LCB File No. R049-04

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

AMENDMENT TO THE PHARMACEUTICAL WHOLESALER REGULATIONS

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;

(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]~~ ***intracompany*** transfer within this state will not be considered to be a wholesale transaction. As used in this subsection, "~~[intercompany]~~ ***intracompany*** 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.

Section 2. NAC 639.594 is hereby amended as follows:

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

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

(b) ~~[Evidence of the existence of two or more sales of a prescription drug to a wholesaler in any 24-month period]~~ ***The wholesaler being identified upon a manufacturer's list of distributors of record maintained on a publicly accessible website maintained by the manufacturer.***

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]~~ ***5*** 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.

Section 3. NAC 639.5975 is hereby amended as follows:

1. ~~[In any calendar month, a wholesaler shall not sell, distribute, transfer or otherwise provide more than 10 percent of its total amount of prescription drugs to 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) Any person or business that is not a wholesaler or a manufacturer; or

(b) Any wholesaler where any of the preceding sellers of the drug was not a wholesaler or a manufacturer.

2. 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~~[.]~~ ***;***

(c) Purchase a contraband drug or a counterfeit drug.

Section 4. NAC 639.599 is hereby amended as follows:

1. Each wholesaler shall, upon receiving a prescription drug, examine each outside shipping container of the drug ***and any accompanying documents, which may include invoices, shipping records, and Statements Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act,*** to determine its identity and to prevent the acceptance of a ~~[contaminated prescription]~~ drug that ~~[is otherwise unfit for distribution]~~ ***violate one or more of the conditions contained in NRS 639.2615(4)(a)(3)***. The examination must be sufficient~~[ly adequate]~~ to detect any damage to the container which would indicate contamination or other damage to the contents of the container.

2. Each wholesaler shall examine each outgoing shipment of prescription drugs to identify the prescription drugs contained in the shipment and to ensure that the prescription drugs contained in the shipment are not damaged and have been stored under proper conditions.

3. If the wholesaler determines that a drug or its accompanying documents violate one or more of the conditions contained in NRS 639.2615(4)(a)(3) pursuant to the inspection conducted pursuant to paragraph 1, regarding each drug it shall notify the board in writing within 5 business days of the inspection of:

(a) The name and address of the supplier from whom the wholesaler purchased the drug;

(b) The name of the drug;

(c) The lot number and expiration date of the drug;

(d) The quantity of the drug;

(e) Whether the drug was returned to the supplier or whether the wholesaler determined to destroy the drug;

(f) The reason for the action taken regarding the drug; and

(g) If the drug was returned to the supplier, the date the drug returned to the supplier.

4. The written notice to the board pursuant to paragraph 3 shall be accompanied with:

(a) The invoice or other document provided to the wholesaler by its supplier when the wholesaler purchased the drug;

(b) The shipping record evidencing the transit of the drug from the supplier to the wholesaler;

(c) The Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act regarding the drug that the wholesaler received from its supplier.

Section 5. NAC 639.601 is hereby amended as follows:

1. A prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated must be separated from other prescription drugs until it is destroyed or returned to the supplier.

2. A prescription drug whose immediate or sealed outer or secondary container has been opened or used must be identified as such and separated from other prescription drugs until it is destroyed or returned to the supplier.

3. If a prescription drug is returned to a wholesaler ***by a purchaser*** under conditions which cast doubt on the drug's safety, identity, strength, quality or purity, the wholesaler shall destroy the drug or return it to the supplier, unless after conducting an examination, testing or other investigation, the wholesaler determines that the drug complies with the appropriate standards of safety, identity, strength, quality and purity as prescribed in ***The United States Pharmacopeia***, 22nd edition, 1990. ***If the wholesaler conducts its own examination, testing, or other investigation, it shall make and maintain all records of such examination, testing, or other investigation, which records must be readily available to the board. If the wholesaler returns or determines to destroy a drug pursuant to the first sentence of this paragraph, regarding each drug it shall notify the board in writing of:***

(a) The name of the drug;

(b) The lot number and expiration date of the drug;

(c) The quantity of the drug;

(d) The name and address of the business returning the drug to the wholesaler;

(e) The action taken regarding the drug;

(f) The reason for the action taken regarding the drug; and

(g) The date the drug was destroyed or returned to the supplier.

