LCB File No. R218-05

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

AMENDMENT TO THE PHARMACEUTICAL WHOLESALER REGULATIONS REGARDING SB 37

Section 1. NAC 639.593 is hereby 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; and

(e) If the applicant is a:

(1) Natural person, the name of the person ***, a set of the person's fingerprints, and written authorization allowing the board to forward the fingerprints to the Central Repository for Nevada Records of Criminal History***.

(2) Partnership, the name of the partnership and the name of each partner ***, a set of each partner's fingerprints, and written authorization allowing the board to forward the fingerprints to the Central Repository for Nevada Records of Criminal History***.

(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 ***, a set of each officer's and director's fingerprints, and written authorization allowing the board to forward the fingerprints to the Central Repository for Nevada Records of Criminal History***.

(4) Sole proprietorship, the name of the sole proprietor and the name of the business entity ***, a set of each sole proprietor's fingerprints, and written authorization allowing the board to forward the fingerprints to the Central Repository for Nevada Records of Criminal History***.

2. For any applicant that is a corporation that is publicly traded, the corporation's officers and directors do not need to submit sets of fingerprints and written authorizations allowing the board to forward the fingerprints to the Central Repository for Nevada Records of Criminal History except that the applicant must submit the fingerprints and written authorization for those people if and as directed by the board's staff.

~~[2.]~~ ***3.*** If a wholesaler distributes prescription drugs from more than one facility, the wholesaler must obtain a license for each facility.

~~[3.]~~ ***4.*** 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 be to 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.]~~ ***5.*** An applicant shall submit to the Board any change in the information required by this section within 30 days after the change occurs.

~~[5.]~~ ***6.*** A license issued by the Board is not transferable.

7. When a wholesaler renews its license, it must submit fingerprints and authorization forms for the same people and in the same manner as if the wholesaler were an applicant under subsections 1(e) and 2.

Section 2. NAC 639.603 is hereby amended as follows:

1. Except as otherwise provided in paragraph (a) of subsection 6 of NAC 639.5975, each wholesaler shall provide a statement 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 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 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 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 of 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. Commencing February 15, 2007 and by the fifteenth day of every month thereafter, a wholesaler shall transmit to the Board's office the information in paragraphs (b), (d), (e), and (f) of subsection 2 for all statements of prior sale made for the preceding month regarding:

(a) All sales of prescription drug to customers in Nevada; or

(b) Made by a wholesaler located in Nevada.

The information shall be transmitted via e-mail or to a webcenter established by the Board in such a format as requested by the Board's staff.

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

1. An applicant for a wholesaler's license may conduct business under a provisional license issued pursuant to SB 37, Section 2, subsection 3 only upon submitting evidence satisfactory to the Board that:

(a) The applicant is licensed in another state and that license is in good standing is not presently under investigation, subject to administrative action, or is otherwise involved in litigation related to its practice as a wholesaler;

(b) The applicant provides to the Board a list of all of its sources of prescription drugs for the 12 months immediately preceding its application;

(c) The applicant provides to the Board a list of all of its customers to whom it has sold or otherwise provided prescription drugs for the 12 months immediately preceding its application; and

(d) The applicant provides whatever documents requested of it by the Board's staff to support its application.

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

For the purposes of SB 37, Section 3, subsection 1, a wholesaler owned by a publicly traded corporation may submit at least once annually a copy of its annual report that it has filed with the Securities and Exchange Commission in lieu of submitting a list of each employee, agent, independent contractor, consultant, guardian, personal representative, lender

or holder of indebtedness who is employed by or otherwise contracts with the wholesaler for every location licensed by the Board that is outside of Nevada.

Section 5. NAC chapter 639 shall be amended to add the following new language:

For the purposes of SB 37, Section 3.5, the following transactions shall not be considered to be prior sales:

1. A transaction made pursuant to NAC 639.593(4); or

2. The return of a prescription drug to a wholesaler who appears earlier on the statement of prior sales.

Section 6. NAC chapter 639 shall be amended to add the following new language:

1. Upon an application from a wholesaler, the Board may allow a single bond of $100,000 to serve as the bond required under SB 37, Section 4 for multiple sites where:

(a) All of the sites are owned by a common publicly traded corporation; or

(b) All of the sites are owned by a common owner that has a net worth exceeding $25 million, which net worth must be proven to the Board by evidence satisfactory to the Board.

2. Upon an application from a wholesaler, the Board may allow a single bond in an amount determined by the Board to serve as the bond required under SB 37, Section 4 for multiple sites where the wholesaler sells or otherwise provides prescription drugs only pursuant to NAC 639.593(4).

Section 7. NAC 639. shall be amended as follows:

1. "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. ***"Authorized warehouse" includes a third-party logistics provider.***

2. "Third-party logistics provider" means a business that contracts with a prescription drug manufacturer:

(a) To provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer without taking title or ownership of the drugs and without responsibility to direct the sale or disposition of the drug; and

(b) Is licensed as an authorized warehouse.