657—42.3(155A) Limited distributor license. Beginning January 1, 2019, no person other than a licensed wholesale distributor, licensed pharmacy, or practitioner shall engage in any of the activities found herein in this state without a limited distributor license. Where operations are conducted at more than one location by a single distributor, each location shall be separately licensed. The applicant shall submit a completed application along with a nonrefundable fee of $175. A limited distributor that engages in distribution of controlled substances into, out of, or within this state shall also obtain a controlled substances Act registration pursuant to 657—Chapter 10.

42.3(1) *License required.* A person engaged in the following activities shall obtain a limited distributor license prior to distribution in or into Iowa:

a. Distribution of a medical gas or device at wholesale or to a patient pursuant to a prescription drug order.

b. Wholesale distribution of a prescription animal drug.

c. Wholesale distribution of a prescription drug, or brokering the distribution of a prescription drug at wholesale, by a manufacturer, a manufacturer's co-licensed partner, or a repackager.

d. Intracompany distribution of a prescription drug, including pharmacy chain distribution centers.

e. Distribution at wholesale of a combination product as defined by the United States Food and Drug Administration, medical convenience kit, intravenous fluid or electrolyte, dialysis solution, radioactive drug, or irrigation or sterile water solution to be dispensed by prescription only.

f. Distribution of a dialysis solution by the manufacturer or the manufacturer's agent to a patient pursuant to a prescription drug order, provided that a licensed pharmacy processes the prescription drug order.

42.3(2) *License optional.* A person engaged in the following activities may, but is not required to, obtain a limited distributor license for distribution in or into Iowa:

a. Distribution of nonprescription drugs or devices with or without a patient-specific prescription.

b. Distribution of medical devices exclusively to a health care practitioner for use in the normal course of professional practice ("professional use").

c. Distribution of blood and blood products that are not subject to the federal Drug Supply Chain Security Act (DSCSA).

42.3(3) *Application.* The applicant shall complete an application which requires demographic information about the limited distributor, ownership information, information about the limited distributor's registered agent located in Iowa, information about the limited distributor's licensure with other state and federal regulatory authorities, criminal and disciplinary history information, information regarding the facility manager, and a detailed description of the services to be provided in this state. An application for a limited 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. Evidence of the mandatory physical inspection of the distribution facility pursuant to subrule 42.3(7).

b. Attestation by facility manager. The applicant shall submit attestation that the facility manager has adequate experience in prescription drug and device distribution; is actively involved in the daily operation of the distribution facility; maintains a functional understanding of federal and state laws, rules, and regulations pertaining to drug and device distribution, as applicable; and has no felony convictions or convictions related to prescription drug and device distribution, including distribution of controlled substances.

42.3(4) *License renewal.* A limited distributor license shall be renewed before January 1 of each year and may be renewed as early as November 1 prior to expiration. The limited distributor shall submit a completed application and nonrefundable application fee as required in this rule.

a. Delinquent license grace period. If a limited distributor license has not been renewed or canceled prior to expiration, the license becomes delinquent on January 1. A limited distributor that submits a completed license renewal application, nonrefundable application fee, and nonrefundable

late penalty fee of $175 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 limited distributor license has not been renewed prior to the expiration date of the one-month grace period identified in paragraph 42.3(4)*"a,"* the limited distributor may not operate or do business in Iowa, unless the activities conducted are those identified in subrule 42.3(2). A limited distributor that continues to do business in Iowa without a current license as required in subrule 42.3(1) may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.6(2). A limited distributor without a current license may apply for reactivation by submitting a license application for reactivation and a nonrefundable reactivation fee of $500. As part of the reactivation application, the limited distributor shall disclose the services, if any, that were provided in this state while the license was delinquent.

42.3(5) *License changes.* If a distributor has a change of name, ownership, or location, a limited distributor license application with a nonrefundable application fee as provided in subrule 42.3(3) shall be submitted to the board. A change of ownership occurs when the owner listed on the limited distributor's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the limited distributor's most recent application. A change of limited distributor location within Iowa, if the new location was not a licensed limited distributor immediately prior to the relocation, shall require a self-inspection as provided in subrule 42.3(7). A limited distributor that has submitted a license change application may continue to service Iowa customers while its license change is pending final approval.

a. For a distributor located in Iowa, a completed application shall be submitted to the board as far in advance as possible prior to the change of name, ownership, or location.

b. For a distributor located outside of Iowa:

(1) If the home state licenses or registers the facility, a completed application shall be submitted within ten days of receipt of an updated license or registration from the home state.

(2) If the home state does not license or register the facility, a completed application shall be submitted as far in advance as possible prior to the change of name, ownership, or location.

c. When a distributor changes its name or location, the distributor shall provide advance written notice of the change to each Iowa customer and patient.

d. Applications for license changes shall be timely submitted pursuant to this subrule. A licensed limited 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 $175 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 $500.

42.3(6) *License cancellation.* If a limited distributor intends to discontinue service into, out of, or within this state, it shall:

a. Notify the board as far in advance as possible of the limited distributor's intent to discontinue services and shall request that the license be administratively canceled. The notification shall include the name, address, and Iowa license number of the pharmacy or distributor at which prescription, patient, and distribution records will be maintained.

b. Ensure that prescription and patient records are transferred to another Iowa-licensed distributor or pharmacy.

c. To the extent possible to avoid unnecessary delays in the availability of services to Iowa customers and patients, provide advance written notice to customers and patients of the date that the distributor intends to cease provision of services.

42.3(7) *Inspection of limited distributor facility.* Each limited distributor location seeking initial or renewal licensure shall, prior to issuance of a license certificate, complete and submit for evaluation a self-inspection packet provided by the board.

[**ARC 4191C**, IAB 12/19/18, effective 1/23/19]