# CHAPTER 17
# WHOLESALE DRUG LICENSES

**657—17.1(155A) Definitions.**

*"Authorized collection program"* means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at www.deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant's Iowa controlled substances Act registration shall not be required.

*"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.

*"DEA"* means the United States Department of Justice, Drug Enforcement Administration.

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

*"Drug sample"* means a drug that is distributed without monetary consideration to a pharmacist or practitioner. "Drug sample" does not include drugs intended for patients who would otherwise not receive needed drugs due to their inability to pay.

*"Manufacturer"* means a person or business engaged in the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes packaging or repackaging of the substances or labeling or relabeling of the substances' containers.

*"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 one 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.
   - Rx only.
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"* or *"over-the-counter (OTC) 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"* or *"wholesaler"* means a person or business 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, dispensed, stocked, exposed, or offered for sale at wholesale in this

state. "Wholesaler" includes, but is 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" does not include those wholesalers who sell only OTC medicines or manufacturers' representatives lawfully distributing drug samples to authorized practitioners.

*"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. "Manufacturer's representative" also means a person designated by a pharmaceutical manufacturer to lawfully distribute drug samples to authorized practitioners.

[**ARC 2408C**, IAB 2/17/16, effective 3/23/16]

**657—17.2** Reserved.

**657—17.3(155A) Wholesale drug license.** Every wholesaler as defined in rule 657—17.1(155A), wherever located, that engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and rules of Iowa before engaging in wholesale distribution of prescription drugs. Where operations are conducted at more than one location by a single wholesaler, each such location shall be separately licensed in Iowa. A wholesaler located within Iowa that engages in wholesale distribution of or collection via an authorized collection program of controlled substances shall also register pursuant to 657—Chapter 10.

**17.3(1)** *Application form.* Application for licensure and license renewal shall be on forms provided by the board. Application for wholesale drug licensure shall require an indication of the type of wholesale operation and the wholesaler ownership classification. If the owner is a sole proprietorship (100 percent ownership), the name and address of the owner shall be indicated. If the owner is a partnership or limited partnership, the names and addresses of all partners shall be listed or attached. If the owner is a corporation, the names and addresses of the officers and directors of the corporation shall be listed or attached. Any other wholesaler ownership classification shall be further identified and explained on the application. The name, address, and telephone numbers of at least one contact person for the licensed facility shall be identified. A list of all states in which the wholesaler is licensed and all trade or business names used by the wholesaler shall be included on or with the application. The application shall identify, if the wholesaler is located outside Iowa, applicable home state license information and DEA and FDA license or registration information. The application shall also provide information regarding any past criminal convictions or adverse actions against licenses or registrations held by the licensee or facility managers.

**17.3(2)** *License expiration and renewal.* A wholesale drug license shall be renewed before January 1 of each year. The fee for a new or renewal license shall be $270.

*a. Late payment penalty.* Failure to renew the license before January 1 shall require payment of the renewal fee and a penalty fee of $270. Failure to renew the license before February 1 following expiration shall require payment of the renewal fee and a penalty fee of $360. Failure to renew the license before March 1 following expiration shall require payment of the renewal fee and a penalty fee of $450. Failure to renew the license before April 1 following expiration shall require payment of the renewal fee and a penalty fee of $540 and may require an appearance before the board. In no event shall the combined renewal fee and penalty fee for late renewal of a wholesale drug license exceed $810.

*b. Delinquent license.* If a license is not renewed before its expiration date, the license is delinquent and the licensee may not operate or do business in Iowa until the licensee renews the delinquent license. A drug wholesaler who continues to do business in Iowa without a current license may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.1(4).

**17.3(3)** *Inspection of new wholesale drug distribution facility.* If a new wholesale drug distribution location within Iowa was not a licensed wholesale drug distribution site immediately prior to the proposed opening of the new wholesale facility, the location shall require an on-site inspection by

a pharmacy board inspector prior to the issuance of the wholesale drug license. The purpose of the inspection is to determine compliance with requirements pertaining to space, equipment, drug storage safeguards, and security. Inspection may be scheduled anytime following submission of necessary license and registration applications and prior to beginning wholesale drug distribution. Prescription drugs, including controlled substances, may not be delivered to a new wholesale drug distribution facility prior to satisfactory completion of the opening inspection.

**17.3(4)** *Wholesale drug license changes.*

*a. Ownership change.* When ownership of a licensed drug wholesaler changes, the licensee shall submit to the board written notification including the name, address, and license number of the wholesaler and the effective date of the change. Notification shall also identify the new ownership classification and the owners, partners, or corporate officers as indicated in subrule 17.3(1). In those cases in which the wholesaler is owned by a corporation, the sale or transfer of all stock of the corporation does not constitute a change of ownership provided the corporation that owns the wholesaler continues to exist following the stock sale or transfer. A new license shall not be required for a change of ownership.

