mail address through which a patient may correspond with a pharmacist;

(b) ~~Contact~~ Assure that one of its pharmacists contacts the prescribing practitioner in the United States:

(1) When the prescription came to the Canadian pharmacy from any source other than directly from the prescribing practitioner’s office to verify the contents of the prescription; and

(2) Before making any change in the prescription as it was written by the prescribing practitioner in the United States;

(c) Assure that before a prescription from a prescribing practitioner in the United States is transmitted to a Canadian physician, a Canadian pharmacist either:

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

(2) Verifies the data regarding a prescription as it was entered into the pharmacy's computer system by another pharmacy employee;

(d) Assure that its pharmacists make and maintain a record, either on paper or in the pharmacy's computer system, that readily identifies the pharmacist who entered or verified the prescription information pursuant to subsection (c) for each prescription; and

(e) Assure that its pharmacists make and maintain a record, either on paper or in the pharmacy's computer system, that readily and accurately identifies the pharmacist who filled a prescription or who verified the correctness of the prescription if it was filled by an employee other than a pharmacist.

The records required in subsections (d) and (e) must be maintained by the pharmacy for at least two years and must be readily available to the Board's staff.

2. A Canadian pharmacy licensed to provide mail order service pursuant to NRS 639.23284 shall not allow a patient to have his prescription dispensed except through the pharmacy licensed by the Board. A Canadian pharmacy may not direct or otherwise allow a patient to use the services of any pharmacy not licensed by the Board. If a Canadian pharmacy does not have a drug in stock with which to dispense a patient's prescription and is unable to transfer the prescription to another pharmacy licensed pursuant to NRS 639.23284 that is able to dispense the prescription, the Canadian pharmacy shall:

(a) Have one of its pharmacists ~~[(C)]~~ contact the prescribing practitioner in the United States to obtain authorization to change the prescription to a drug that the Canadian pharmacy does have in stock; or

(b) Contact the patient in such a time that the patient's drug therapy will not be interrupted or disturbed to inform the patient that the Canadian pharmacy cannot dispense the prescription.

Section 4. NAC chapter 639 shall be amended to add the following new language:

1. In addition to the requirements of NRS 639.23286 and NAC 639.708, a Canadian pharmacy shall assure that:

(a) The normal business hours,

(b) The toll-free telephone number, and

(c) The e-mail address at which the patient may direct inquiries,

are all published on the pharmacy's website and upon any written materials provided by the pharmacy to the patient.

2. In addition to the requirements of NRS 639.2801, a Canadian pharmacy shall also include on a prescription's container:

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

If the pharmacy cannot print either or both of the names of the prescribing practitioners or the designators for either or both on the prescription's label, the pharmacy may include that information on auxiliary labels affixed to the prescription container.