

**PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY**

LCB File No. R013-01

July 11, 2001

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

AUTHORITY: §§1-9, NRS 639.070 and 639.100.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 and 3 of this regulation.

Sec. 2. 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 received by another wholesaler, distributor or manufacturer.*

2. Except as otherwise provided in this subsection, a wholesaler shall not purchase or otherwise receive a prescription drug from a pharmacy. A wholesaler may receive a prescription drug from a pharmacy if the prescription drug was originally purchased by the pharmacy from the wholesaler.

3. A wholesaler shall not:

(a) Receive from a pharmacy an amount or quantity of a prescription drug larger than the amount or quantity that was originally sold by the wholesaler to the pharmacy; or

(b) Pay the pharmacy an amount, either in cash or credit, more than the pharmacy originally paid to the wholesaler for the prescription drug.

Sec. 3. 1. *Except as otherwise provided in this subsection, an applicant for a license, or a licensee with a license, to operate as a wholesaler shall designate at least one natural person*

to serve as the representative of the wholesaler. The board will not issue or renew a license of an applicant or licensee 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 as the 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 with the wholesaler;

(c) Must be physically present at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leave, vacation leave 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 a facility unless that representative is actually employed full time in the operation of the wholesaler and is physically present at the facility 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 facility of the wholesaler and to ensure that the wholesaler does not conduct business during the period of the suspension.

Sec. 4. 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 and 3 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. 5. 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) 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. *As used in this subsection, “intercompany transfer” means any sale, distribution or other transaction involving a prescription drug in which:*

(a) A wholesaler licensed by the board 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.

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.

Sec. 6. NAC 639.594 is hereby amended to read as follows:

639.594 *1.* An ongoing relationship between a wholesaler and a manufacturer must be established by:

~~[1.]~~ *(a)* Evidence of the existence of a written franchise, license or other agreement between a manufacturer and wholesaler to distribute prescription drugs; or

~~[2.]~~ *(b)* Evidence of the existence of two or more sales of a prescription drug to a wholesaler in any 24-month period.

2. The records establishing an ongoing relationship between a wholesaler and a manufacturer must be:

(a) Maintained at the facility of the wholesaler throughout the period that such a relationship exists;

(b) Maintained for 2 years after the termination of any such relationship; and

(c) Available for review and copying by the board or by any authorized representative of a federal, state or local agency.

Sec. 7. NAC 639.596 is hereby amended to read as follows:

639.596 *1.* Each facility must:

~~[1.]~~ *(a)* Provide adequate lighting of at least 25 foot-candles;

~~[2.]~~ *(b)* 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.]~~ *(c)* Be maintained in a clean and orderly condition;

~~[4.]~~ *(d)* Be free from infestation by insects, rodents, birds or vermin;

~~[5.]~~ *(e)* Be secure from entry by unauthorized persons; ~~and~~

~~—6.]~~ *(f)* Be equipped with an alarm system to detect entry to the facility after business hours ~~]~~
; and

(g) 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.

2. If a wholesaler sells or deals in controlled substances, the wholesaler shall maintain a representative stock sufficient to serve the expected and ordinary needs of the practitioners and pharmacies with which it ordinarily transacts business.

3. A wholesaler shall not maintain any stock of controlled substances unless it ordinarily sells controlled substances to the practitioners and pharmacies with which it ordinarily transacts business.

Sec. 8. NAC 639.602 is hereby amended to read as follows:

639.602 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.

4. If the records are not maintained at the facility *because the facility is located outside of this state* 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.

Sec. 9. A wholesaler subject to the requirements of section 3 of this regulation that was licensed before the effective date of section 3 of this regulation shall submit an application not later than October 31, 2001, on a form provided by the board, for the approval of a qualified natural person as a representative of the wholesaler pursuant to section 3 of this regulation. On and after November 1, 2001, any wholesaler that operates without a qualified natural person as a representative who has been approved by the board is subject to the provisions of subsection 7 of section 3 of this regulation.