ADOPTED REGULATION OF

THE STATE BOARD OF PHARMACY

LCB File No. R051-07

Effective December 4, 2007

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

AUTHORITY: §1, NRS 639.070 and 639.515; §2, NRS 639.070; §3, NRS 639.070, 639.100 and 639.500; §4, NRS 639.070 and 639.505.

A REGULATION relating to prescription drugs; establishing provisions relating to bonds or other forms of security for certain wholesalers of prescription drugs; revising provisions relating to the licensing of wholesale distributors; revising the provisions relating to the submission of updated information concerning certain persons associated with a wholesaler; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. Unless the Board otherwise requires, a wholesaler shall file with the Board a bond or other security in the amount of $25,000 pursuant to NRS 639.515 if the wholesaler is:

(a) Accredited by the National Association of Boards of Pharmacy under the Verified-Accredited Wholesale Distributors program;

(b) A manufacturer of prescription drugs; or

(c) A facility that distributes prescription drugs manufactured by a single manufacturer.

2. The Board will reduce the bond or other security to the amount of $5,000 if any wholesaler described in subsection 1 has been licensed with the Board for 5 consecutive years or more.

3. Any bond or other security filed with the Board pursuant to subsection 1 may be substituted by a different bond or other security of equal value. The Board will release the previous bond or other security to the applicant upon receipt of the new bond or security.

Sec. 2. NAC 639.585 is hereby amended to read as follows:

639.585 As used in NAC 639.585 to 639.607, inclusive, ***and section 1 of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 639.587 to 639.592, inclusive, have the meanings ascribed to them in those sections.

Sec. 3. NAC 639.593 is hereby amended to read as follows:

639.593 1. Each applicant for a license to engage in the wholesale distribution of prescription drugs must submit an application to the Board. The application must be made on a form furnished by the Board. The application must include:

(a) The name, business address and telephone number of the applicant and the address of the facility, if different from the address of the applicant;

(b) All trade or business names used by the applicant;

(c) The address, telephone number and name of the person who manages the facility;

(d) The type of ownership or operation of the facility;

(e) Except as otherwise provided in subsection 7:

(1) A complete set of fingerprints from each person required to submit fingerprints pursuant to NRS 639.500; and

(2) Written permission from each person who submitted fingerprints authorizing the Board to forward his fingerprints to the Central Repository for Nevada Records of Criminal History for submission to the Federal Bureau of Investigation for its report; and

(f) If the applicant is a:

(1) Natural person, the name of the person.

(2) Partnership, the name of the partnership and the name of each partner.

(3) Corporation, the name and title of each officer and director of the corporation, the corporate name and the state of incorporation, and the name of the parent company, if any.

(4) Sole proprietorship, the name of the sole proprietor and the name of the business entity.

2. If a wholesaler distributes prescription drugs from more than one facility, the wholesaler must obtain a license for each facility.

3. The Board will not consider the sale or distribution of a prescription drug to be a wholesale transaction if the sale, distribution or other transaction involving the prescription drug is a sale, distribution or other transaction in which:

(a) A wholesaler licensed by the Board or the relevant authority of another state sells, distributes or otherwise provides a prescription drug to a wholesaler or pharmacy licensed by the Board;

(b) Both the transferring wholesaler and the transferee are wholly owned by a common owner; and

(c) The common owner is a publicly traded corporation.

➥ For the purposes of this subsection, a wholesaler whose transaction does not comply with the provisions of paragraphs (a), (b) and (c) may apply to the Board to consider the transaction of the wholesaler not to be a wholesale transaction if the wholesaler provides proof that is satisfactory to the Board that the proposed transaction will not endanger the public and is not proposed for the purpose of evading the provisions of this chapter and chapter 639 of NRS. The Board will

consider such a transaction to be a wholesale transaction until the Board approves the application of the wholesaler.

4. An applicant shall submit to the Board any change in the information required by this section within 30 days after the change occurs.

5. A license issued by the Board is not transferable.

6. Except as otherwise provided in subsection 7, each wholesaler applying for renewal of a license to engage in the wholesale distribution of prescription drugs must submit:

(a) A complete set of fingerprints from each person required to submit fingerprints pursuant to NRS 639.500; and

(b) Written permission from each person who submitted fingerprints authorizing the Board to forward his fingerprints to the Central Repository for Nevada Records of Criminal History for submission to the Federal Bureau of Investigation for its report.

7. ~~[A wholesaler whose]~~ ***Unless the Board otherwise requires, a wholesaler is not required to submit fingerprints pursuant to subsection 6 if:***

(a) The wholesaler's securities are publicly traded and regulated by the Securities Exchange Act of 1934, as amended, 15 U.S.C. §§ 78a et ~~[seq., or that]~~ ***seq.;***

(b) The wholesaler is owned by a corporation whose securities are publicly traded and regulated by the Act ~~[is not required to submit fingerprints or written permission pursuant to NRS 639.500, unless the Board otherwise requires.]~~ ***;***

(c) The wholesaler is accredited by the National Association of Boards of Pharmacy under the Verified-Accredited Wholesale Distributors program;

(d) The wholesaler is a manufacturer of prescription drugs; or

(e) The wholesaler is a facility that distributes prescription drugs manufactured by a single manufacturer.

Sec. 4. NAC 639.6065 is hereby amended to read as follows:

639.6065 ***1.*** A wholesaler who:

~~[1.]~~ ***(a)*** Does not have a facility in the State of Nevada; and

~~[2.]~~ ***(b)*** Is a corporation whose securities are publicly traded and regulated by the Securities Exchange Act of 1934, as amended, 15 U.S.C. §§ 78a et seq., or is owned by a corporation whose securities are publicly traded and regulated by the Act,

➥ may submit to the Board a copy of its annual report that is filed with the Securities and Exchange Commission. The Board may deem a copy of the report as satisfying the requirement for an updated list pursuant to NRS 639.505.

2. A wholesaler who is accredited by the National Association of Boards of Pharmacy under the Verified-Accredited Wholesale Distributors program may submit annually to the Board a copy of its most current proof of accreditation issued by the National Association of Boards of Pharmacy. The Board may deem a copy of the proof of accreditation as satisfying the requirement for an updated list pursuant to NRS 639.505.

3. A wholesaler who is a manufacturer of prescription drugs or a facility that distributes prescription drugs manufactured by a single manufacturer may submit annually to the Board a copy of its most current proof of registration with the Food and Drug Administration as a manufacturer or distributor. The Board may deem a copy of the proof of registration as satisfying the requirement for an updated list pursuant to NRS 639.505.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R051-07

The State Board of Pharmacy adopted regulations assigned LCB File No. R051-07 which pertain to chapter 639 of the Nevada Administrative Code.

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.

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 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 adverse economic impact on affected businesses or on the public. The beneficial economic effect will be on the businesses where VAWD certified wholesalers will have a lesser bond to pay upon licensure.

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 additional or special costs 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.