

PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to adopt new Chapter 42, “Limited Distributor Licenses,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 147.76 and 155A.42.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 124.301 through 124.308, 126.3, 126.9 through 126.12, 126.22, 155A.3, 155A.4, 155A.13, 155A.17, 155A.21, 155A.23, and 155A.42.

Purpose and Summary

Pursuant to Iowa Code section 155A.42, the Board proposes this new chapter to establish the minimum standards for entities engaged in the distribution of prescription drugs and devices but which do not meet the definition of a wholesale distributor. The proposed rules address licensure and renewal processes; grounds for licensure denial; required policies and procedures; facility and operation requirements; records requirements; reporting of discipline or convictions; and grounds for discipline.

Fiscal Impact

This rule making has no fiscal impact to the state of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Public Comment

Any interested person may submit comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on _____, 2018. Comments should be directed to: Sue Mears, RPh, Compliance Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309; or via e-mail at sue.mears@iowa.gov.

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows: _____, 2018 at the Iowa Board of Pharmacy office, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309.

Persons who wish to make oral comments at the public hearing may be asked to state their names for the record and to confine their remarks to the subject of this proposed rule making.

Any persons who intend to attend the hearing and have special requirements, such as those related to hearing or mobility impairments, should contact the Board and advise of specific needs.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special

meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Adopt the following **new** 657—Chapter 42:

CHAPTER 42

LIMITED DISTRIBUTOR LICENSES

657—42.1(155A.42) Purpose and scope. The purpose of this chapter is to establish the minimum standard of practice for limited drug and device distribution in the state of Iowa. This chapter applies to a person involved in the distribution of drugs and devices but who does not meet the definition of a wholesale distributor under federal or state law. In addition to the rules of the board, any distribution of prescription drugs and devices shall be in compliance with all applicable federal and state laws and regulations.

657—42.2(155A.42) Definitions. In addition to the definitions found in Iowa Code section 155A.3, which are adopted for the purposes of this chapter, the following definitions shall apply:

“*Board*” means the Iowa Board of Pharmacy.

“*Distribute*” means the delivery or transfer of a prescription drug or device from one person to another.

“*Facility manager*” means the individual responsible for managing the daily operations of the limited distributor facility.

“*Limited distributor*” means a person operating or maintaining a location, regardless of the location, where prescription drugs or devices are manufactured, repackaged, distributed at

wholesale, or distributed to a patient pursuant to a prescription drug order, who is not eligible for a wholesale distributor license or a pharmacy license. Included in the definition of “limited distributor” are the activities identified in subrule 42.3(1).

657—42.3(155A.42) 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 non-prescription drugs or devices with or without a patient-specific prescription.

b. Distribution of medical devices exclusively to a health care practitioner for use in their 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 applications. 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. Facility manager. 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 cancelled 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 “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 who 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 \$500 reactivation fee. 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 who 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 10 days of receiving 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.

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 its intent to discontinue services and shall request that the license be administratively cancelled. 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 complete a self-inspection packet provided by the board and submit for evaluation prior to issuance of a license certificate.

657—42.6(155A.42) Grounds for denial. The board may deny a limited distributor license application, or refuse to renew a license, for any of the following:

1. Any criminal convictions of the applicant related to the distribution of drugs or devices;
2. Any felony convictions of the applicant;
3. Insufficient experience in the distribution of prescription drugs or devices, including a lack of knowledge regarding the requirements of applicable federal and state laws or regulations;
4. The furnishing of false or fraudulent material;
5. Suspension, revocation, or other disciplinary action taken by the licensing authority of another state for federal agency against any license or registration currently or previously held by the applicant;
6. Noncompliance with licensing requirements under previously granted licenses, if any;
7. Noncompliance with the requirements to maintain or make available to the board, its agents, or to federal, state, or local law enforcement officials those records required to be maintained;
8. Conducting transactions with a person that is not properly licensed, registered, or authorized; and
9. Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

657—42.7(155A.42) Policies and procedures. Distributors shall have policies and procedures for all aspects of the distributor's operation that, at a minimum, address the rules in this chapter

and any other applicable federal, state, and local laws, rules, and regulations. The policies shall address, at a minimum:

- a. Security of the facility and of patient information;
- b. Storage of products, including proper storage conditions and handling of outdated, recalled, and returned products;
- c. Records, including the retention period, for all required records;
- d. Security, storage and records for products in the possession of a distributor's authorized representative; and
- e. Employment of personnel with the education and experience appropriate to the responsibilities of the position held.

