CHAPTER 17
WHOLESALE DRUG LICENSES

657—17.1(155A) Definitions.

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the Iowa board of pharmacy examiners.

"Distribute" means the delivery of a prescription drug or device.

"Drug sample" means a drug that is distributed without consideration to a pharmacist or practitioner.

"Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling of a prescription drug.

"Prescription drug" means any of the following:

1. A substance for which federal or state law requires a prescription before it may be legally dispensed to the public.
2. A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:
   - Caution: Federal law prohibits dispensing without a prescription.
   - Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
3. A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

"Proprietary medicine" means a nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with applicable state or federal law.

"Reverse distribution" means the receipt of prescription drugs including controlled substances, whether received from Iowa locations or shipped to Iowa locations, for the purposes of destroying the drugs or returning the drugs to their original manufacturers or distributors.

"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

1. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this chapter, "emergency medical reasons" includes transfers of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;
2. The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;
3. The lawful distribution of drug samples by manufacturers' representatives or wholesale salespersons;
4. The sale, purchase, or trade of blood and blood components intended for transfusion; or
5. Intracompany sales.

"Wholesale distributor" means anyone engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; reverse distributors; and pharmacies that conduct wholesale distributions exceeding 5 percent of gross annual sales of prescription drugs.

"Wholesaler" means a person operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs, medicinal chemicals, medicines, or poisons are sold, manufactured, compounded, dispensed, stocked, exposed, or offered for sale at wholesale in this state. "Wholesaler" does not include those wholesalers who sell only proprietary medicines.

"Wholesale salesperson" or *"manufacturer's representative"* means an individual who takes purchase orders on behalf of a wholesaler for prescription drugs, medicinal chemicals, medicines, or poisons. "Wholesale salesperson" or "manufacturer's representative" does not include an individual who sells only proprietary medicines.

657—17.2(155A) Wholesale drug distributor licensing requirements.

17.2(1) Every wholesale distributor, wherever located, who engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and regulations of Iowa before engaging in wholesale distribution of prescription drugs.

17.2(2) Where operations are conducted at more than one location by a single wholesale distributor, each such location shall be licensed by the board.

17.2(3) An Iowa wholesale drug license shall expire on December 31 of each year. The fee for a new or renewal license shall be $100. A wholesale drug license form shall be issued upon receipt of the license application information required in subrule 17.3(1) and payment of the license fee.

Failure to renew the license before January 1 following expiration shall require a renewal fee of $200. Failure to renew the license before February 1 following expiration shall require a renewal fee of $300. Failure to renew the license before March 1 following expiration shall require a renewal fee of $400. Failure to renew the license before April 1 following expiration shall require an appearance before the board and a renewal fee of $500. In no event shall the fee for late renewal of the license exceed $500.

657—17.3(155A) Minimum required information for licensure.

17.3(1) The board requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

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 the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

d. The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

e. The name(s) of the owner and operator of the license, including:

(1) If a person, the name and address of the person;

(2) If a partnership, the name of each partner, and the name and address 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 the name and address of the parent company, if any;

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

17.3(2) Changes in any information in this rule shall be submitted in written form within 30 days after such change to Executive Secretary/Director, Iowa Board of Pharmacy Examiners, Executive Hills West, 1209 East Court Avenue, Des Moines, Iowa 50319.

657—17.4(155A) Minimum qualifications.

17.4(1) The board will consider the following factors in determining eligibility for licensure of persons who engage in the wholesale distribution of prescription drugs:

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 applicant's past experience in the manufacture or distribution of prescription 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. Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

f. Compliance with licensing requirements under previously granted licenses, if any;

g. Compliance with the requirements to maintain or make available to the board, its agents or authorized personnel, or to the federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors; and

h. Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

17.4(2) The board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

657—17.5(155A) Personnel. The licensed wholesale distributor shall employ personnel with the education or experience appropriate to the responsibilities of positions related to compliance with the licensing requirements of this chapter.

657—17.6(155A) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
3. Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
4. Be maintained in a clean and orderly condition;
5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

657—17.7(155A) Security.

17.7(1) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

a. Access from outside the premises shall be kept to a minimum and be well controlled.

b. The outside perimeter of the premises shall be well lighted.

c. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

17.7(2) All facilities shall be equipped with an alarm system to detect entry after hours.

17.7(3) 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.

657—17.8(155A) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with requirements in the current edition of an official compendium.

17.8(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

17.8(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs.

17.8(3) The storage requirements of this rule do not apply to reverse distributors.

657—17.9(155A) Examination of materials.

17.9(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription 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.

17.9(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

657—17.10(155A) Returned, damaged, and outdated prescription drugs.

17.10(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

17.10(2) 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 quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

17.10(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, 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 conditions of the drug and its container, carton, or labeling as a result of storage or shipping.

17.10(4) The requirements of this rule do not apply to reverse distributors.

657—17.11(155A) Record keeping. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs, including outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

17.11(1) Inventory and transaction records shall include the following information:

a. 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;

b. The identity and quantity of the drugs received and distributed or disposed of;

c. The dates of receipt and distribution or other disposition of the drugs; and

d. If a distribution transaction, the recipient of the drugs, including the name and principal address of the purchaser or transferee and the address of the location to which the drugs were shipped.

17.11(2) Inventories and records shall be made available for inspection and photocopying by any authorized official of any governmental agency charged with enforcement of these rules for a period of two years following disposition of the drugs.

17.11(3) Records described in this rule 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 any governmental agency charged with enforcement of these rules.

657—17.12(155A) 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 prescription drugs, including 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 in their written policies and procedures the following:

17.12(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

17.12(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

a. 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 Iowa board of pharmacy examiners;

b. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

c. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

17.12(3) 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.

17.12(4) 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 prescription drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

17.12(5) The procedures required by subrules 17.12(1) and 17.12(2) do not apply to reverse distributors. All other procedures addressed in this rule are required of reverse distributors.

657—17.13(155A) 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.

657—17.14(155A) Compliance with federal, state, and local laws. Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

17.14(1) Wholesale drug distributors shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect 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. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

17.14(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local, and DEA regulations.

657—17.15(155A) Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including Chapter 21, parts 207, 210d and 211 of the Code of Federal Regulations, April 1, 1991.

657—17.16(155A) Discipline. Pursuant to 657—Chapter 9, the board may deny, suspend, or revoke a wholesale drug license for any violation of Iowa Code chapters 155A, 126, 124, 124A, 124B, and 205, or a rule of the board promulgated thereunder.

These rules are intended to implement Iowa Code section 155A.17.

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