PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R049-04

April 14, 2004

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

AUTHORITY: §§1-8, 10 and 12-19, NRS 639.070; §9, NRS 639.070 and 639.2176; §§11 and 12, NRS 639.070 and 639.100.

A REGULATION relating to pharmacy; requiring a supplier to obtain certain documents following the sale of a drug to a purchasing wholesaler; requiring a wholesaler that destroys a drug to complete certain requirements; prohibiting a wholesaler from purchasing a contraband drug or counterfeit drug; establishing a procedure for the inspection of drugs received by a wholesaler; requiring certain documents to be included in a record of inventory of a wholesaler; requiring wholesalers to store drugs purchased from suppliers separate from drugs purchased from manufacturers; 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. ***"Contraband drug" means a prescription drug that is offered for sale by a purchaser to a wholesaler in violation of an agreement requiring the purchaser to use the drug only for the benefit of the patients of the purchaser.***

Sec. 3. ***"Counterfeit drug" means a prescription drug that is adulterated, mislabeled or misbranded pursuant to chapter 585 of NRS.***

Sec. 4. ***"Purchaser" means a wholesaler, pharmacy or practitioner that purchases a drug from a wholesaler licensed pursuant to NRS 639.233.***

Sec. 5. ***"Purchasing wholesaler" means a wholesaler that purchases a drug from a wholesaler licensed pursuant to NRS 639.233.***

Sec. 6. ***"Supplier" means a wholesaler that sells a drug to a wholesaler licensed pursuant to NRS 639.233.***

Sec. 7. ***1. For each sale of a drug to a purchasing wholesaler, the supplier must obtain from the purchasing wholesaler as a reasonable assurance that the purchasing wholesaler is in compliance with the provisions of subparagraph (2) of paragraph (b) of subsection 2 of NRS 639.2615:***

(a) The invoice or other document made by the purchasing wholesaler that accompanied the drug when it was shipped from the purchasing wholesaler to the pharmacy or practitioner that purchased the drug and a shipping document evidencing the shipment of the drug from the purchasing wholesaler to the pharmacy or practitioner that purchased the drug; or

(b) The "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" described in NAC 639.603 that accompanied the drug when it was shipped from the purchasing wholesaler to the pharmacy or practitioner that purchased the drug and a shipping document evidencing the shipment of the drug from the purchasing wholesaler to the pharmacy or practitioner that purchased the drug.

2. The supplier must receive the documents required by subsection 1 not later than:

(a) Thirty days after the date on which the supplier shipped the drug to the purchasing wholesaler; or

(b) Five business days after the date on which the purchasing wholesaler shipped the drug to the pharmacy or practitioner that purchased the drug,

➥ whichever occurs earlier.

Sec. 8. ***1. If a wholesaler in this state decides to destroy a drug pursuant to subsection 3 of NAC 639.599 or NAC 639.601, the wholesaler shall:***

(a) Segregate the drug in a manner that will ensure that the drug cannot be sold or otherwise disposed of; and

(b) Within 48 hours after the wholesaler sends the written notice to the Board required by subsection 3 of NAC 639.599 or NAC 639.601, arrange a time with the staff of the Board during which a member of the staff of the Board can be present to witness the destruction of the drug.

2. The member of the staff of the Board who witnesses the destruction of the drug and an authorized representative of the wholesaler shall prepare and sign a written record that must include:

(a) The date and time of the destruction of the drug;

(b) The name of the drug that was destroyed;

(c) The lot number of the drug that was destroyed; and

(d) The quantity of the drug that was destroyed.

Sec. 9. NAC 639.330 is hereby amended to read as follows:

639.330 1. Except as otherwise provided in NAC 639.335, the Board will not ~~[issue a certificate as a registered pharmacist to any person pursuant to NRS 639.133, or]~~ renew the certificate of any registered pharmacist ~~[,]~~ until the applicant submits proof to the Board of

receipt of 30 continuing education units within the biennium immediately preceding the current renewal period. The continuing education units must include not less than:

(a) Fifteen continuing education units in accredited programs; and

(b) One continuing education unit earned:

(1) In a jurisprudence program approved or presented by the Board relating to the practice of pharmacy or the law relating to pharmacy in this state; or

(2) By attending any meeting of the Board for not less than 4 hours.

2. No applicant may carry over any excess continuing education units earned in a previous biennium for purposes of compliance with the requirements of this section.

3. Work-related experience acquired in fields other than the practice of pharmacy is not acceptable as credit toward the requirements of continuing education established by NRS 639.2171 to 639.2176, inclusive, and NAC 639.300 to 639.390, inclusive.

Sec. 10. 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 8, inclusive, of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 639.587 to 639.592, inclusive, ***and sections 2 to 6, inclusive, of this regulation*** have the meanings ascribed to them in those sections.

Sec. 11. 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]~~ ***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.

Sec. 12. 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:

(a) ~~[Evidence of the existence of a]~~ ***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 presence of the wholesaler on a list of distributors with which the manufacturer does business created by the manufacturer and located 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.

