ARC 4190C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to wholesale distributor licenses

The Board Pharmacy hereby rescinds Chapter 17, "Wholesale Drug Licenses," and adopts new Chapter 17, "Wholesale Distributor Licenses," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 147.76 and 155A.17.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 124.301 to 124.308, 126.3, 126.9 to 126.12, 155A.3, 155A.4, 155A.17, 155A.19, 155A.21, 155A.23 and 155A.40 and the Drug Supply Chain Security Act (DSCSA).

Purpose and Summary

In November 2013, Congress enacted the Drug Quality and Security Act, which included the Drug Supply Chain Security Act. DSCSA sets national minimum standards for entities engaged in the wholesale distribution of drugs in the United States. DSCSA also prohibits any state from enacting any law or rule more or less strict than DSCSA. The revised chapter establishes the minimum standards for wholesale distributor licenses and addresses the following topics: licensure and renewal processes; grounds for denial of licensure; required policies and procedures; requirements of facilities, security, and storage; reporting of discipline and convictions; and grounds for discipline.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on August 29, 2018, as **ARC 3974C**. A public hearing was held on September 25, 2018, at 9 a.m. in the Shared Conference Room, Suite E, 400 SW 8th Street, Des Moines, Iowa. Representatives from the National Association of Boards of Pharmacy (NABP) attended the hearing and provided a verbal review of NABP's written comments.

The Board received a number of comments on this rule making. Five comments were received in opposition to the requirement that a wholesale distributor be verified-accredited wholesale distributors (VAWD)-accredited. The reasons for the opposition included concern about the expense of attaining VAWD accreditation and the belief that the requirement was inconsistent with federal law. The Board considered these comments and declined the requests to remove the requirement. Of the wholesale distributors which are currently licensed in Iowa, over 360 currently hold VAWD accreditation, with an additional 35 in the process of obtaining accreditation. Fewer than 60 current Iowa-licensed wholesale distributors are not VAWD-accredited. Iowa would join three other states which also require this accreditation as a condition for licensure. Further, the Board agrees with the comments which state that the federal law is intended to establish national minimum standards for wholesale distributors, but disagrees with the assertion that the federal law on its own has established those standards. DSCSA directs the FDA to publish regulations to implement the federal law and establish licensing standards. Those regulations were to have been published by November 1, 2015. To date, regulations have not been published. Further, the process of publication and public comment, not unlike Iowa's rule making process, will take many months. The regulations then will not be effective until two years after the date of final publication in the Federal Register. Therefore, the minimum standards could be at least another three years away. Until those regulations are known, Iowa must ensure the legitimacy of the drug supply chain for products entering this state, and the Board believes such accreditation will provide

that assurance. The Board fully recognizes that, if the final FDA regulations do not allow or require such accreditation, the Board's rule would be superseded as of the enforcement date of the federal regulations. Indeed, upon final publication, the Board will have two years to amend its rules to conform to the regulations.

Comments received also suggested revisions to the proposed rules relating to storage, records, purpose and scope, license application, license renewal, license denial, policies and procedures, and disciplinary action. The suggested addition of a new rule identifying all record-keeping requirements was declined by the Board due to rule 657—17.7(124,155A), which requires compliance with all federal laws and regulations, including all record-keeping requirements. The proposed revision to the purpose and scope relating to the federal preemption was declined by the Board, as the language proposed is sufficient. Requested changes to the background check, surety bond, and grace period subrules in licensure application and renewal; license denial subrules; and disciplinary action subrules were declined by the Board.

The suggested revision of the storage rule to provide more clarity was accepted by the Board. The request for additional clarification on what "adequate experience" means was accepted by the Board, and the subrule was revised to identify adequate experience to mean at least three years working in the business of prescription drug distribution. The request for the removal of the policy and procedures relating to drug stock distribution was accepted; the requirement was removed. The request for the removal of the provision stating that an FDA warning letter would be considered conclusive evidence of a violation was accepted by the Board, and the provision was removed.

As described above, some rules were revised based on comments received. In addition, references to 2018 Iowa Acts, Senate File 2298, have been removed since the amendments in the Senate File have been codified in the 2019 Iowa Code.

Adoption of Rule Making

This rule making was adopted by the Board on November 14, 2018.

Fiscal Impact

With the changes to the licensure of wholesale distributors and creation of the new licensure categories of limited distributors and third-party logistics providers (each in separate rule makings), several hundred licensees will no longer hold a wholesale distributor license but rather an LD or 3PL license. As such, the Board's expected revenue from licensure of wholesale distributors will be reduced by approximately $220,500 and expected expenditures for office staff will be increased by approximately $9,150, resulting in an overall decrease in Board funds by approximately $229,650 annually. Simultaneously, the Board will expect an increase in expected revenue from licensure in LD and 3PL categories with a similar increase in expected expenditures for office staff.

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.

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).

Effective Date

This rule making will become effective on January 23, 2019.

The following rule-making action is adopted:

Rescind 657—Chapter 17 and adopt the following **new** chapter in lieu thereof:

CHAPTER 17
WHOLESALE DISTRIBUTOR LICENSES

657—17.1(155A) Purpose and scope. This chapter establishes the licensing requirements and standards applicable to a wholesale distributor of human prescription drugs as defined by Iowa Code section 155A.3(49) and the Drug Supply Chain Security Act. In the event the requirements in this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter.

657—17.2(155A) 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:

"Drug Supply Chain Security Act" or *"DSCSA"* means the law enacted by Congress in November 2013 which establishes the minimum standards for ensuring a legitimate drug supply chain.

"Facility manager" means the individual responsible for managing the daily operations of the wholesale distribution facility.

