ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R049-04

Effective February 28, 2005

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

AUTHORITY: §§1-17, NRS 639.070, 639.100 and 639.2615.

A REGULATION relating to pharmacy; requiring a wholesaler to comply with certain requirements as reasonable assurance that the wholesaler is in compliance with certain statutory requirements; 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 examination of drugs received by a wholesaler; requiring certain documents to be included in a record of inventory of a wholesaler; 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 6, inclusive, of this regulation.

Sec. 2. ***"Purchaser" means a pharmacy or practitioner that purchases a prescription drug from a wholesaler licensed pursuant to NRS 639.233.***

Sec. 3. ***"Purchasing wholesaler" means a wholesaler that purchases a prescription drug from a wholesaler licensed pursuant to NRS 639.233.***

Sec. 4. ***"Supplier" means a wholesaler that sells a prescription drug to a wholesaler licensed pursuant to NRS 639.233.***

Sec. 5. ***1. For each sale of a prescription drug to a purchasing wholesaler, the wholesaler must, 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) Before the sale of the prescription drug, obtain from the purchasing wholesaler a written statement that contains a representation by the purchasing wholesaler that, for transactions which occur in this State, the purchasing wholesaler will only sell the prescription drug to a pharmacy or practitioner;

(b) Possess written correspondence between the wholesaler and the purchasing wholesaler or between the purchasing wholesaler and other purchasers that evidences the compliance by the purchasing wholesaler with the provisions of subparagraph (2) of paragraph (b) of subsection 2 of NRS 639.2615; and

(c) Ensure that the following statement is written on the face of the invoice or other document which evidences the sale and on the face of any "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" described in NAC 639.603 that accompanied the sale of the prescription drug printed in all capital letters and in at least 10-point type:

> ***NEVADA LAW REQUIRES THAT YOU MUST SELL THE PRESCRIPTION DRUGS SOLD TO YOU AS SET FORTH IN THIS DOCUMENT ONLY TO PHARMACIES OR PRACTITIONERS. THE SALE OF ANY OF THE PRESCRIPTION DRUGS SOLD TO YOU AS SET FORTH IN THIS DOCUMENT TO ANY PERSON OR BUSINESS OTHER THAN A PHARMACY OR PRACTITIONER WILL RESULT IN A TERMINATION OF FUTURE SALES AND MAY SUBJECT YOU TO OTHER PENALTIES AS PRESCRIBED BY LAW.***

2. For the purposes of this section, the Board will consider the sale by a wholesaler to a purchasing wholesaler whose sole function is to distribute prescription drugs to pharmacies under common ownership with the purchasing wholesaler to be a sale to a pharmacy.

Sec. 6. ***If a wholesaler in this State decides to destroy a prescription drug pursuant to NAC 639.5975, 639.599 or 639.601, the wholesaler shall:***

1. Segregate the prescription drug in a manner that will ensure that the prescription drug cannot be sold or otherwise used; and

2. Destroy the prescription drug and its packaging in such a manner that the prescription drug cannot be resold or used and which is in compliance with any applicable laws or regulations concerning the destruction of drugs and drug packaging.

Sec. 7. 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 6, 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 4, inclusive, of this regulation*** have the meanings ascribed to them in those sections.

Sec. 8. 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 ***Board will not consider 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]~~ ***if the*** sale, distribution or other transaction involving ~~[a]~~ ***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 to be 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. 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. 9. 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.]~~

(b) 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; or

(c) The existence of the purchase by the wholesaler of at least 5,000 sales units of prescription drugs from the manufacturer within the 12 months immediately preceding the transaction for which the wholesaler claims to have an ongoing relationship and:

(1) The Board or a purchasing wholesaler verifying the purchase with the manufacturer at its main corporate office in the United States; or

(2) The wholesaler maintaining invoices showing that the purchase was made directly from the manufacturer which include an account number assigned by the manufacturer to the wholesaler's address of record on file with the Board.

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

(a) ~~[Maintained]~~ ***If the facility is located within this State, maintained*** at the facility of the wholesaler throughout the period that such a relationship exists;

(b) Maintained for ~~[2]~~ ***3*** 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.

3. An ongoing relationship between a wholesaler and a manufacturer may be attributed to an affiliated wholesaler if:

(a) The affiliated wholesaler is licensed by the Board or the relevant authority of another state;

(b) The wholesaler who has the ongoing relationship with the manufacturer and the affiliated wholesaler are wholly owned by a common owner; and

(c) The common owner is a publicly traded corporation.

4. As used in this section, "sales unit" means any standard container or unit of packaging used by the manufacturer for the prescription drug.

Sec. 10. 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]~~ ***person who is not a wholesaler or manufacturer*** if the prescription drug was originally purchased by ~~[the pharmacy]~~ ***that person*** from the wholesaler.