*b. Name or location change.* When a licensed drug wholesaler changes its name or location, a new wholesale drug license application with a license fee as provided in 17.3(2) shall be submitted to the board office. Upon receipt of the fee and properly completed application, the board will issue a new license certificate. The old license certificate shall be returned to the board office within ten days of the change of name or location. A change of wholesaler location within Iowa, if the new location was not a licensed drug wholesaler immediately prior to the relocation, shall require an on-site inspection of the new location as provided in subrule 17.3(3).

**17.3(5)** *Drug wholesaler closing.* A licensee discontinuing wholesale distribution of prescription drugs in or into Iowa shall submit to the board, with the current wholesale drug license certificate, written notification indicating the effective date of closing or discontinuing business in Iowa. If the drug wholesaler had been engaged in the distribution of controlled substances in Iowa, the written notification shall identify by name, address, and appropriate license numbers the facility or facilities to which controlled substances records and any final inventory of controlled substances have been transferred.

**17.3(6)** *Failure to complete licensure process.* An application for a wholesale drug license, including an application for registration pursuant to 657—Chapter 10, if applicable, will become null and void if the applicant fails to complete the licensure process within six months of receipt by the board of the required applications. The licensure process shall be complete upon the wholesaler's opening for business at the licensed location following an inspection rated as satisfactory by an agent of the board if such an inspection is required pursuant to this rule. When an applicant fails to timely complete the licensure process, fees submitted with applications will not be transferred or refunded.

[**ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 2408C**, IAB 2/17/16, effective 3/23/16]

**657—17.4(155A) Minimum qualifications.** The board will consider the following factors in determining eligibility for licensure of persons or businesses that engage in the wholesale distribution of prescription drugs:

1. Any convictions of the applicant under federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
2. Any felony convictions of the applicant under federal, state, or local laws;
3. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
5. 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;
6. Compliance with licensing requirements under previously granted licenses, if any;

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

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

**657—17.5(155A) Personnel.** Licensed wholesalers 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. The wholesaler shall employ personnel with the education or experience appropriate to the responsibilities of the position held by the individual.

**657—17.6(155A) Responsibility for conduct.** A licensed drug wholesaler shall be held responsible for actions of the wholesaler's managerial agent when the conduct of the agent may fairly be assumed to represent the policy of the wholesaler. "Managerial agent" includes, but is not necessarily limited to, an officer or director of a corporation or an association or a partner of a partnership, and includes a person having management responsibility for submissions to the FDA regarding the development or approval of any drug product; the production, quality assurance, or quality control of any drug product; or research and development of any drug product.

**17.6(1)** *Misrepresentative deeds.* A managerial agent shall not make any statement intended to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the manufacture, distribution, or marketing of prescription drugs.

**17.6(2)** *Unethical conduct or behavior.* A managerial agent shall not exhibit unethical behavior in connection with the manufacture, distribution, or marketing of prescription drugs or refuse to provide reasonable information or answer reasonable questions for the benefit of a health professional or a patient. Unethical behavior shall include, but not be limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.

**657—17.7(124,155A) Distribution to authorized licensees.** A wholesaler shall be responsible for verifying, prior to the distribution of a prescription drug, the authority of the person or business to whom the distribution is intended. Such verification may include, but is not limited to, obtaining a copy of the license under which the person or business claims authority to possess the prescription drug or contacting the appropriate licensing authority for verification of the licensee's authority to possess the prescription drug.

**657—17.8(124,155A) Written policies and procedures.** Wholesalers shall establish, maintain, and adhere to written policies and procedures 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. Wholesalers shall also include in their written policies and procedures the following:

**17.8(1)** *Oldest stock distributed first.* 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.

**17.8(2)** *Recalls and market withdrawals.* 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 agency or other government agency, including the board;

*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.

**17.8(3)** *Emergency and disaster plan.* A procedure to ensure that wholesalers 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.

**17.8(4)** *Outdated drugs.* 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.

**17.8(5)** *Exception.* The procedure required by subrule 17.8(1) does not apply to reverse distribution operations. All other procedures addressed in this rule are required of reverse distribution operations.

**17.8(6)** *Drugs supplied to salesperson/representative.* If supplying drugs to wholesale salespersons or manufacturers' representatives, a procedure directing that the security, storage, and record-keeping requirements contained in these rules shall be maintained by those wholesale salespersons or manufacturers' representatives.

