

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 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.