

CHAPTER 43
THIRD-PARTY LOGISTICS PROVIDER LICENSES

Chapter rescission date pursuant to Iowa Code section 17A.7: 1/1/28

657—43.1(155A) 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 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.

[ARC 4192C, IAB 12/19/18, effective 1/23/19]

657—43.2(155A) 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 in interstate commerce 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.

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657—43.3(155A) 3PL license. Beginning April 1, 2019, every 3PL as defined in rule 657—43.2(155A), 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 provide evidence that the home state does not require licensure. The applicant shall provide 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 pursuant to subrule 43.3(3). 3PL distributors located in Iowa shall provide evidence of drug distributor accreditation on or before license renewal. 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 application(s).

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 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 application 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 canceled 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 43.3(4) "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 reactivation fee of \$2,000. 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 licensed 3PL immediately prior to the relocation, shall require an on-site inspection of the new location as provided in subrule 43.3(3). A 3PL that 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 ten days of the 3PL's receipt of an updated license or registration from the home state regulatory authority or the FDA, as applicable.

c. License change application submission. Applications for license changes shall be timely submitted pursuant to this subrule. A licensed 3PL 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 3PL 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 3PL 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 3PL license application identifying the permanent facility manager, along with the appropriate fee, shall be submitted to the board.

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 that the license be administratively canceled.

[ARC 4192C, IAB 12/19/18, effective 1/23/19; ARC 5008C, IAB 3/25/20, effective 4/29/20; ARC 5351C, IAB 12/30/20, effective 2/3/21]

657—43.4 Reserved.

657—43.5(155A) 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 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.

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657—43.6(155A) 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:

1. Storage practices;
2. Maintaining adequate security;
3. Receipt, inventory, shipment, and distribution of product;
4. Theft or loss;
5. Inventory errors and inaccuracies;
6. Manufacturer recalls and withdrawals;
7. Emergency and disaster plan;
8. Records, including the retention period for all required records;
9. Drug diversion detection and prevention; and
10. Outdated, adulterated, or suspect products.

[ARC 4192C, IAB 12/19/18, effective 1/23/19]

657—43.7 and 43.8 Reserved.

657—43.9(155A) 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 the sentence is deferred.

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657—43.10(155A) 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 the facility manager.
3. Refusing access to the 3PL facility or records to an agent of the board or other authorized regulatory authority 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 chapter 124, 126, 155A, or 205, or rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

[ARC 4192C, IAB 12/19/18, effective 1/23/19]

These rules are intended to implement Iowa Code chapter 124B and sections 124.301 through 124.308, 126.3, 126.9 through 126.12, 155A.3, 155A.4, 155A.17A, and 155A.40 and the federal Drug Supply Chain Security Act.

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