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

"Returns processor" means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from a purchaser, manufacturer, or seller who purchased or received such product at wholesale, such that the product may be processed for credit to the purchaser, manufacturer, or seller, or disposed of for no further distribution.

"Wholesale distribution" means the distribution of a drug to a person other than a consumer or patient, or the receipt of a drug by a person other than a consumer or patient, but does not include transactions identified in Iowa Code section 155A.3(48) and DSCSA.

"Wholesale distributor" means a person, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager, engaged in the wholesale distribution of a prescription drug.

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 verified-accredited wholesale distributors (VAWD) accreditation by the National Association of Boards of Pharmacy. 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 VAWD 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.

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.

657—17.4(155A) Grounds for denial. The board may deny a wholesale distributor license application, or refuse to renew a wholesale distributor license, for any of the following:

1. Any criminal convictions of the applicant or facility manager related to wholesale distribution;
2. Any felony convictions of the applicant;
3. Insufficient experience in the wholesale distribution business, 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 or 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 by wholesale distributors;
8. Conducting transactions with a person that is not properly licensed or registered; and
9. Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

657—17.5 and **17.6** Reserved.

657—17.7(124,155A) Compliance with federal and state laws. A wholesale distributor is responsible for complying with all applicable federal and state laws, including those not specifically identified in this chapter.

17.7(1) A licensed wholesale distributor shall meet the requirements set forth in the Drug Supply Chain Security Act, including but not limited to:

a. 21 U.S.C. §360eee-1, relating to product tracing, product identifiers, authorized trading partners, suspect products, and illegitimate products;

b. 21 U.S.C. §360eee-2, relating to national standards for drug wholesale distributors; and

c. Any regulations promulgated thereunder.

17.7(2) A licensed wholesale distributor shall permit agents of the board to enter and inspect the facility for compliance with federal and state laws. A licensed wholesale distributor shall cooperate with other regulatory or law enforcement officials with jurisdiction over the facility.

657—17.8(124,155A) Written policies and procedures. Wholesale distributors shall establish, maintain, and adhere to written policies and procedures that are in compliance with federal law for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale distributors shall also include in their written policies and procedures the following:

17.8(1) *Recalls and market withdrawals.* A procedure to be followed for handling recalls and withdrawals of prescription drugs.

a. The procedure shall be adequate to deal with recalls and withdrawals due to:

(1) Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement agency or other government agency, including the board;

(2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

b. The requirement of this subrule shall not apply to a returns processor.

17.8(2) *Emergency and disaster plan.* A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

17.8(3) *Outdated drugs.* A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. The requirement of this subrule shall not apply to a returns processor.

17.8(4) *Security and storage.* A procedure to ensure adequate security in accordance with rule 657—17.10(124,155A) and proper storage conditions in accordance with rule 657—17.11(155A). The requirement for proper storage conditions shall not apply to a returns processor.

17.8(5) *Drugs supplied to salesperson/representative.* If supplying drugs to wholesale distributor salespersons, a procedure directing that the security, storage, and record-keeping requirements contained in these rules shall be maintained by those salespersons.

17.8(6) *Personnel.* A procedure to ensure the wholesale distributor employs personnel with the education and experience appropriate to the responsibilities of the position held by the individual. Licensed wholesale distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

657—17.9(155A) Facilities. All wholesale distribution facilities shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
3. Except for returns processors, have a quarantine area for storage of outdated, damaged, unsafe, deteriorated, misbranded, or adulterated prescription drugs; for drugs that are in immediate or sealed outer or sealed secondary containers that have been opened; for drugs that have been identified as being defective or are believed to be defective; and for drugs that do not meet the FDA-approved criteria for the product;
4. Be maintained in a clean and orderly condition;
5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

657—17.10(124,155A) Security.

17.10(1) *Secure from unauthorized entry.* All wholesale distribution facilities shall be secure from unauthorized entry.

a. Access from outside the premises shall be kept to a minimum and be well controlled.

b. The outside perimeter of the premises shall be well lighted.

c. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

17.10(2) *Alarm.* All wholesale distribution facilities shall be equipped with an alarm system to deter entry after hours.

17.10(3) *Security system.* All wholesale distribution facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

657—17.11(155A) Storage and handling. All prescription drugs shall be stored and shipped at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with requirements in the current edition of the United States Pharmacopeia. Manual, electromechanical, or electronic temperature and humidity monitoring and recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs to prevent and detect excursions. Shipment of prescription drugs requiring refrigeration shall maintain temperature requirements in accordance with the manufacturer requirements or as described in the current edition of the United States Pharmacopeia. All excursions shall be evaluated to determine any adverse impact on the integrity of the drug. The requirements of this rule do not apply to nonsaleable returns handled by returns processors.

657—17.12 to **17.16** Reserved.

657—17.17(155A) Reporting discipline and criminal convictions. No later than 30 days after the final action, a wholesale 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 wholesale 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 conviction, a wholesale 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 wholesale distributor, any owner of the wholesale distributor, or facility manager, if the conviction is related to prescription drug distribution. The term "criminal conviction" includes instances when the judgment of conviction or sentence is deferred.

657—17.18(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a wholesale 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.
2. Any conviction of a crime related to the distribution of prescription drugs committed by the wholesale distributor, its owners, or the facility manager.
3. Refusing access to the wholesale 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 wholesale distributor.
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.

These rules are intended to implement Iowa Code sections 124.301 through 124.308, 126.3, 126.9 through 126.12, 155A.3, 155A.4, 155A.17, 155A.19, 155A.21, 155A.23, and 155A.40 and the federal Drug Supply Chain Security Act.

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