3. ***A wholesaler that was not the original wholesaler which sold prescription drugs to a person who is not a wholesaler or manufacturer may receive the prescription drugs if:***

(a) The person no longer does business with the original wholesaler;

(b) The original wholesaler no longer does business with the person; or

(c) The original wholesaler refuses to allow the return of the prescription drugs.

4. A wholesaler shall not:

(a) Receive from a ~~[pharmacy]~~ ***person who is not a wholesaler or manufacturer*** an amount or quantity of a prescription drug larger than the amount or quantity that was originally sold by the ***original*** wholesaler to ~~[the pharmacy; or~~

~~(b) Pay the pharmacy]~~ ***that person;***

(b) Pay that person an amount, either in cash or credit, ***that is*** more than ~~[the pharmacy]~~ ***:***

(1) The amount the person originally paid to the ***original*** wholesaler for the prescription drug ~~[.]~~ ***; or***

(2) The price the receiving wholesaler would have charged that person for the prescription drug at the time of the return; or

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

5. A wholesaler that receives a prescription drug from a person who is not a wholesaler or manufacturer pursuant to this section may dispose of the prescription drug by:

(a) Destroying the prescription drug.

(b) Selling the prescription drug to another person who is not a wholesaler or manufacturer;

(c) Selling the prescription drug to another wholesaler; or

(d) Providing the prescription drug to another wholesaler or the manufacturer of the prescription drug solely for the purposes of destruction or disposal.

6. If a wholesaler:

(a) Sells a prescription drug to another person who is not a wholesaler or manufacturer pursuant to paragraph (b) of subsection 5, the wholesaler is not required to provide a "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" described in NAC 639.603.

(b) Sells or provides a prescription drug to another wholesaler or the manufacturer of the prescription drug pursuant to paragraph (c) or (d) of subsection 5, the wholesaler must provide a "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" as described in NAC 639.603 for that sale and must indicate on the statement that the prescription drug was received from the person from whom the wholesaler accepted the prescription drug.

Sec. 11. 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 and the "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" described in NAC 639.603,*** to determine its identity and to prevent the acceptance of a ~~[contaminated]~~ prescription drug that ~~[is otherwise unfit for distribution.]~~ ***is:***

(a) Counterfeit;

(b) Deemed to be adulterated or misbranded in accordance with the provisions of chapter 585 of NRS;

(c) Mislabeled;

(d) Damaged or compromised by improper handling, storage or temperature control;

(e) From a foreign or unlawful source; or

(f) Manufactured, packaged, labeled or shipped in violation of any state or federal law relating to prescription drugs.

➥ 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 that a prescription drug has one or more of the conditions set forth in paragraphs (a) to (f), inclusive, of subsection 1, the wholesaler:

(a) If the prescription drug is not subject to a recall or withdrawn from the market, shall:

(1) Separate the prescription drug from other prescription drugs; and

(2) Provide to the Board, not later than 10 business days after the inspection, a written notice that includes:

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

(II) The name of the prescription drug;

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

(IV) The quantity of the prescription drug;

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

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

(VII) If the prescription drug was returned to the supplier, the date on which the prescription drug was returned to the supplier.

(b) If the prescription drug is not subject to a recall or withdrawn from the market, may return the prescription drug to the supplier or destroy the prescription drug.

4. Within 48 hours after receipt by the Board of a notice required pursuant to subsection 3, a member of the staff of the Board shall inspect the prescription drug at the facility of the wholesaler and may impound or remove the prescription drug. If the member of the staff of the Board does not impound or remove the prescription drug, the wholesaler may return the prescription drug to the supplier or destroy the drug.

Sec. 12. 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 or purchasing wholesaler*** under conditions which cast doubt on the ***prescription*** drug's safety, identity, strength, quality or purity, the wholesaler shall destroy the ***prescription*** drug or return it to the supplier ~~[,]~~ unless **,** after conducting an examination, testing or other investigation, the wholesaler determines that the ***prescription*** drug complies with the appropriate standards of safety, identity, strength, quality and purity as prescribed in ~~[*The United States Pharmacopeia, 22nd edition, 1990.*]~~ ***the package insert as approved by the Food and Drug Administration or in 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. Unless the reason a prescription drug must be destroyed or returned to the supplier is related to the expiration date of the prescription drug, a wholesaler that is required to destroy a prescription drug or return it to the supplier pursuant to subsection 3 shall provide to the Board a written notice that includes:

(a) The name of the prescription drug;

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

(c) The quantity of the prescription drug;

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

(e) Whether the wholesaler will:

(1) Return the prescription drug to the supplier; or

(2) Destroy the prescription drug; and

(f) The reason for the action taken by the wholesaler.

