Chapter 453 of NAC

LCB File No. T021-07

ADOPTED TEMPORARY REGULATION OF THE STATE BOARD OF PHARMACY

(Filed with the Secretary of State on July 13, 2007)

Section 1. NAC 453.460 shall be amended as follows:

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]~~ ***Unless the board in its discretion otherwise requires, a*** wholesaler ***is not required to submit fingerprints or written permission pursuant to NRS 639.500 where:*** ~~[whose]~~ ***(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 is]~~ ***; (b) The wholesaler is wholly*** 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 VAWD certified by the National Association of Boards of Pharmacy; or (d) The wholesaler is a manufacturer or distribution facility for a manufacturer that only sells drugs made by that manufacturer***

Section 2. NAC 639.6065 shall be amended to read as follows:

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 VAWD certified by the National Association of Boards of Pharmacy may submit annually to the Board a copy of its most current proof of certification provided by the National Association of Board of Pharmacy, and the Board may deem a copy of the certification as satisfying the requirement for an updated list pursuant to NRS 639.505.

3. A wholesaler who is a manufacturer or distribution facility for a manufacturer that only sells drugs made by that manufacturer may submit annually to the Board a copy of its most current proof of registration as a manufacturer with the federal Food and Drug Administration, and the Board may deem a copy of the certification as satisfying the requirement for an updated list pursuant to NRS 639.505.

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

Unless the board in its discretion otherwise requires, a wholesaler shall post security of $5,000 pursuant to NRS 639.515 where the wholesaler is:

1. 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.;

2. Is wholly owned by a corporation whose securities are publicly traded and regulated by the Act;

3. VAWD certified by the National Association of Boards of Pharmacy; or

4. A manufacturer or distribution facility for a manufacturer that only sells drugs made by that manufacturer.

Section 4. An entity that qualifies under Section 3 for the posting of a $5,000 security may substitute a $5,000 security for whatever security it has already posted with the board at any time by providing to the board evidence of the new security. The board will thereafter release any existing security in the board's possession or control back to the entity.

NOTICE OF ADOPTION OF TEMPORARY REGULATION
LCB File No. T021-07

The State Board of Pharmacy adopted temporary regulations assigned LCB File No. T021-07 which pertain to chapter 453 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.

The number of persons who attended the hearing was ___2__.
The number of persons who testified at the hearing was __2___.
The number of agency submitted statements was __0___.

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.

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 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.