Board of Pharmacy

Adopted Permanent Rules Relating to Drug Manufacturers and Wholesalers Licensing

Rules as Adopted

6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE.

Subpart 1. **Licensing; fees.** Every person engaged in manufacturing, wholesale distribution, or selling of drugs, medicines, chemicals, or poisons for medicinal purposes other than to the consuming public or patient shall annually be licensed by the board. Upon the filing of an application, and upon payment of a fee of $150 for manufacturing or wholesale distribution of prescription drugs only, not including medical gases; $150 for manufacturing or wholesale distribution of prescription and nonprescription drugs, not including medical gases; $125 for manufacturing or wholesale distribution of nonprescription drugs or veterinary drugs only; $100 for manufacturing or wholesale distribution of prescription medical gases only; and $75 for licensed pharmacies engaged in wholesale distribution, the board may issue or renew a license in such form as it may prescribe to the manufacturer or wholesale distributor. The license shall be exposed in a conspicuous place in the manufacturer's or wholesaler's place of business for which it is issued, shall expire at midnight on June 1 of each year, and shall be renewed annually upon the filing of an application therefor, on or before May 1 of each year together with the applicable fee. Renewal applications received after June 1 shall be subject to a late filing fee of one-half of the renewal fee in addition to the amount of the renewal fee.

Subp. 2. **Prohibition.** No license may be issued to any manufacturer or wholesale distributor whose intended place of business is a personal residence.

Subp. 3. **Separate licenses required.** A separate license is required for each separate location where drugs are stored

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within this state. Out-of-state wholesale drug distributors shipping drugs into Minnesota who do not maintain or operate a physical facility within Minnesota are not required to license each separate location from which drugs are shipped to Minnesota, but may instead obtain licensure for the primary location of the parent entity and any divisions, subsidiaries, or affiliated companies.

6800.1410 MINIMUM INFORMATION REQUIRED FOR LICENSURE.

The following information is required from each wholesale drug distributor applying for licensure or renewal:

A. the name, full business address, and telephone number of the licensee;

B. all trade or business names used by the licensee;

C. addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of drugs;

D. whether the ownership or operation is a partnership, corporation, or sole proprietorship; and

E. the name of the owner and operator of the licensee, including:

(1) if an individual, the name of the individual;

(2) if a partnership, the name of each partner, and the name of the partnership;

(3) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(4) if a sole proprietorship, the full name of the sole proprietor, and the name of the business entity.

Changes in any information in items A to E shall be submitted to the board within 30 days of the change.

6800.1420 MINIMUM QUALIFICATIONS.

The board may deny, suspend, revoke, or refuse to renew any license for a wholesale drug distributor based on the board's finding of any of the following factors:

A. any convictions of the applicant under any

federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

B. any felony convictions of the applicant under federal, state, or local laws;

C. the lack of previous experience on the part of the applicant in the manufacture or distribution of drugs, including controlled substances;

D. the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

E. the suspension or revocation by federal, state, or local government bodies of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

F. the lack of compliance by the applicant with licensing requirements under previously granted licenses, if any;

G. the lack of compliance by the applicant with requirements to maintain or make available to the board of pharmacy or to federal, state, or local law enforcement officials those records required under this part; and

H. the lack of compliance by the applicant with requirements for the storage and handling of drugs as specified in part 6800.1440.

6800.1430 PERSONNEL.

Each wholesale drug distributor shall ~~establish training programs which, when combined with the~~ require each person employed in any prescription drug wholesale activity to have enough education, training, and experience ~~of the personnel, will enable the personnel to~~, in any combination, sufficient for that person: (1) to do assigned work in a manner that maintains the quality, safety, and security of the drug products in accordance with parts 6800.1400 to 6800.1440; and (2) to assume responsibility for ~~positions related to~~ compliance with ~~state~~

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and-federal the licensing requirements of parts 6800.1400 to 6800.1440.