4. The written notice to the board pursuant to paragraph 3 shall be accompanied with:

(a) The invoice or other document provided to the wholesaler by its supplier when the wholesaler purchased the drug;

(b) The shipping record evidencing the transit of the drug from the supplier to the wholesaler;

(c) The Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act regarding the drug that the wholesaler received from its supplier;

(d) The invoice or other document provided by the wholesaler to the purchaser who is returning the drug to the wholesaler;

(e) The shipping record evidencing the transit of the drug from the wholesaler to the purchaser who is returning the drug to the wholesaler; and

(f) The Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act regarding the drug that the wholesaler provided to the purchaser who is returning the drug to the wholesaler.

Section 6. NAC 639.602 is hereby amended as follows:

1. Each wholesaler shall ~~[establish]~~ ***make*** 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***s that must be made and maintained by a wholesaler include, but are not limited to, the following***:

~~[(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.]~~

(a) The purchase order, correspondence, and any other document evidencing the ordering of the drug by the wholesaler from its supplier;

(b) The invoice or other documents provided by the supplier that accompanied the drug;

(c) The shipping document evidencing the transit of the drug from the supplier to the wholesaler;

(d) The purchase order, correspondence, and any other document evidencing the ordering of the drug from the wholesaler by its purchaser;

(e) The invoice or other documents provided by the wholesaler that accompanied its shipment of the drug to its purchaser;

(f) The shipping document evidencing the transit of the drug from the wholesaler to its purchaser;

(g) A copy of the current license of the supplier who sold the drug to the wholesaler;

(h) For any supplier who represents that he has an ongoing relationship with a manufacturer, a copy of the written document made and maintained pursuant to NAC 639.594 evidencing the ongoing relationship, which document must be obtained by the wholesaler before the wholesaler may purchase the drug from the supplier; and

(i) One or more of the types of records required by section 10 of this regulation that evidence the reasonable assurance that the wholesaler has received from its purchasing wholesaler.

2. The wholesaler shall maintain the records described in subsection 1 for at least ~~[2]~~ ***5*** 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.

Section 7. NAC 639.603 is hereby amended as follows:

1. Each wholesaler shall provide a statement identifying each sale of a prescription drug before the drug is sold to another wholesaler or to a pharmacy when supplying 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 drug was purchased; or

(b) Purchased the 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 drug was purchased;

(e) Include the date of the sale; and

(f) Include the:

(1) Name of the drug;

(2) Strength of the drug;

(3) Size of the container;

(4) Number of containers;

(5) Lot number of the 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]~~ ***5*** years ~~[after the expiration date of the drug]~~;

(b) 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. Every wholesaler who purchases a drug from a supplier shall maintain the drug purchased from the supplier separate and apart from drugs purchased from a manufacturer. The two different stocks must be readily identifiable and must be established such that no integration or intermingling of the two stocks may occur. Any sale of a drug from the stock of drugs that was purchased from a supplier must be accompanied with a statement made pursuant to paragraphs 1 and 2 of this section regardless of:

(a) Whether the wholesaler has an ongoing relationship with the manufacturer of the drug; and

(b) Who is the purchaser of the drug.

Section 8. NAC 639.605 is hereby amended as follows:

1. Each wholesaler shall establish written policies and procedures for the receipt, security, storage, inventory and distribution of prescription drugs.

2. The written policies and procedures must include:

(a) A procedure for identifying, recording and reporting any losses or thefts of prescription drugs.

(b) A procedure for correcting any errors or inaccuracies concerning the wholesaler's inventory.

(c) A procedure that requires the oldest approved stock of a prescription drug to be distributed first. The procedure may allow deviation from that requirement if the deviation is temporary and appropriate.

(d) A procedure relating to the recall or withdrawal of a prescription drug because of:

(1) Any action taken at the request of the Food and Drug Administration or other federal agency or state or local law enforcement agency or other governmental agency, including the Board;

(2) Any voluntary action taken by a manufacturer to remove defective or potentially defective drugs from the market; or

(3) Any action taken by a manufacturer to promote public health and safety by the replacement of existing prescription drugs with an improved product or new design of a package.

