PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to adopt new Chapter 43, "Third-Party Logistics Provider 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.17A, as created by Senate File 2298 during the 2018 session of the 87th General Assembly.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code Sections 124.301 through 124.308, 124B, 126.3, 126.9 through 126.12, 155A.3, 155A.4, 155A.17A, 155A.40, and the federal Drug Supply Chain Security Act.

Purpose and Summary

Pursuant to Iowa Code section 155A.17A, the Board proposes this new chapter to establish the minimum standards for entities engaged in third-party logistics of prescription drugs and devices as established in the Drug Supply Chain Security Act (DSCSA), enacted by Congress in November 2013. The proposed rules address licensure and renewal processes, required policies and procedures, required reporting of discipline and convictions, and grounds for disciplinary action.

Fiscal Impact

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

Jobs Impact

After analysis and review of this rule making, impact on jobs cannot be determined.

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 to 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 43:

Chapter 43

Third-Party Logistics Provider Licenses

657—43.1(155A.17A) Purpose and scope. The purpose of this chapter is to establish the minimum standards required of third-party logistics providers as defined in Iowa Code section 155A.3 in this state pursuant to national standards as established by federal law. This chapter of rules applies to logistics providers operating in or into this state. A 3PL does not include an entity that solely engages in shipping activities. Applicable activities of a 3PL include, but are not limited to, picking, packing, and shipping; inventory management; and warehousing or distribution management. In the event the requirements of this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter.

657—43.2(155A.17A) Definitions. For the purposes of this chapter, the definitions found in Iowa Code section 155A.3 and the following definitions apply.

"*Board"* means the Iowa board of pharmacy.

"*Facility manager*" means the individual who is responsible for the daily operation of a third-party logistics licensed location.

"FDA" means the United States Food and Drug Administration.

"*Home state*" means the state in which a third-party logistics provider is located.

"*Third-party logistics provider"* or "*3PL"* means an entity that provides or coordinates warehousing or other logistics services of a product on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product nor have responsibility to direct the sale or other disposition of the product.

657—43.3(155A.17A) 3PL license. Beginning April 1, 2019, every 3PL as defined in rule 657—43.2(155A.17A), wherever located, that provides or coordinates warehousing or other logistics services of products 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 such logistics operations. Where activities are conducted at more than one location by a single 3PL, each location shall be separately licensed. The applicant shall submit a completed application with a nonrefundable application fee of $750. A 3PL that handles controlled substances shall also obtain a controlled substances act registration pursuant to 657—Chapter 10.

43.3(1) *Application.* The applicant shall complete an application which requires demographic information about the 3PL, ownership information, information about the 3PL's registered agent located in Iowa, information about the 3PL's licensure or registration with other state and federal regulatory authorities, criminal and disciplinary history information, and a description of the scope of services to be provided in Iowa. If the applicant is not located in Iowa, the applicant shall submit evidence that the applicant has a valid license or registration in the home state or evidence of licensure with the federal Food and Drug Administration. An application for a 3PL 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.

43.3(2) *Facility manager.* The applicant shall attest that the facility manager has adequate experience in providing or coordinating warehousing or other logistics services of products; is actively involved in the daily operation of the facility; maintains a functional understanding of federal and state laws, rules, and regulations pertaining to drug and device distribution; and has no felony conviction or convictions related to prescription drug or device distribution, including distribution of controlled substances. 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.

43.3(3) *Inspection of new 3PL facility.* Each new 3PL location seeking licensure shall be inspected prior to issuance of a license.

a. Iowa location. If the applicant is located within Iowa, an inspection shall be conducted by the board or its authorized agent prior to the issuance of the license and periodically thereafter.

b. Nonresident location. If the applicant is located outside of Iowa, an inspection shall be conducted by the applicant's home state regulatory authority or another board-approved inspecting authority and a report of such inspection shall be submitted with the application. The application shall also include evidence of corrective action taken to satisfy any deficiencies

identified in the inspection report and compliance with all legal directives of the inspecting authority, if applicable. With each license renewal and license reactivation for a 3PL outside of Iowa, the application shall include a copy of the most recent inspection report issued as a result of an inspection conducted by the home state regulatory authority or other board-approved inspecting authority.