6800.1440 MINIMUM REQUIREMENTS FOR STORAGE AND HANDLING OF DRUGS AND FOR ESTABLISHMENT AND MAINTENANCE OF DRUG DISTRIBUTION RECORDS.

Subpart 1. **Application.** The minimum requirements in this part apply to all wholesale drug distributors located in this state and to their officers, agents, representatives, and employees.

Subp. 2. **Incorporation by reference.** "United States Pharmacopeia/National Formulary" means the United States Pharmacopeia/National Formulary published by the United States Pharmacopeial Convention Inc. (Rockville, Maryland, 1990), which is incorporated by reference. The United States Pharmacopeia/National Formulary is subject to frequent change. The book is available for inspection and copying at the Biomedical Library, University of Minnesota, Diehl Hall, 505 Essex Street S.E., Minneapolis, Minnesota 55455, or through the Minitex interlibrary loan system.

Subp. 3. **Facilities.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

A. be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

B. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

C. have a physically separate area for storage of all prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

D. be maintained in a clean and orderly condition; and

E. be free from infestation by insects, rodents, birds, or vermin of any kind.

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Subp. 4. **Security.** The requirements in items A to C govern security.

A. All facilities used for wholesale drug distribution shall be secure from unauthorized entry as follows:

(1) access from outside the premises shall be kept to a minimum and be well-controlled;

(2) the outside perimeter of the premises shall be well-lighted; and

(3) entry into areas where prescription drugs are held shall be limited to authorized personnel.

B. All facilities shall be equipped with an alarm system to detect entry after hours.

C. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Subp. 5. **Storage.** Items A to D govern storage of drugs.

A. All drugs shall be stored at temperatures and under conditions in accordance with the requirements, if any, in the labeling of such drugs, or with requirements in the current edition of the United States Pharmacopeia/National Formulary.

B. If no storage requirements are established for a drug, the drug may be held at "controlled room temperature," as defined in the United States Pharmacopeia/National Formulary, to help ensure that its identity, strength, quality, and purity are not adversely affected.

C. Manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document proper storage of prescription drugs.

D. The record keeping requirements in subpart 8 shall be followed for all stored drugs.

Subp. 6. **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This

examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

The record keeping requirements in subpart 8 shall be followed for all incoming and outgoing drugs.

Subp. 7. **Returned, damaged, and outdated drugs.** Items A to D govern returned, damaged, outdated, deteriorated, misbranded, and adulterated drugs.

A. Drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separated from other drugs until they are destroyed or returned to their supplier.

B. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be physically separated from other drugs until they are either destroyed or returned to the supplier.

C. If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

D. The record keeping requirements in subpart 8 shall be followed for all damaged, outdated, deteriorated, misbranded,

or adulterated drugs.

Subp. 8. **Record keeping.** Items A to C govern record keeping.

A. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following information:

(1) the source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(2) the identity and quantity of the drugs received and distributed or disposed of; and

(3) the dates of receipt and distribution or other disposition of the drugs.

B. Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.

C. Records described in this part that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency.

Subp. 9. **Written policies and procedures.** Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs. They must include policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include the written policies and procedures described in items A to D.

A. A procedure where the oldest approved stock of a

drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

B. A procedure to be followed for handling recalls and withdrawals of drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(1) any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board of pharmacy;

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

(3) any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

C. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

D. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

Subp. 10. **Responsible persons.** Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Subp. 11. **Compliance with federal, state, and local law.** Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

Wholesale drug distributors shall permit the board of pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect both their premises and delivery vehicles and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

Wholesale drug distributors who deal in controlled substances shall register with the board of pharmacy and with the Drug Enforcement Administration, and shall comply with all applicable state, local, and Drug Enforcement Administration regulations.

Subp. 12. **Salvaging and reprocessing.** Wholesale drug distributors are subject to any applicable federal, state, or local laws or regulations that relate to drug product salvaging or reprocessing, including Code of Federal Regulations, title 21, parts 207, 210, and 211, and Minnesota Statutes, section 151.39.