**657—17.9(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 outdated, damaged, unsafe, deteriorated, misbranded, or adulterated prescription drugs; for drugs that are in immediate or sealed outer or sealed secondary containers that have been opened; for drugs that have been identified as being defective or are believed to be defective; and for drugs that do not meet the FDA-approved criteria for the product;
4. Be maintained in a clean and orderly condition;
5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

**657—17.10(124,155A) Security.**

**17.10(1)** *Secure from unauthorized entry.* 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.

**17.10(2)** *Alarm.* All facilities shall be equipped with an alarm system to deter entry after hours.

**17.10(3)** *Security system.* 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.

**17.10(4)** *Authorized collection program.* Licensees that are authorized to administer a controlled substances collection program shall provide security pursuant to 657—Chapter 10 and federal regulations.

[**ARC 2408C**, IAB 2/17/16, effective 3/23/16]

**657—17.11(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.

**17.11(1)** *Controlled room temperature.* If no storage requirements are established for a prescription drug, the drug may be held at "controlled room temperature" to help ensure that its identity, strength, quality, and purity are not adversely affected. "Controlled room temperature" means the room temperature is maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit).

**17.11(2)** *Documentation.* Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs.

**17.11(3)** *Exception.* The storage requirements of this rule do not apply to reverse distribution operations.

**657—17.12** Reserved.

**657—17.13(155A) Drugs in possession of representatives.** If a wholesaler is supplying samples or other forms of prescription drugs to wholesale salespersons or manufacturers' representatives, the wholesaler shall be responsible for ensuring that those representatives maintain distribution records and maintain the drugs under appropriate security and storage conditions pursuant to the requirements of these rules.

**657—17.14(155A) Examination of materials.**

**17.14(1)** *Receipt shipment.* 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.

**17.14(2)** *Outgoing shipment.* 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.

**17.14(3)** *Type of inspection.* Examination or inspection shall be completed in a manner to ensure the stated intent of this rule. Inspection may be completed by use of electronic surveillance or personal examination.

**17.14(4)** *Authorized collection program.* Substances, including controlled substances, collected through an authorized collection program shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.

[**ARC 2408C**, IAB 2/17/16, effective 3/23/16]

**657—17.15(155A) Returned, damaged, and outdated prescription drugs.**

**17.15(1)** *Quarantine required.* 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 the supplier.

**17.15(2)** *Seal opened.* 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.

**17.15(3)** *Drug safety, purity uncertain.* Unless examination, testing, or other investigation proves that a drug meets appropriate standards of safety, identity, strength, quality, and purity, a prescription drug that has been returned under conditions that cast doubt on the drug's safety, identity, strength, quality, or purity shall be destroyed or returned to the supplier. 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 wholesaler 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.

**17.15(4)** *Exception.* The requirements of this rule do not apply to reverse distribution operations.

**657—17.16(124,155A) Record keeping.** Wholesalers 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.

**17.16(1)** *Transaction records.* 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 to which the drugs were shipped.

**17.16(2)** *Records maintained.* Inventories and records shall be made available for inspection and photocopying by any authorized official of the board or of any governmental agency charged with enforcement of these rules for a period of two years following disposition of the drugs. The annual inventory of controlled substances shall be maintained for a minimum of two years from the date of the inventory.

**17.16(3)** *Inspection of records.* 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 available for inspection within two working days of a request by an authorized official of the board or of any governmental agency charged with enforcement of these rules.

**17.16(4)** *Confidentiality of patient information.* A wholesaler shall obtain and maintain patient-specific data only as necessary for the health and safety of the patient. Any patient-specific information in the possession of a wholesaler shall be maintained in compliance with the patient confidentiality and security requirements of rules 657—8.16(124,155A) and 657—21.2(124,155A).

**17.16(5)** *Authorized collection program.* A licensee that is authorized to administer a collection program shall maintain all records and inventories as required by 657—Chapter 10, this chapter, and federal regulations.

[**ARC 8669B**, IAB 4/7/10, effective 5/12/10; **ARC 2408C**, IAB 2/17/16, effective 3/23/16]

**657—17.17(124,155A) Compliance with federal, state, and local laws.** Wholesalers shall operate in compliance with applicable federal, state, and local laws, rules, and regulations.

**17.17(1)** *Access by authorized officials.* Wholesalers 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 wholesalers' premises and delivery vehicles.

**17.17(2)** *Controlled substance registrations.* Wholesalers 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 federal, state, and local laws, rules, and regulations.

**657—17.18(155A) Discipline.** Pursuant to 657—Chapters 35 and 36, the board may deny, suspend, or revoke a wholesale drug license for any violation of Iowa Code chapter 124, 124B, 126, 155A, or 205 or a rule of the board promulgated thereunder.

[**ARC 3857C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 124.301 through 124.303, 124.306, 155A.4, and 155A.17.

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