ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R218-05

Effective May 4, 2006

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

AUTHORITY: §§1, 2, 4, 5, 7-9 and 11-14, NRS 639.070; §3, NRS 639.070 and section 2 of Senate Bill No. 37, chapter 406, Statutes of Nevada 2005, at page 1608 (NRS 639.500); §6, NRS 639.070 and section 4 of Senate Bill No. 37, chapter 406, Statutes of Nevada 2005, at page 1610 (NRS 639.515); §10, NRS 639.070 and 639.100.

A REGULATION relating to prescription drugs; revising provisions relating to an application for a license to engage in the wholesale distribution of prescription drugs; exempting certain wholesalers from certain requirements associated with a license to engage in the wholesale distribution of prescription drugs; requiring a third-party logistics provider to obtain a license to engage in business as an authorized warehouse; 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 8, inclusive, of this regulation.

Sec. 2. ***"Statement of prior sales" has the meaning ascribed to it in section 5 of Senate Bill No. 37, chapter 406, Statutes of Nevada 2005, at page 1611 (NRS 639.535).***

Sec. 3. ***The Board may issue a provisional license to an applicant pursuant to subsection 3 of section 2 of Senate Bill No. 37, chapter 406, Statutes of Nevada 2005, at page 1608 (NRS 639.500), if the applicant:***

1. Submits evidence satisfactory to the Board establishing that the applicant is licensed in another state as a wholesaler, that such license is in good standing and that he is not:

(a) Under investigation;

(b) Subject to an administrative action; or

(c) Otherwise engaged in litigation,

➥ for a matter related to the practice of the applicant.

2. Provides to the Board a list of all sources from which the applicant obtained prescription drugs during the 12 months immediately preceding the date on which the application was submitted.

3. Provides to the Board a list of all customers to whom the applicant sold or otherwise provided prescription drugs during the 12 months immediately preceding the date on which the application was submitted.

4. Provides all other documents as may be requested by the Board.

Sec. 4. *A wholesaler who:*

1. Does not have a facility in the State of Nevada; and

2. 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 section 3 of Senate Bill No. 37, chapter 406, Statutes of Nevada 2005, at page 1609 (NRS 639.505).

Sec. 5. *A wholesaler shall not report the following transactions on a statement of prior sales:*

1. A transaction that the Board considers not to be a wholesale transaction pursuant to subsection 3 of NAC 639.593.

2. The return of a prescription drug to a wholesaler who appears on the statement of prior sales for the prescription drug at an earlier point in the chain of distribution.

Sec. 6. *Upon application from a wholesaler, the Board may allow a single bond:*

1. Of $100,000 to serve as the bond required pursuant to section 4 of Senate Bill No. 37, chapter 406, Statutes of Nevada 2005, at page 1610 (NRS 639.515), for multiple sites if all sites are owned by a common owner who has a net worth of more than $25,000,000. The owner must provide evidence satisfactory to the Board demonstrating adequate net worth.

2. In an amount determined by the Board to serve as the bond required pursuant to section 4 of Senate Bill No. 37, chapter 406, Statutes of Nevada 2005, at page 1610 (NRS 639.515), for multiple sites where the wholesaler participates exclusively in transactions that the Board considers not to be a wholesale transaction pursuant to subsection 3 of NAC 639.593.

Sec. 7. *"Third-party logistics provider" means a business that contracts with a manufacturer to provide or coordinate warehousing, distribution or other services on behalf of the manufacturer without taking title to or ownership of the prescription drugs and without authority to direct the sale or disposition of the prescription drugs.*

Sec. 8. *A third-party logistics provider in this State shall obtain a license to engage in business as an authorized warehouse pursuant to, and shall otherwise comply with, the provisions of NAC 639.620 to 639.644, inclusive, and sections 7 and 8 of this regulation.*

Sec. 9. NAC 639.585 is hereby amended to read as follows:

639.585 As used in NAC 639.585 to 639.607, inclusive, *and sections 2 to 6, inclusive, of this regulation,* unless the context otherwise requires, the words and terms defined in NAC

639.587 to 639.592, inclusive, ***and section 2 of this regulation*** have the meanings ascribed to them in those sections.

Sec. 10. 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; ~~[and]~~

(e) ***Except as otherwise provided in subsection 7:***

(1) A complete set of fingerprints from each person required to submit fingerprints pursuant to section 2 of Senate Bill No. 37, chapter 406, Statutes of Nevada 2005, at page 1608 (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 section 2 of Senate Bill No. 37, chapter 406, Statutes of Nevada 2005, at page 1608 (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 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 is not required to submit fingerprints or written permission pursuant to section 2 of Senate Bill No. 37, chapter 406, Statutes of Nevada 2005, at page 1608 (NRS 639.500), unless the Board otherwise requires.