(e) A procedure for the operation of a facility in the event of a strike, fire, flood or other natural disaster or emergency.

(f) A procedure to ensure that any outdated prescription drug is separated from other drugs that are not outdated and is destroyed or returned to the manufacturer. The procedure must provide for the establishment and maintenance of written records of the disposition of each outdated prescription drug. The wholesaler shall keep the records for ~~[2]~~ ***5*** years after the disposition of the drug.

(g) A procedure to gather, make, and maintain all records required by NRS 639.234 and these regulations.

(h) A procedure to assure that drugs received from a supplier are kept separate and apart from drugs received from manufacturers as required by these regulations.

(i) A procedure to assure that drugs received from a supplier always contain the statements required by NAC 639.603(1) and (2) whenever such drugs are sold.

(j) A procedure to assure that all drugs received are inspected to assure that the drugs are not contraband, counterfeit, and that the inspections comply with NAC 639.599 and 639.601.

Section 9. NAC 639.607 is hereby amended as follows:

Each wholesaler shall allow the board and any other authorized person to:

1. Inspect its facility and any motor vehicles it uses to transport prescription drugs; and
2. Examine its records and procedures for the operation of the facility,

➥during normal business hours. ***If a member of the board's staff determines to obtain copies of some of a wholesaler's documents and the number of copies exceeds fifty pages, the member of the board's staff may copy the documents at the wholesaler's facility or may remove the records for copying at the member of the board's staff's discretion.***

Section 10. NAC 639.709 is hereby amended as follows:

1. A pharmacy may furnish drugs, controlled substances, poisons, chemicals, devices or appliances restricted by federal law to sale by or on the order of a physician only to:

(a) The ultimate user;

(b) A licensed practitioner; ***or***

(c) Another pharmacy to alleviate a temporary shortage~~[; or~~

~~(d) A wholesaler or manufacturer licensed pursuant to NRS 639.233 to engage in the business of wholesale distribution or furnishing of drugs, controlled substances, poisons, chemicals, devices or appliances that are restricted by federal law to sale by or on the order of a physician~~**]**.

2. **[**~~Except as otherwise provided in this subsection, a pharmacy shall not transfer in any calendar year more than 10 percent of the total amount of drugs, controlled substances, poisons, chemicals, devices or appliances purchased by the pharmacy in the immediately preceding calendar year to wholesalers or manufacturers pursuant to paragraph (d) of subsection 1. If a pharmacy is in operation less than 2 calendar years, the pharmacy shall not transfer during the period the pharmacy is in operation more than 10 percent of the total amount of drugs, controlled substances, poisons, chemicals, devices or appliances purchased by the pharmacy to wholesalers or manufacturers pursuant to paragraph (d) of subsection 1.~~**]** Drugs, controlled substances, poisons, chemicals, devices or appliances that are returned by a pharmacy for credit, in an amount equal to or less than the actual purchase price, to the wholesaler or manufacturer from which those products were purchased are not subject to the provisions of this **[**~~sub~~**]**section.

3. **[**~~For each transfer made by the pharmacy pursuant to paragraph (d) of subsection 1, the pharmacy shall provide to each wholesaler or manufacturer to whom a drug, controlled substance, poison, chemical, device or appliance is transferred during the current year a statement identifying each such transfer.~~

~~4. The statement required pursuant to subsection 3 must:~~

~~(a) Be in writing and bear the title "Statement Identifying Transfers of Drugs, Controlled Substances, Poisons, Chemicals, Devices or Appliances by Pharmacists to Wholesalers or Manufacturers";~~

~~(b) Set forth all necessary identifying information concerning each transfer in the chain of distribution of the product from the wholesaler or manufacturer;~~

~~(c) Set forth the business name and address of the person from whom the product was obtained;~~

~~(d) Set forth the date of transfer; and~~

~~(e) Set forth the:~~

~~(1) Name of the product;~~

~~(2) Strength of the product, if applicable;~~

~~(3) Size of the container, if applicable;~~

~~(4) Number of containers, if applicable;~~

~~(5) Lot number of the product, if applicable; and~~

~~(6) Name of the manufacturer of the finished dosage form, if applicable.~~

~~5. The statement required pursuant to subsection 3 must be:~~

~~(a) Maintained by the person to whom the product is transferred and pharmacist for 3 years after the:~~