657—42.8 and 42.9 Reserved

657—42.10(155A.42) Requirements.

42.10(1) *Physical requirements.* A distributor's location shall:

- a. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- b. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
- c. Have a quarantine area for storage of outdated, damaged, unsafe, deteriorated, misbranded, or adulterated products and for any suspect products;

d. Be maintained in a clean and orderly condition;

e. Be free from infestation by insects, rodents, birds, or vermin of any kind.

42.10(2) Operation requirements. Distributors shall operate in compliance with all applicable federal, state, and local laws, rules, and regulations.

a. Purchasing. Distributors shall purchase products from a legitimate source that is properly licensed in the state in which it is located and that is properly licensed in the distributor's home state, if such licensure is required. Distributors shall exercise due diligence in determining the legitimacy of a product's source and maintain documentation of the distributor's verification of the legitimate source.

b. Examination of materials. Distributors shall ensure, upon receipt and prior to distribution, that a product is suitable for distribution.

c. Verification. Qualified personnel shall verify, prior to distribution, that the product matches the order for which the product is being distributed.

d. Instructions for use. Qualified personnel shall provide to the patient or the patient's caregiver adequate instructions for use when a product is distributed pursuant to a prescription order.

657—42.11 Reserved

657—42.12(155A.42) Records. Distributors shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of products, including outdated, damaged, deteriorated, misbranded, or adulterated products.

42.12(1) *Transaction records.* Records for receipt and distribution transactions for all products shall include the following information:

a. The source of the products, including the name and principal address of the seller or transferor and the address of the location from which the products were shipped;

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

c. The date of receipt or distribution of the products; and

d. The identity of the purchaser of the products, including the name and principal address of the purchaser or transferee and the address to which the products were shipped or distributed.

42.12(2) *Prescription order records.* Each prescription order that results in the distribution of a product shall be retained, in the original format received, and be available for inspection and copying by the board, its representative, or other authorized individual for at least two years from the date of last activity of the prescription order.

a. Prescription orders shall contain all the required elements identified in Iowa Code section 155A.27.

b. Prescription orders for noncontrolled prescription drugs shall be valid for no longer than 18 months following the date issued or 13 fills, whichever is less.

c. A one month supply of a medical gas, such as oxygen, shall be considered to be a single refill. Such prescription must be reissued at least every 13 months.

d. Prescription orders for controlled substances shall be valid for no longer than six months following the date issued or six fills, whichever is less.

42.12(3) *Records maintained.* All records generated pursuant to the distributor's policies and procedures, this chapter, and all federal, state, and local rules, laws and regulations shall be maintained, readily retrievable, and available for inspection and copying by the board, its representative, or other authorized individual for at least two years from the date of the record.

42.12(4) *Confidentiality of patient information.* Any patient information in the possession of a distributor shall be maintained in compliance with the patient confidentiality and security requirements of 657—Chapter 8, 657—Chapter 21, and federal law.

657—42.13 Reserved

657—42.14(155A.42) Reporting discipline and criminal convictions. No later than 30 days after the final action, a limited distributor shall provide to the board written notice, including an unredacted copy of the action or order, of any disciplinary or enforcement action imposed by any licensing or regulatory authority on any license or registration held by the distributor. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. No later than 30 days after the conviction, a limited distributor shall provide to the board written notice, including an unredacted copy of the judgment of conviction or sentence, of any criminal conviction of the distributor, any owner of the distributor, or any individual responsible for managing the daily operations of the distribution facility, if the conviction is related to prescription drug or device distribution. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

657—42.15(155A.42) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a limited distributor license for any of the following:

1. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulation promulgated under the Act. A warning letter issued by the United States food and drug administration shall be conclusive evidence of a violation.
2. Any conviction of a crime related to the distribution of prescription drugs or devices committed by the distributor, its owners, or the facility manager.
3. Refusing access to the distribution facility or records to an agent of the board for the purpose of conducting an inspection or investigation.
4. Failure to maintain registration pursuant to 657—Chapter 10 when distributing controlled substances into, out of, or within this state.
5. Any act of unethical or unprofessional conduct by an employee of the distributor.
6. Any violation of Iowa Code chapters 124, 126, 155A, 205, or rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

These rules are intended to implement Iowa Code sections 124.301 through 124.308, 126.3, 126.9 through 126.12, 126.22, 155A.3, 155A.4, 155A.13, 155A.17, 155A.21, 155A.23, and 155A.42.