DISCLAIMER

Electronic versions of the exhibits in these minutes may not be complete.

This information is supplied as an informational service only and should not be relied upon as an official record.

Original exhibits are on file at the Legislative Counsel Bureau Research Library in Carson City.

Contact the Library at (775) 684-6827 or library@lcb.state.nv.us.

10. A lead-shielded drawing station.
11. Decontamination supplies.
12. Appropriate supplies to perform procedures to assure the quality of radiopharmaceuticals.
13. Lead transport shields for syringes and vials.
14. USA Type A, 7A transport containers approved by the Department of Transportation and other labels and supplies for shipping radioactive materials.

(Added to NAC by Bd. of Pharmacy, eff. 11-9-95)

WHOLESALERS

NAC 639.585 Definitions. (NRS 639.070, 639.100) As used in NAC 639.585 to 639.607, inclusive, 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.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92; A 10-1-93; R013-01, 11-1-2001)

NAC 639.587 "Facility" defined. "Facility" means a facility of a wholesaler where prescription drugs are stored, handled, repackaged or offered for sale.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.588 "Manufacturer" defined. "Manufacturer" has the meaning ascribed to it in NRS 639.009.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.589 "Ongoing relationship" defined. "Ongoing relationship" means a continuing business relationship in which a wholesaler distributes a manufacturer's prescription drugs which is established pursuant to NAC 639.594.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.592 "Wholesaler" defined. "Wholesaler" has the meaning ascribed to it in NRS 639.016.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.593 Licensing. (NRS 639.070, 639.100)

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.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92; A by R013-01, 11-1-2001)

NAC 639.5935 Representative of wholesaler: Designation requirement; exceptions; qualifications; presence required to operate. (NRS 639.070, 639.100)

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 secretary of 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 as a wholesaler or the licensee presents proof satisfactory to the secretary of 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 secretary of 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 secretary of the board may take such action as deemed necessary to secure the facility of the wholesaler and to ensure that the wholesaler does not conduct business during the period of the suspension.

(Added to NAC by Bd. of Pharmacy by R013-01, eff. 11-1-2001)

NAC 639.594 Establishment of ongoing relationship. (NRS 639.070, 639.100)

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.

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.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92; A by R013-01, 11-1-2001)

NAC 639.595 Qualifications of employees. Each wholesaler licensed by the board shall ensure that any person he employs who engages in the storage or distribution of drugs in a facility has the education and experience necessary to engage safely and lawfully in the storage or distribution of those drugs.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.596 Facilities: General requirements; maintenance of stock. (NRS 639.070, 639.100)

1. Each facility must:

(a) Provide adequate lighting of at least 25 foot-candles;

(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;

(c) Be maintained in a clean and orderly condition;

(d) Be free from infestation by insects, rodents, birds or vermin;

(e) Be secure from entry by unauthorized persons;

(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.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92; A by R013-01, 11-1-2001)

NAC 639.597 Facilities: Security.

1. Access to the facility must be kept to a minimum and be well-controlled.

2. The outside perimeter of the facility must be properly lighted.

3. Access to the area of the facility where the controlled substances are stored must be limited to authorized persons.

4. The area of the facility where controlled substances are stored must be securely enclosed with a material made of steel of at least 10 gauge in thickness with openings not more than 2 1/2 inches wide. The material must be mounted on steel posts which must be at least 1 inch in diameter. The posts must be placed not more than 10 feet apart. If the material does not extend to the structural ceiling of the facility, the ceiling of the enclosed area must be constructed of material made of steel at least 10 gauge in thickness with openings not more than 2 1/2 inches wide. A lighter gauge mesh may be used for the ceiling of a large enclosed area if the walls of the area are at least 14 feet in height.

5. Access to the enclosed area must be limited to persons who are responsible for ensuring the security of the controlled substances stored within that enclosed area. The enclosed area must be equipped with a security system which includes an alarm that will transmit a signal to a local law enforcement agency or a private business which provides security services if an unauthorized person obtains access to the enclosed area.

6. The secretary of the board may approve an alternate method for ensuring the security of the area where the controlled substances are stored if he determines that the method will ensure that entry to the area is accessible only to authorized persons.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.5975 Prescription drugs: Restrictions on purchases, sales, distribution and transfers. (NRS 639.070, 639.100)

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 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.

