ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R165-01

Effective December 17, 2001

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

AUTHORITY: §§1-6, Section 3 of Senate Bill No. 544 of the 71st session of the Nevada Legislature, chapter 344, Statutes of Nevada 2001, at page 1631 (NRS 639.0725) and Section 43 of Senate Bill No. 397of the 71st session of the Nevada Legislature, chapter 236, Statutes of Nevada 2001, at page 1067 (NRS 639.23288).

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 6, inclusive, of this regulation.

Sec. 2. ***As used in sections 2 to 6, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3 and 4 of this regulation have the meanings ascribed to them in those sections.***

Sec. 3. ***"Certified Internet pharmacy" means an Internet pharmacy that has been certified by the board pursuant to section 5 of this regulation.***

Sec. 4. ***"Internet pharmacy" has the meaning ascribed to it in NRS 639.00865.***

Sec. 5. ***1. A licensed pharmacy may practice as an Internet pharmacy only if the pharmacy is certified by the board pursuant to this section. To be certified by the board pursuant to this section, a pharmacy must apply to the board for certification on an application provided by the board.***

2. The board will grant an application for certification as an Internet pharmacy pursuant to this section if:

(a) The pharmacy is certified by the Verified Internet Pharmacy Practice Sites Program of the National Association of Boards of Pharmacy; or

(b) The board determines that the pharmacy satisfies the requirements of subsection 3.

3. The board will grant an application for certification pursuant to paragraph (b) of subsection 2 if the board determines that the pharmacy:

(a) Is licensed to practice pharmacy in each state in which the pharmacy will practice pharmacy;

(b) Maintains and enforces policies and procedures which ensure that:

(1) The pharmacy is able to establish the authenticity of a prescription which the pharmacy receives;

(2) The pharmacy will not fill any prescription which has been previously filled by another pharmacy, and if the pharmacy fills any prescription, that prescription will not also be filled by another pharmacy;

(3) The identity of the patient and the prescribing practitioner is verified to be authentic;

(4) A prescription is filled in compliance with all applicable federal and state laws;

(5) A patient or the caregiver of the patient may make a complaint to the pharmacy regarding the prescription of the patient, and if such a complaint is made, the complaint will be investigated thoroughly, the results of the investigation will be communicated to the patient or caregiver, and if the investigation reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action will be taken by the pharmacy;

(6) The pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device; and

(7) The pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices;

(c) Obtains and maintains patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes;

(d) Provides review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides;

(e) Maintains controls of its computer system, information concerning patients and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents;

(f) Complies with applicable federal and state laws regarding:

(1) The dispensing of prescription drugs;

(2) Recordkeeping related to the patients served by the pharmacy, the purchase of prescription drugs, and the sale and dispensing of prescription drugs; and

(3) The sale of over-the-counter products, including, without limitation, any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs;

(g) Ships prescriptions to a patient using a secure and traceable means; and

(h) Ships prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the United States Pharmacopeia, 25th edition, 2002, which is hereby

adopted by reference. A copy of the publication may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, for the price of $589, plus $13 for shipping and handling.

Sec. 6. *1. By applying for and being granted certification as a certified Internet pharmacy pursuant to section 5 of this regulation, a certified Internet pharmacy shall be deemed to have given its consent to:*

(a) Allow free access, at all times during business hours, to all places where drugs, medicines, poisons, devices or appliances are kept and to all records regarding the purchase, sale, dispensing and shipping of, and all other dealings with, such drugs, medicines, poisons, devices or appliances, to members of the board and its inspectors and investigators, investigators of the investigation division of the department of public safety, inspectors for the Food and Drug Administration, and other persons authorized by the board to inspect or investigate at the board's direction and control.

(b) Provide records or copies of records by mail, electronic mail or other means, within a reasonable time as established by the person making the request for the records or copies of records, to members of the board and its inspectors and investigators, investigators of the investigation division of the department of public safety, inspectors for the Food and Drug Administration, and other persons authorized by the board to inspect or investigate at the board's direction and control.

2. If a certified Internet pharmacy fails to comply with any provision of this section, the secretary of the board may summarily suspend the certification and license of the Internet pharmacy until proceedings can be initiated pursuant to NRS 639.241 to 639.2576, inclusive.

The secretary of the board may lift a summary suspension imposed under this subsection if the secretary determines that the Internet pharmacy has provided the requested access or records.

LCB File No. R165-01

INFORMATIONAL STATEMENT

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

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.

The number of persons who attended the hearing was ___0__.
The number of persons who testified at the hearing was __0___.
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 without change as no testimony was offered.

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.

There will be no cost incurred by the board for enforcement of this regulation.

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.