Sec. 11. NAC 639.603 is hereby amended to read as follows:

639.603 1. Except as otherwise provided in paragraph (a) of subsection 6 of NAC 639.5975 ~~[,]~~ ***and section 5 of this regulation,*** each wholesaler shall provide a statement ***of prior sales*** identifying each sale of a prescription drug before the prescription drug is sold to another wholesaler or to a pharmacy when supplying prescription drugs ~~[which are to be sold to other than retail consumers]~~ if the wholesaler:

(a) Has not established an ongoing relationship with the manufacturer from whom the prescription drug was purchased; or

(b) Purchased the prescription drug from another wholesaler.

2. The statement ***of prior sales*** must:

(a) Be in writing and bear the title “Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act”;

(b) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or wholesaler;

(c) Accompany all prescription drugs purchased from a wholesaler, even if they are resold to another distributor;

(d) Include the business name and address of the person from whom the prescription drug was purchased;

(e) Include the date of the sale; and

(f) Include the:

(1) Name of the prescription drug;

(2) Strength of the prescription drug;

(3) Size of the container;

(4) Number of containers;

(5) Lot number of the prescription drug; and

(6) Name of the manufacturer of the finished dosage form.

3. Each statement ***of prior sales*** must be:

(a) Maintained by the buyer and the wholesaler for 3 years;

(b) Except as otherwise provided in subsection 4, available for copying or inspection upon a request by an authorized representative of any federal, state or local agency, a manufacturer of prescription drugs or a pharmacist or practitioner who purchases prescription drugs from the wholesaler; and

(c) Maintained by the wholesaler at its facility.

4. If a wholesaler cannot provide a statement ***of prior sales*** upon request made pursuant to paragraph (b) of subsection 3 because the wholesaler purchased a prescription drug with a particular lot number from more than one source, the wholesaler must provide:

(a) Copies of all the "Statements Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act," as described in subsection 2 ***,*** that relate to the prescription drug with the particular lot number; or

(b) A statement certifying how much of a prescription drug the wholesaler purchased directly from the drug's manufacturer and how much of the prescription drug the wholesaler purchased from other wholesalers, which must accurately account for the wholesaler's purchases of a prescription drug for the 12 months immediately preceding the request and may be made in the form of a percentage, ratio or per unit accounting. The wholesaler must provide, upon request, all "Statements Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" that were the basis for the statement made pursuant to this paragraph.

5. Beginning February 15, 2007, a wholesaler shall transmit to the Board, on or before the 15th day of each month, the information collected pursuant to subsection 2 for all statements of prior sales made for the immediately preceding month regarding the sale of a prescription drug to:

(a) Each customer in Nevada; and

(b) Each wholesaler located in Nevada.

➥ The information required by this subsection must be transmitted by electronic mail to the Board or to a website established by the Board in a format required by the Board.

Sec. 12. NAC 639.620 is hereby amended to read as follows:

639.620 As used in NAC 639.620 to 639.644, inclusive, ***and sections 7 and 8 of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 639.621 to 639.629, inclusive, ***and section 7 of this regulation*** have the meanings ascribed to them in those sections.

Sec. 13. NAC 639.622 is hereby amended to read as follows:

639.622 "Authorized warehouse" means a warehouse or other business in this State that receives, stores or ships prescription drugs and goods pursuant to a written contract with a manufacturer, wholesaler, pharmacy or chain warehouse under which the authorized warehouse acts solely as the agent or bailee of the manufacturer, wholesaler, pharmacy or chain warehouse. ***The term includes a third-party logistics provider.***

Sec. 14. NAC 639.644 is hereby amended to read as follows:

639.644 1. The Board may bring an action to enjoin the activities of an authorized warehouse pursuant to NRS 639.097 or take any other action authorized by law if the warehouse has not obtained a license to engage in business as an authorized warehouse.

2. An authorized warehouse that fails to comply with any of the provisions of NAC 639.620 to 639.643, inclusive, ***and sections 7 and 8 of this regulation*** is subject to disciplinary action pursuant to NRS 639.241 to 639.2576, inclusive.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R218-05

The State Board of Pharmacy adopted regulations assigned LCB File No. R218-05 which pertain to chapter 639 of the Nevada Administrative Code on March 2, 2006.

Notice date: 1/18/2006 **Date of adoption by agency:** 3/2/2006
Hearing date: 3/2/2006 **Filing date:** 5/4/2006

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 __4__.
The number of persons who testified at the hearing was __4__.
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.

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.

SB 37, the enabling legislation for the regulation, required pharmaceutical wholesalers to post a bond of $100,000. The regulations allow for limited exceptions that will allow, in some cases, for one bond to serve for multiple locations. The regulations also allow a process for which the Board could lessen the bond amount. All other effects of the regulations are believed to be fiscally neutral.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

The $100,000 bond will go into effect in the 2006 renewal cycle, meaning that the bond will be due no later than October 31, 2006.

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.