(Added to NAC by Bd. of Pharmacy by R013-01, eff. 11-1-2001)

NAC 639.598 Prescription drugs: Storage.

1. Each wholesaler shall store prescription drugs held in the facility in the manner prescribed in *The United States Pharmacopeia*, 22nd edition, 1990, which is hereby adopted by reference. A copy of the publication may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, for the price of $91, plus $7 for shipping and handling.

2. If there are no specific requirements concerning the temperature at which a prescription drug must be stored, the drug must be stored at a controlled room temperature as defined in the *United States Pharmacopeia*, 22nd edition, 1990.

3. Each wholesaler shall provide the appropriate manual, electromechanical or electrical equipment to record the temperature and humidity of the area where the prescription drugs are stored.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.599 Prescription drugs: Shipment.

1. Each wholesaler shall, upon receiving a prescription drug, examine each outside shipping container of the drug to determine its identity and to prevent the acceptance of a contaminated prescription drug that is otherwise unfit for distribution. The examination must be sufficiently 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.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.601 Prescription drugs: Separation and disposal of certain drugs.

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 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.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.602 Prescription drugs: Records. (NRS 639.070, 639.100)

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.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92; A by R013-01, 11-1-2001)

NAC 639.603 Prescription drugs: Statement identifying prior sales by wholesalers.

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;

(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.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92; A 10-1-93)

NAC 639.604 Maintenance and availability of list of wholesalers with whom manufacturer has ongoing relationship. Each manufacturer shall maintain at its principal place of business a list of wholesalers with whom the manufacturer has an ongoing relationship. The list must be available for inspection upon a request by any authorized representative of a federal, state or local agency. The manufacturer shall provide a copy of the list upon request. The manufacturer may charge a fee to cover the cost of copying the list.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92; A 10-1-93)

NAC 639.605 Establishment and maintenance of policies and procedures regarding prescription drugs.

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 years after the disposition of the drug.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.606 Establishment and maintenance of lists regarding certain personnel. Each wholesaler shall establish and maintain a list of the officers, directors, managers of the facility and any persons who have access to the facility. The list must include a description of their duties and a summary of their qualifications.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

NAC 639.607 Inspections; examination of records and procedures. 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.

(Added to NAC by Bd. of Pharmacy, eff. 7-16-92)

MANUFACTURERS

NAC 639.610 Minimum standards for premises. The premises occupied by any person holding a manufacturer's permit or the premises to be occupied by any applicant for such a permit must meet the following minimum standards:

1. The premises must be well lighted and well ventilated and must be maintained in a clean and orderly manner.
2. Adequate lavatory and toilet facilities and dressing areas must be provided, and washbasins to be used in connection with those facilities must be supplied with hot and cold running water. All such facilities must be maintained in a clean and orderly condition and in good repair.
3. The building must be constructed in such a manner as to provide maximum security and must be equipped with an adequate alarm system.

[Bd. of Pharmacy, § 639.420, eff. 6-26-80]—(NAC A 5-14-92)

NAC 639.615 Equipment and requirements for operation; employees.

1. Any person to whom a manufacturer's permit has been issued shall provide and maintain the following equipment if it is needed in the operation of the business, and shall comply with the following requirements as they apply to the operation of the business:

(a) If drugs requiring refrigeration are stocked, the holder of the permit shall provide refrigerators for proper storage.

(b) The area in which drugs are stocked must be arranged so that dangerous drugs, chemicals, poisons, controlled substances and devices are not accessible to unauthorized persons.

(c) Drugs which are damaged, deteriorated, misbranded, adulterated or outdated must be stored in an area separate from the area containing the drugs, chemicals, poisons, controlled substances or devices which are to be sold or distributed for resale.

(d) The holder of a permit shall maintain such records as may be necessary to provide accountability for the disposition of dangerous drugs, controlled substances, chemicals and devices.

(e) Equipment must be provided and maintained as may be considered necessary and consistent with the licensed operation, and maintained in proper working order at all times.

2. All persons who in the course of their employment with a manufacturer handle any drugs, chemicals or devices shall keep themselves and their apparel in a clean and sanitary condition.

[Bd. of Pharmacy, § 639.415, eff. 6-26-80]—(NAC A 5-14-92)—(Substituted in revision for NAC 639.600)