

PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend 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 proposed 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 proposed 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 to modify the license of the wholesale distributor or 3PL to reflect a change in facility manager. The proposed amendments also correct references to the Iowa Code.

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 _____, 2019. Comments should be directed to:

Sue Mears

Board of Pharmacy

400 S.W. 8th Street, Suite E

Des Moines, Iowa 50309

Email: sue.mears@iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)“b,” an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

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:

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 ~~455A.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 ~~455A.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 facility manager, along with the appropriate fee, shall be submitted to the board within ten days of the change.

(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. 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 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 of facility manager, the licensee shall provide notice to the board on forms provided by the board within 10 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 facility manager, along with the appropriate fee, shall be submitted to the board within ten days of the change.

(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. 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 appropriate fee, shall be submitted to the board.