43.3(4) *License renewal*. The 3PL license shall be renewed by April 1 each year. The 3PL shall submit the completed license application and nonrefundable fee of $750. A 3PL may renew its license beginning February 1 prior to license renewal. An initial 3PL license issued between February 1 and March 31 shall not require renewal until the following calendar year.

a. *Delinquent license grace period*. If a 3PL license has not been renewed or cancelled prior to expiration, but the 3PL is in the process of renewing the license, the license becomes delinquent on April 1. A 3PL that submits a completed license renewal application, nonrefundable application fee, and nonrefundable late penalty fee of $750 postmarked or delivered to the board by April 30 shall not be subject to disciplinary action for continuing to provide services to Iowa customers in the month of April.

b. *Delinquent license reactivation beyond grace period*. If a 3PL license has not been renewed prior to the expiration of the one month grace period identified in paragraph "*a*", the 3PL may not continue to provide services to Iowa customers. A 3PL that continues to provide services to Iowa customers without a current license may be subject to disciplinary sanctions. A 3PL 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 3PL shall disclose the services, if any, that were provided to Iowa customers while the license was delinquent.

43.3(5) *License changes.* When a licensed 3PL changes its name, ownership, location, or facility manager, a completed 3PL license application with nonrefundable fee of $750 shall be submitted to the board. A change of ownership occurs when the owner listed on the 3PL's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the 3PL's most recent application. A change of 3PL location within Iowa, if the new location was not a license 3PL immediately prior to the relocation, shall require an on-site inspection of the new location as provided in 43.3(3). A 3PL who has submitted a license change application may continue to service Iowa customers while its license change is pending final approval.

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

b. Locations outside of Iowa. An application for license change shall be submitted to the board within 10 days of the 3PL receiving an updated license or registration from the home state regulatory authority or the FDA, as applicable.

43.3(6) *License cancellation*. If a 3PL intends to discontinue service into, out of, or within this state, the licensee shall notify the board and shall request the license be administratively cancelled.

657—43.4 Reserved

657—43.5(155A.17A) Compliance with federal and state laws. A 3PL is responsible for complying with all applicable federal and state laws, including those not specifically identified in this chapter.

1. A licensed 3PL shall meet the requirements set forth in section 582 of the Drug Supply Chain Security Act, 21 U.S.C. § 360eee-3 relating to third-party logistics and regulations promulgated thereunder.

2. A licensed 3PL shall permit agents of the board to enter and inspect the facility for compliance with federal and state laws. A licensed 3PL shall cooperate with other regulatory or law enforcement officials with jurisdiction over the facility.

657—43.6(155A.17A) Policies and procedures. A licensed 3PL shall establish, maintain, and adhere to written policies and procedures that are in compliance with standards established pursuant to federal and Iowa law and which address, at a minimum, the following:

a. Storage practices;

b. Maintaining adequate security;

c. Receipt, inventory, shipment, and distribution of product;

d. Theft or loss;

e. Inventory errors and inaccuracies;

f. Manufacturer recalls and withdrawals;

g. Emergency and disaster plan;

h. Records, including the retention period, for all required records;

i. Drug diversion detection and prevention; and

j. Outdated, adulterated, or suspect products.

657—43.7 and **43.8** Reserved

657—43.9(155A.17A) Reporting discipline and criminal conviction. No later than 30 days after the final action, a 3PL shall provide to the board written notice, including an unredacted copy of the action or order, of any disciplinary sanction imposed on any license or registration held by the 3PL or its owner or owners. 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 3PL shall provide to the board written notice, including an unredacted copy of the judgment of conviction or sentence, of any criminal convictions related to product distribution, including convictions of any of its owners, or its facility manager. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

657—43.10(155A.17A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a 3PL license for any of the following:

1. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulation promulgated under the Act related to third-party logistics and drug or device distribution.

2. Any conviction of a crime related to the distribution of prescription drugs or devices committed by the 3PL, its owners, or facility manager.

3. Refusing access by an agent of the board or other authorized regulatory authority to the 3PL facility or records 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 3PL.

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, 124B, 126.3, 126.9 through 126.12, 155A.3, 155A.4, 155A.17A, 155A.40, and the federal Drug Supply Chain Security Act.