Sec. 13. NAC 639.5975 is hereby amended to read as follows:

639.5975 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,]~~ ***section,*** a wholesaler shall not purchase or otherwise receive a prescription drug from ~~[a pharmacy.]~~ ***:***

(a) Any person who is not a wholesaler or manufacturer; or

(b) A wholesaler if any previous seller 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 ~~[.]~~ ***; or***

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

Sec. 14. NAC 639.599 is hereby amended to read as follows:

639.599 1. Each wholesaler shall, upon receiving a prescription drug, examine each outside shipping container of the drug ***and any accompanying document including, without limitation, the invoice, the shipping record or the "Statement 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.]~~ ***violates subparagraph (2) of paragraph (b) of subsection 2 of NRS 639.2615.*** The examination must be ~~[sufficiently adequate]~~ ***sufficient*** 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 a wholesaler determines pursuant to subsection 1 that the acceptance of a drug violates subparagraph (2) of paragraph (b) of subsection 2 of NRS 639.2615, the wholesaler shall:

(a) Return the drug to the supplier or decide to destroy the drug; and

(b) Provide to the Board, not later than 5 business days after the inspection:

(1) A written notice that includes:

(I) The name and address of the supplier of the drug;

(II) The name of the drug;

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

(IV) The quantity of the drug;

(V) Whether the wholesaler returned the drug to the supplier or decided to destroy the drug;

(VI) The reason for the action taken by the wholesaler; and

(VII) If the drug was returned to the supplier, the date on which the drug was returned to the supplier; and

(2) The following documents, if applicable:

(I) The invoice or other document provided to the wholesaler by the supplier concerning the purchase of the drug;

(II) The shipping record evidencing the shipment of the drug from the supplier to the wholesaler; and

(III) The "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" that the wholesaler received from the supplier.

Sec. 15. NAC 639.601 is hereby amended to read as follows:

639.601 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.*]~~ ***the United States Pharmacopeia - National Formulary in effect as of March 1, 2000. The wholesaler shall keep a record of any examination, testing or other investigation conducted and make any records available for inspection by the Board.***

4. A wholesaler that is required to destroy a drug or return it to the supplier pursuant to subsection 3 shall provide to the Board:

(a) A written notice that includes:

(1) The name of the drug;

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

(3) The quantity of the drug;

(4) The name and address of the business that returned the drug to the wholesaler;

(5) Whether the wholesaler:

(I) Returned the drug to the supplier; or

(II) Decided to destroy the drug;

(6) The reason for the action taken by the wholesaler; and

(7) The date on which the drug was destroyed or returned to the supplier; and

(b) The following documents, if applicable:

(1) The invoice or other document provided to the wholesaler by the supplier concerning the purchase of the drug;

(2) The shipping record evidencing the shipment of the drug from the supplier to the wholesaler;

(3) The "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" that the wholesaler received from the supplier;

(4) The invoice or other document provided by the wholesaler to the purchaser who returned the drug to the wholesaler;

(5) The shipping record evidencing the shipment of the drug from the wholesaler to the purchaser who returned the drug to the wholesaler; and

(6) The "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" that the wholesaler provided to the purchaser who returned the drug to the wholesaler.

Sec. 16. NAC 639.602 is hereby amended to read as follows:

639.602 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 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.~~~~]~~ ***, without limitation:***

(a) The purchase order, correspondence and any other document evidencing that the wholesaler ordered the drug from the supplier;

(b) The invoice or other document provided to the wholesaler by the supplier concerning the purchase of the drug;

(c) The shipping record evidencing the shipment of the drug from the supplier to the wholesaler;

(d) The purchase order, correspondence and any other document evidencing that the purchaser ordered the drug from the wholesaler;

(e) The invoice or other document provided by the wholesaler when the purchaser purchased the drug;

(f) The shipping record evidencing the shipment of the drug from the wholesaler to the purchaser;

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

(h) If the supplier has an ongoing relationship with a manufacturer, a copy of the records maintained pursuant to NAC 639.594 which must be obtained by the wholesaler before the wholesaler may purchase a drug from the supplier; and

(i) One or more of the documents required by section 7 of this regulation as reasonable assurance that the purchasing wholesaler is in compliance with subparagraph (2) of paragraph (b) of subsection 2 of NRS 639.2615.

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.

Sec. 17. NAC 639.603 is hereby amended to read as follows:

639.603 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 years after the expiration date of the drug;]~~ ***5 years;***

(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. A wholesaler who purchases a drug from a supplier must maintain that drug in a separate stock from drugs purchased from a manufacturer. The separate stocks must be readily identifiable and must be maintained so that no intermingling of the drugs can occur.

Each sale of a drug from the stock that was purchased from a supplier must be accompanied by the statement required pursuant to subsections 1 and 2 regardless of:

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

(b) Who purchased the drug from the wholesaler.

Sec. 18. NAC 639.605 is hereby amended to read as follows:

639.605 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 pursuant to NRS 639.234 and NAC 639.585 to 639.607, inclusive, and sections 2 to 8, inclusive, of this regulation.

(h) A procedure to ensure that drugs received from a supplier are kept separate from drugs received from manufacturers as required pursuant to NAC 639.585 to 639.607, inclusive, and sections 2 to 8, inclusive, of this regulation.

(i) A procedure to ensure that a drug received from a supplier contains the statements required pursuant to subsections 1 and 2 of NAC 639.603.

(j) A procedure to ensure that all drugs received are examined pursuant to NAC 639.599 and 639.601.

(k) A procedure to ensure that the drugs are not contraband drugs or counterfeit drugs.

Sec. 19. NAC 639.607 is hereby amended to read as follows:

639.607 ***1.*** Each wholesaler shall allow ~~[the Board and any other authorized person]~~ ***a member of the staff of the Board*** to:

~~[1.]~~ ***(a)*** Inspect its facility and any motor vehicles it uses to transport prescription drugs; and

~~[2.]~~ ***(b)*** Examine its records and procedures for the operation of the facility,

↪ during normal business hours.

2. If a member of the staff of the Board wishes to make a copy of a document of the wholesaler and the number of copies will exceed 50 pages, the member of the staff of the Board may, in his discretion, copy the document at the facility of the wholesaler or remove the document to make a copy at another location.

Sec. 20. NAC 639.709 is hereby amended to read as follows:

639.709 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.]~~

2. 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 ~~[subsection.]~~ ***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~~ ~~]~~ ***"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.]~~