

657—17.3(155A) Wholesale distributor license. Every wholesale distributor that engages in wholesale distribution into, out of, or within this state must be licensed by the board before engaging in wholesale distribution. Where operations are conducted at more than one location by a single wholesale distributor, each such location shall be separately licensed. The applicant shall submit a completed application with a nonrefundable application fee of \$750. A wholesale distributor that engages in wholesale distribution of controlled substances into, out of, or within this state shall also obtain a controlled substances Act registration pursuant to 657—Chapter 10.

17.3(1) Application. The applicant shall complete an application which requires demographic information about the wholesale distributor, ownership information, information about the wholesale distributor's registered agent located in Iowa, information about the wholesale distributor's licensure with other state and federal regulatory authorities, criminal and disciplinary history information, information regarding the facility manager, a detailed description of the services to be provided in this state, and other necessary information as determined by the board. An application for a wholesale distributor 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, including opening for business, within six months of receipt by the board of the required application(s). The following shall also be submitted by the applicant for the application to be considered complete:

a. Criminal history record check. Upon receipt of a licensure application, the board shall provide a fingerprint packet to the applicant's facility manager, who shall submit the completed fingerprint packet and a signed waiver form to facilitate a national criminal history background check of the facility manager. The cost of the evaluation of the fingerprint packet and the Iowa division of criminal investigation and the United States Federal Bureau of Investigation criminal history background checks will be assessed to the applicant.

b. Surety bond or equivalent security. The applicant shall file with the board a \$100,000 surety bond or evidence that the wholesale distributor possesses the required bond in another state where the wholesale distribution facility does business. If a wholesale distributor's annual gross receipts from the previous tax year were \$10 million or less, the wholesale distributor need only file a \$25,000 surety bond. In lieu of a surety bond, the applicant may submit an irrevocable standby letter of credit in the amount of \$100,000 or \$25,000 as applicable. A government-owned wholesale distributor is exempt from the surety bond requirement.

c. Evidence of current drug distributor accreditation by the National Association of Boards of Pharmacy (NABP), the National Coalition for Drug Quality and Security (NCDQS), or another accreditation body approved by the board. This requirement does not apply to new applicants located in Iowa which must undergo an opening inspection by a board compliance officer or agent of the board prior to issuance of an initial license. Wholesale distributors located in Iowa shall provide evidence of drug distributor accreditation on or before license renewal.

d. Attestation by facility manager. The applicant shall submit attestation that the facility manager has been employed full-time for at least three years in a position related to prescription drug distribution; is actively involved in the daily operation of the wholesale distribution facility; maintains a functional understanding of federal and state laws, rules, and regulations pertaining to wholesale drug distribution; and has no felony convictions or convictions related to prescription drug distribution, including distribution of controlled substances.

17.3(2) License renewal. A wholesale drug license shall be renewed before January 1 of each year and may be renewed as early as November 1 prior to expiration. The wholesale distributor shall submit a completed application and nonrefundable application fee as required in this rule.

a. *Delinquent license grace period.* If a wholesale drug license has not been renewed or canceled prior to expiration, the license becomes delinquent on January 1. A wholesale distributor that submits a completed license renewal application, nonrefundable application fee, and nonrefundable late penalty fee of \$750 postmarked or delivered to the board by January 31 shall not be subject to disciplinary action for continuing to provide services in this state in the month of January.

b. *Delinquent license reactivation beyond grace period.* If a wholesale drug license has not been renewed prior to the expiration of the one-month grace period identified in paragraph 17.3(2) "a," the

wholesale distributor may not operate or do business in Iowa. A wholesale distributor that continues to do business in Iowa without a current license may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.6(22). A wholesale distributor without a current license may apply for reactivation by submitting a license application for reactivation and a nonrefundable \$2,000 reactivation fee. As part of the reactivation application, the wholesale distributor shall disclose the services, if any, that were provided in this state while the license was delinquent.

17.3(3) License changes. When a licensed wholesale distributor changes its name, ownership, facility manager, or location, a wholesale drug license application with a nonrefundable application fee as provided in subrule 17.3(1) shall be submitted to the board. A change of ownership occurs when the owner listed on the wholesale distributor's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the wholesale distributor's most recent application. A change of wholesale distributor location within Iowa, if the new location was not a licensed wholesale distributor immediately prior to the relocation, shall require an on-site inspection of the new location as provided in paragraph 17.3(1) "c."

a. Locations in Iowa. Applications for license changes shall be submitted to the board as far in advance as possible prior to the anticipated change.

b. Locations outside of Iowa. Applications for license changes shall be submitted to the board within ten days of the wholesale distributor's receipt of an updated license from the home state regulatory authority.

c. License change application submission. Applications for license changes shall be timely submitted pursuant to this subrule. A licensed wholesale distributor that has timely submitted a license change application and fee may continue to service Iowa customers while the license change is pending final approval. An applicant that has submitted an application for license changes after the required date of submission pursuant to this subrule but within 30 days of the required date of submission shall be assessed a nonrefundable late penalty fee of \$750 in addition to the license fee. An applicant that has submitted an application for license changes 31 days or later following the required date of submission pursuant to this subrule shall be assessed a nonrefundable reactivation fee of \$2,000.

d. Change in facility manager. When a wholesale distributor has a change in facility manager, a new facility manager shall be identified pursuant to this paragraph. If a permanent facility manager is not currently the facility manager of a licensed facility, the facility manager shall submit to a criminal background check.

(1) If a permanent facility manager has been identified at the time of the vacancy, a wholesale distributor license application identifying the new permanent facility manager, along with the appropriate fee, shall be submitted to the board within ten days of the vacancy.

(2) If no permanent facility manager has been identified at the time of the vacancy, a temporary facility manager shall be identified and notice of such shall be submitted in writing to the board within ten days of the vacancy. A temporary facility manager shall not be required to submit a fingerprint packet and signed waiver to facilitate a national criminal history check unless the temporary facility manager subsequently is identified as the permanent facility manager. Within 90 days of the vacancy, a permanent facility manager shall be identified and a wholesale distributor license application identifying the permanent facility manager, along with the appropriate fee, shall be submitted to the board.

17.3(4) License cancellation. A licensee intending to discontinue wholesale distribution into, out of, or within this state shall notify the board in writing of its intent as far in advance as possible of the discontinuation of services and shall request that the license be administratively canceled. Such notification shall include the name and license number of the wholesale distributor, the anticipated date of discontinuation of service, and the identification of the wholesale distributor to which drugs and records will be transferred. To the extent possible to avoid unnecessary delays in obtaining product for patients, a wholesale distributor that intends to discontinue services in this state should provide advance notice to its customers of the date that the wholesale distributor intends to cease distribution in this state.

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