

PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby amends Chapter 17, “Wholesale Distributor Licenses,” Chapter 42, “Limited Distributor Licenses,” and Chapter 43, “Third-Party Logistics Provider Licenses,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 147.76, 155A.17, 155A.17A, 155A.40 and 155A.42.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 147.76, 155A.17, 155A.17A, 155A.40 and 155A.42.

Purpose and Summary

The amendments provide the process by which a limited distributor, wholesale distributor, or third-party logistics provider (3PL) would notify the board of a change in facility manager, and by which the license of the wholesale distributor or 3PL would be modified to reflect a change in facility manager. The amendments also correct references to the Iowa Code.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on October 29, 2019, as **ARC 4691C**. The board received one comment from the Healthcare Distribution Alliance (HDA). The commenter suggested the board extend the notification period from 10 days to 30 days to provide consistency with requirements in other states, requested clarification on the need for a background check for a temporary facility manager, and requested the board modify its definition of “facility manager.” The board declined to modify the 10 day notification requirement or the definition of facility manager, but did agree that clarification language would be beneficial to make clear that a background check is not required to be completed for a temporary facility manager. As such, the board made a change to 17.3(3)”d”(2) in item 3 (relating to wholesale distributors) and to 43.3(5)”d”(2) in item 5 (relating to 3PLs) to reflect this clarification.

Adoption of Rule Making

This rule making was adopted by the Board on _____, 2020.

Fiscal Impact

This rule making has unknown fiscal impact to the state of Iowa. The Board cannot determine the number, if any, wholesale distributor or 3PL licensees that will undergo a change in facility manager which necessitates a change to the facility license.

Jobs Impact

After analysis and review of this rule making, no impact on jobs can 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.

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 _____, 2020.

The following rule-making action is adopted:

ITEM 1. Amend rule 657—17.1(155A) as follows:

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)~~ 155A.3 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.

ITEM 2. Amend rule **657—17.2(155A)**, definition of “Wholesale distribution,” as follows:

“*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)~~ 155A.3 and DSCSA.

ITEM 3. Adopt the following **new** paragraph **17.3(3)“d”**:

d. Change in facility manager. When a wholesale distributor 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 wholesale distributor 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 wholesale distributor license application identifying the permanent facility manager, along with the appropriate fee, shall be submitted to the board.

ITEM 4. Adopt the following **new** subrule 42.3(8):

42.3(8) *Change in facility manager.* If a distributor has a change in facility manager, the licensee shall provide notice to the board on forms provided by the board within ten days of the change.

ITEM 5. Adopt the following **new** paragraph **43.3(5)“d”**:

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.