LCB File No. T032-00

ADOPTED TEMPORARY REGULATION OF THE STATE BOARD OF PHARMACY

(Effective November 21, 2000)

Section 1. NAC 639.593 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; and

(e) 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; and

(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 sale or distribution of a prescription drug by intercompany transfer within this state will not be considered to be a wholesale transaction. ***An intercompany transfer means any sale, distribution or other providing of a prescription drug where:***

(a)A wholesaler licensed by the board sells, distributes, or otherwise provides a prescription drug to a wholesaler or pharmacy licensed by the board where both the transferring wholesaler and the transferee are wholly owned by the same owner; and

(b)The common owner is a publicly-traded corporation.

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.

Section 2. NAC 639.594 shall be amended as follows:

An ongoing relationship between a wholesaler and a manufacturer must be established by:

1. Evidence of the existence of a written franchise, license or other agreement between a manufacturer and wholesaler to distribute prescription drugs; or

2. Evidence of the existence of two or more sales of a prescription drug to a wholesaler in any 24-month period.

Records establishing an ongoing relationship between and wholesaler and a manufacturer must be maintained at the wholesaler's facility throughout the period such relationship exists and for two years after the termination of any such relationship and must be available for review and copying by the board and any authorized representative.

Section 3. NAC 639.596 shall be amended as follows:

Each facility must:

1. Provide adequate lighting of at least 25 foot-candles;

2. Provide an adequate area for the storage of the prescription drugs within the facility in such a manner as to facilitate access to those drugs;

3. Be maintained in a clean and orderly condition;

4. Be free from infestation by insects, rodents, birds or vermin;

5. Be secure from entry by unauthorized persons; ~~[and]~~

6. Be equipped with an alarm system to detect entry to the facility after business hours~~[.]~~***;***

and

7. Maintain a stock of prescription drugs on its shelves sufficient to serve the expected and ordinary needs of the practitioners and pharmacies with which it ordinarily transacts business. If the wholesaler sells or deals in controlled substances, the wholesaler must maintain a representative stock sufficient to serve the expected and ordinary needs of the practitioners and pharmacies with which it ordinarily transacts business, and a wholesaler may not

maintain any stock of controlled substances unless it ordinarily sells controlled substances to the practitioners and pharmacies with which it ordinarily transacts business.

Section 4. NAC 639.602 shall be amended as follows:

1. Each wholesaler shall establish and maintain a record of its inventory and of each transaction relating to the receipt and distribution or other disposition of a prescription drug. The record must include:

(a) The supplier of the drug, including the name and principal address of the location from which the drug was shipped;

(b) The identity and quantity of the drug received and distributed or disposed of; and

(c) The date of the receipt and distribution or other disposition of the drug.

2. The wholesaler shall maintain the records described in subsection 1 for at least 2 years after the receipt, distribution or other disposition of the drug. The records must be made available for copying and inspection by any person authorized to inspect those records.

3. Except as otherwise provided in this subsection, a wholesaler shall maintain the records required by this section at the facility. If the records are maintained by a computer, the records must be immediately retrievable and readily available for inspection. If the records are not maintained at the facility ***because the facility is located outside of Nevada*** and are not immediately retrievable by computer, the records must be made available for inspection within 2 working days after a request is made by a person authorized to examine those records.

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

1. In any calendar month, a wholesaler shall not sell, distribute, transfer, or otherwise provide more than 10 percent of the total amount of prescription drugs to another wholesaler, distributor or manufacturer.

2. A wholesaler may not purchase or otherwise receive a prescription drug from a pharmacy except that a wholesaler may receive a prescription drug from a pharmacy that was originally purchased by the pharmacy from the wholesaler. A wholesaler may not receive back from a pharmacy more of a prescription drug than was originally sold by the wholesaler to the pharmacy nor may a wholesaler pay more to the pharmacy, either in cash or credit, than the pharmacy originally paid to the wholesaler for the prescription drug.

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

1. Except as otherwise provided in this subsection, an applicant for a license to operate a wholesaler shall designate at least one natural person who will be the representative of the wholesaler. The board will not issue a license to an applicant that is required to designate a representative of a wholesaler pursuant to this section unless the board determines that the designated natural person meets the qualifications set forth in subsection 2 and approves that natural person to be the designated representative of the wholesaler. The requirement to designate a representative set forth in this subsection does not apply to:

(a) An applicant that is a publicly traded corporation; or

(b) An applicant in which a majority interest of the applicant is owned by a pharmacist who is:

(1) Licensed by the board;

(2) A resident of this state; and

(3) Not an owner of any interest in a pharmacy licensed by the board.

2. Except as otherwise provided in subsection 3, the board will approve a natural person to be a representative of a wholesaler if the applicant for a license to operate a wholesaler or the licensee presents proof satisfactory to the board that the natural person:

(a) Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;

(b) Has received a score of at least 75 percent on an examination given by the board regarding federal and state laws and wholesaler practices; and

(c) Is at least 21 years of age.

3. The board may, based upon any of the grounds set forth in NRS 639.210, refuse to approve a natural person for service as the representative of a wholesaler, regardless of whether the person is otherwise qualified.

4. A representative of a wholesaler designated pursuant to this section:

(a) Must be actively involved in and aware of the actual daily operation of the wholesaler;

(b) Must be employed full time in a managerial level position in the wholesaler.

(c) Must be physically present at the site of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and

(d) May serve in this representative capacity for only one wholesaler at a time.

5. A wholesaler that is required to designate a natural person as its representative pursuant to this section shall not open or operate the wholesaler unless that representative is actually employed full time in the operation of the wholesaler and is physically present at the site of the wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. If the natural person designated as the representative of a wholesaler leaves the employ of the wholesaler, thus leaving the wholesaler without a representative in violation of this section, the wholesaler shall:

(a) Immediately cease conducting business until another qualified natural person is approved by the board to serve as the representative of the wholesaler; and

(b) Not later than 48 hours after that person leaves its employ, notify the board that the person designated as the representative of the wholesaler has left the employ of the wholesaler.

6. Before a wholesaler that is in violation of this section because the natural person designated as the representative of the wholesaler left the employ of the wholesaler may continue conducting business:

(a) The wholesaler must designate, on a form provided by the board, a new natural person to serve as the representative of the wholesaler; and

(b) The board must approve the natural person so designated.

7. A wholesaler that operates without a representative in violation of this section is subject to the immediate suspension of its license until it employs a qualified natural person to be its representative. The board may take such action as it deems necessary to secure the premises of the wholesaler and assure that no business may be transacted by the wholesaler during the period of suspension.

8. A wholesaler to whom this section applies that was licensed prior to the effective date of this section shall submit an application no later than October 31, 2001 on a form provided by the board for the approval of a qualified natural person pursuant to the terms of this section. After October 31, 2001, any wholesaler that operates without a qualified natural person shall be subject to the provisions of subsection 7 of this section.

INFORMATIONAL STATEMENT

(639.593-594-596-602-new language)

November 14, 2000

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 with minor changes.

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 the public.

It is unknown at this time if there will be an economic impact on the affected businesses.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation should have, if any, only a minor economic impact on affected businesses and should have no economic impact on 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.