~~(1) Expiration date of the product, if the product is a drug, controlled substance, poison or chemical; or~~

~~(2) Date of transfer, if the product is a device or appliance;~~

~~(b) Available for copying or inspection upon a request by an authorized representative of any federal, state or local agency, a manufacturer of drugs, controlled substances, poisons, chemicals, devices or appliances or a pharmacist or practitioner to whom drugs, controlled substances, poisons, chemicals, devices or appliances are transferred by the pharmacy; and~~

~~(c) Maintained by the pharmacy at its place of business.~~

~~6.~~**]** As used in this section:

(a) "Ultimate user" means a person who lawfully possesses a drug, controlled substance, poison, chemical, device or appliance restricted by federal law to sale by or on the order of a physician for his own use, the use of a member of his household or the use of any person for whom he is caring, or for administering to any animal owned by him or by a member of his household.

(b) "Transfer" includes to sell, furnish or otherwise provide.

Section 11. NAC ch. 639 is hereby amended to add the following new language:

1. "Contraband drug" shall mean a prescription drug that was purchased subject to or as a result of an agreement by which the purchaser agreed that the prescription drugs purchased thereby would only be used by the purchaser for the benefit of its patients, which prescription drug is thereafter sold by the purchaser to a wholesaler.

2. "Counterfeit drug" shall mean a prescription drug that is adulterated or misbranded pursuant to NRS chapter 585.

3. "Supplier" shall mean a wholesaler who sells drugs to a wholesaler licensed pursuant to the provisions of NRS 639.233.

4. "Purchaser" shall mean a wholesaler, pharmacy, or practitioner who has purchased drugs from a wholesaler licensed pursuant to the provisions of NRS 639.233.

5. "Purchasing wholesaler" shall mean a wholesaler who has purchased drugs from a wholesaler licensed pursuant to the provisions of NRS 639.233.

Section 12. NAC ch. 639 is hereby amended to add the following new language:

1. For each transaction regarding the sale of a drug to a purchasing wholesaler, the wholesaler shall obtain from its purchasing wholesaler one or more of the following documents as reasonable assurance that the purchasing wholesaler's disposition of the drug complies with NRS 639.2615(4)(b):

(a) The invoice or other document made by the purchasing wholesaler that accompanied the drug when it was shipped by the purchasing wholesaler to the pharmacy or practitioner who purchased the drug. Attached to the invoice or other document made by the purchasing wholesaler under this paragraph must be the shipping document evidencing the transit of the drug from the purchasing wholesaler to the pharmacy or practitioner who purchased the drug.

(b) The Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act made by the purchasing wholesaler that preceded or accompanied the drug when it was shipped by the purchasing wholesaler to the pharmacy or practitioner who purchased the drug. Attached to the Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act made by the purchasing wholesaler under this paragraph must be the shipping document evidencing the transit of the drug from the purchasing wholesaler to the pharmacy or practitioner who purchased the drug.

2. The wholesaler must receive the documents in paragraph 1 from the purchasing wholesaler no later than the earliest occurring of the following events:

(a) 30 days after the date that the wholesaler shipped the drug to the purchasing wholesaler; or

(b) 5 business days after the date on which the purchasing wholesaler shipped the drug to the pharmacy or practitioner to whom the purchasing wholesaler sold the drug.

Section 13. NAC ch. 639 is hereby amended to add the following new language:

1. If a wholesaler resident in Nevada determines to destroy a drug pursuant to NAC 639.599(3) or NAC 639.601, the wholesaler shall:

(a) Segregate the drug in a place that will assure that the drug cannot be sold or otherwise disposed; and

(b) Arrange with board staff within 48 hours of the time at which it sends the notice to the board required by NAC 639.599(3) or NAC 639.601 a time mutually convenient to the wholesaler and board staff at which board staff can be present to witness the destruction of the drug.

2. Board staff and the authorized representative for the wholesaler shall make a written record on which both shall sign that will evidence the:

(a) Date and time of the destruction;

(b) Name of the drug subject to destruction;

(c) Lot number of the drug subject to destruction; and

(d) Quantity of drug subject to destruction.