5. Within 48 hours after receipt by the Board of a notice required pursuant to subsection 4, a member of the staff of the Board shall inspect the prescription drug at the facility of the wholesaler and may impound or remove the prescription drug. If the member of the staff of the Board does not impound or remove the prescription drug, the wholesaler may return the prescription drug to the supplier or destroy the prescription drug.

Sec. 13. 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 prescription drug from the supplier;

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

(c) The shipping record, which may be a manifest, shipping label, shipping bill or any similar document, evidencing the shipment of the prescription drug from the supplier to the wholesaler;

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

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

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

(g) A copy of the license of the supplier that sold the prescription 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 sell a prescription drug received from the supplier; and

(i) One or more of the documents required by section 5 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]~~ ***3*** years after the receipt, distribution or other disposition of the ***prescription*** 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. 14. NAC 639.603 is hereby amended to read as follows:

639.603 1. ~~[Each]~~ ***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 ~~[after the expiration date of the drug;~~

~~(b) Available]~~ ***;***

(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.

Sec. 15. 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]~~ ***3*** years after the disposition of the ***prescription*** 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 6, inclusive, of this regulation.

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

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

3. As used in this section:

(a) "Contraband drug" means a prescription drug that is offered for sale by a purchaser to a wholesaler in violation of an agreement to which the purchaser is a party or is otherwise in privity of contract that would prohibit or otherwise disallow such a sale or resale.

(b) "Counterfeit drug" means a prescription drug that is adulterated, mislabeled or misbranded pursuant to chapter 585 of NRS.

Sec. 16. NAC 639.607 is hereby amended to read as follows:

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

~~1.]~~ ***to:***

(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 copies of documents 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 documents at the facility of the wholesaler or remove the documents to make copies at a commercial facility for reproduction mutually agreed upon by the wholesaler and the member of the staff of the Board. Upon request, the member of the staff of the Board who removes documents for the purpose of copying them pursuant to this section shall provide a receipt to the wholesaler which describes the documents removed.

Sec. 17. 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;

(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.]~~ ***only for the purposes of, and subject to the conditions set forth in, NAC 639.5975.***

2. Drugs, controlled substances, poisons, chemicals, devices or appliances that are returned by a ~~[pharmacy]~~ ***person*** for credit, in an amount equal to or less than the actual purchase price, to ~~[the]~~ ***a*** wholesaler or manufacturer ~~[from which those products were purchased]~~ ***pursuant to subsections 2, 3 and 4 of NAC 639.5975*** 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.]~~

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R049-04

The State Board of Pharmacy adopted regulations assigned LCB file number R049-04 that pertain to chapter 639 of the Nevada Administrative Code on January 13, 2005.

Notice date: 12/9/2004
Hearing date: 1/13/2005
Date of adoption by agency: 1/13/2005
Filing date: 2/28/2005

INFORMATIONAL STATEMENT

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.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 555 Double Eagle Court, Suite 1100, Reno, Nevada, 89521.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was __3__.
The number of persons who testified at the hearing was __3__.
The number of agency submitted statements was __0__.

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 amended slightly as a result of testimony offered at the hearing.

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.

Beneficial Effects of Regulation: The regulation improves the assurance that all transactions and business conducted by Nevada's licensed pharmaceutical wholesalers are safe to the public and promote good wholesaling practices. The regulations are intended to lessen the risk that drugs handled by Nevada's licensed pharmaceutical wholesalers are counterfeited, mislabeled, adulterated, or otherwise compromised. Terms and conditions of licensure that some of Nevada 's licensed pharmaceutical wholesalers claimed were ambiguous or subject to uncertainty and interpretation have been defined and clarified. Additionally, the former "10% Rule" that was of great concern to some Nevada licensed pharmaceutical wholesalers has been repealed through the regulation.

Adverse Effects of Regulation: The regulation will cost Nevada licensed pharmaceutical wholesalers an undetermined but relatively small amount if the pharmaceutical wholesalers were not making and maintaining their records according to the new standards set in the regulations and had not trained their employees to the increased levels of diligence required by NRS 639.2615 and the new regulations. Additionally, some business relationships maintained by some Nevada licensed pharmaceutical wholesalers will require reexamination and readjustment or may require termination if the relationships cannot be conformed to the new regulations.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

Immediate Effects of Regulation: Since many of the regulations refine or define concepts that have already been in place since October 1, 2003, when NRS 639.2615 became effective, many of the immediate effects of the regulation should have already occurred. Wholesalers who have not developed policies and procedures to address the changes made through NRS 639.2615 will need to immediately develop such policies and procedures pursuant to the regulations.

Long-Term Effects of Regulation: Once Nevada's licensed pharmaceutical wholesalers have addressed the immediate effects of compliance with NRS 639.2615 and the regulations, the only substantial long-term effects from the regulations should be a better and safer prescription drug supply for all prescription drugs handled by Nevada's licensed pharmaceutical wholesalers.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There will be no additional or special costs 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.