

PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby amends Chapter 8, “Universal Practice Standards,” and Chapter 19, “Nonresident Pharmacy Practice,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 155A.13 and 155A.13A.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 155A.13 and 155A.13A and 2022 Iowa Acts, House File 2169.

Purpose and Summary

The amendments are, in part, in response to an overall five-year review of Chapter 19 as required in Iowa Code section 17A.7(2). The amendments provide for conforming edits, the modification of the handling of ownership changes for resident and nonresident pharmacies, a requirement that nonresident pharmacies that directly dispense to Iowa patients provide evidence of a toll-free telephone number with access to a pharmacist who has access to the patient’s records during the pharmacy’s regular business hours, and the process by which a pharmacy can temporarily relocate pharmacy operations in response to an exceptional circumstance or disaster rendering the pharmacy unsafe.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on April 7, 2022, as **ARC 6281C**.

A public hearing was held on April 27, 2022, at 10:30am at the office of the Iowa Board of Pharmacy and via Zoom. Five individuals attended the hearing. Between written and oral comments, the board received two comments. One comment requested clarification as to the board’s intention of calendar or business days in Item 4. The other comment recommended the board retain the original language relating to “majority ownership” in a change of ownership to ensure transparency for the public.

Throughout the board’s rules, requirements in terms of “days” have historically meant calendar days, with very few instances (only five out of approximately 200 instances) specifying “business” or “calendar.” As it relates to “majority ownership” of pharmacies, the Board notes that the amendment seeks

to align with the process used by the federal Drug Enforcement Administration in handling ownership changes and to alleviate the burden on pharmacies resulting from a license change (renegotiating contracts with third-party payers, suppliers, 340B program, etc.). No changes to the amendments were made as a result of the comments.

Adoption of Rule Making

This rule making was adopted by the Board on _____, 2022.

Fiscal Impact

This rule making has minimal fiscal impact to the state of Iowa. As a result of the removal of the language that states a change to the majority ownership of a pharmacy constitutes an ownership change, the Board anticipates processing approximately 20 fewer applications annually, resulting in a reduction in licensing fees of approximately \$2,700.

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 _____, 2022.

The following rule-making actions are adopted:

ITEM 1. Amend paragraphs **8.35(6)“b”** and **“c”** as follows:

b. Location. Except as provided in subrule 8.35(10) for a temporary relocation due to an exceptional circumstance, a change of pharmacy location shall require submission of a pharmacy license application and appropriate fee prior to the change of location. A pharmacy undergoing a change in location is required to notify patients of the change in accordance with paragraph 8.35(7)“d.” A change of pharmacy location

in Iowa may require an on-site inspection of the new location as provided in subrule 8.35(4).

c. Ownership. A change in ownership of a pharmacy shall require submission of a pharmacy license application and appropriate fee prior to the change in ownership. A change of ownership occurs when the owner listed on the pharmacy's most recent application changes ~~or when there is a change affecting the majority ownership interest of the owner listed on the pharmacy's most recent pharmacy application.~~ A pharmacy undergoing a change in ownership is required to notify the pharmacist in charge and patients of the change in accordance with subrule 8.35(7). A change of ownership effectively consists of closing a pharmacy and opening a new pharmacy.

ITEM 2. Adopt the following new subrule 8.35(10):

8.35(10) Emergency temporary location changes. In response to a proclamation of disaster emergency or in the event of a natural or man-made disaster, fire, or other occurrence which results in sufficient damage to a pharmacy location as to render it unsafe to operate, a pharmacy may relocate to a temporary or mobile location only as provided herein.

a. Within one business day of the damage to the pharmacy rendering it unsafe, the pharmacy shall provide notice to the board of its intent to temporarily relocate pharmacy operations and provide the address of the temporary or mobile location.

b. A board compliance officer shall conduct an on-site inspection of the temporary or mobile location within five business days of the relocation.

c. A pharmacy may operate from the temporary or mobile location for no more than six months. If the pharmacy is not able to return to the original location within six months, the pharmacy shall submit an application and fee pursuant to paragraph 8.35(6) "b" prior to the expiration of the six-month temporary relocation period.

d. A pharmacy shall notify the board of its intent to return pharmacy operations to the original location at least five business days in advance of its return.

e. A board compliance officer shall conduct an on-site inspection of the original location prior to the return of pharmacy operations.

ITEM 3. Amend rule ~~657—19.1(155A)~~, definition of "Nonresident pharmacy," as follows:

"*Nonresident pharmacy*" means a pharmacy ~~, including an Internet-based pharmacy,~~ located outside the state of Iowa that delivers, dispenses, or distributes, by any method, prescription drugs, devices, or pharmacy services to or intended for an ultimate user physically located in this state, including a pharmacy which engages in central fill or central processing functions as described in 657—Chapter 18 on behalf of a pharmacy located in Iowa.

ITEM 4. Adopt the following new paragraph **19.2(4)"d"**:

d. Ownership. A change of ownership of a pharmacy shall require submission of a pharmacy license application and fee within ten days after issuance by the home state regulatory authority of a license under the new ownership or within ten days of the change if the home state does not require issuance of a new license for a change of ownership. A change of ownership occurs when the owner listed on the pharmacy's most recent application changes. A pharmacy undergoing a change in ownership is required to notify the pharmacist in charge and patients of the change in accordance with subrule 8.35(7). A change of ownership effectively consists of closing a pharmacy and opening a new pharmacy.

ITEM 5. Adopt the following **new** subrule 19.2(6):

19.2(6) Access to pharmacist via toll-free telephone number. Each nonresident pharmacy that dispenses or proposes to dispense any prescription drug or device directly to a patient located in Iowa shall provide on its application for nonresident pharmacy licensure evidence of labeling which provides a toll-free telephone number for patients to access a pharmacist who has access to the patient's medication record during the pharmacy's regular business hours.

ITEM 6. Amend rule 657—19.3(155A), introductory paragraph, as follows:

657—19.3(155A) Registered pharmacist in charge. The permanent pharmacist in charge of the nonresident pharmacy shall be designated as such on the nonresident pharmacy license application. ~~Beginning January 1, 2018~~ Unless currently licensed in Iowa, the pharmacist in charge shall be registered with the board. The pharmacist in charge shall submit a completed application and a registration fee of \$75. The registration shall expire on December 31 following the date of issuance of the registration. An initial registration issued between November 1 and December 31 shall not require renewal until the following calendar year.