PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend Chapter 8, "Universal Practice Standards," and Chapter 13, "Telepharmacy Practice," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 147.76, 147.80, and 155A.13.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 147.80, 155A.13, and 155A.26.

Purpose and Summary

These proposed amendments provide more clear language relating to the distance requirement between a proposed telepharmacy site and a currently licensed pharmacy that provides prescription drugs to outpatients, consistent with language found in Iowa Code, which pharmacy may be another licensed telepharmacy; require a pharmacy which intends to change license type to submit an application and may be subject to an inspection by a board compliance officer prior to issuance of the new license; implement a late penalty fee for late submission of license change application; and authorize the board to collect a fee for a written verification of a pharmacy license.

Fiscal Impact

This rule making is not anticipated to have a 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 _____, 2018. Comments should be directed to:

Sue Mears

Iowa Board of Pharmacy

400 S.W. 8th Street, Suite E

Des Moines, Iowa 50309

E-mail: 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 subrule 8.35(4) as follows:

8.35(4) *Inspection of ~~new~~ pharmacy location.*

a. A new pharmacy location in Iowa shall require an on-site inspection by an authorized agent of the board. Application for a pharmacy license and other required registrations shall be submitted to the board at least 14 days prior to the anticipated inspection. Any deficiencies identified during the inspection shall be corrected and verified by an authorized agent of the board prior to the issuance of the pharmacy license. Prescription drugs, including controlled substances, may not be delivered to a new pharmacy location prior to the delivery of the pharmacy license and registration certificates.

b. A pharmacy location in Iowa which is applying for a different license type than previously held may be subject to an inspection prior to the issuance of the new license.

ITEM 2. Amend subrule 8.35(6) as follows:

8.35(6) *Pharmacy license changes.* When a pharmacy changes its name, location, ownership, ~~or~~ pharmacist in charge, or license type, a completed pharmacy license application with a nonrefundable $135 fee shall be submitted to the board pursuant to subrule 8.35(2). Upon receipt of the completed application and fee, the board shall issue an updated pharmacy license certificate, pending any necessary inspection pursuant to subrule 8.35(4), paragraph "*b*", unless the board identifies any ground for denial of the license. Any restrictions or disciplinary history associated with the previous pharmacy shall remain unchanged. A pharmacy wishing to disassociate itself from the previously licensed pharmacy restrictions or disciplinary history may

petition the board for such disassociation. The burden is on the pharmacy to demonstrate that the current pharmacy is not associated with or responsible for the pharmacy as it previously existed. The old license certificate shall be returned to the board within ten days of receiving the updated license certificate.

a. through *d.* No change.

e. License type. A change in pharmacy license type shall require submission of a pharmacy license application and appropriate fee prior to the change. A pharmacy changing licensure type shall notify the pharmacist in charge and patients of the change in accordance with subrule 8.35(7).

f. License change application submission. Applications for license changes shall be timely submitted pursuant to this subrule. A licensed pharmacy that has timely submitted a license change application and fee may continue to service Iowa patients 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 $135 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 late penalty fee of $540.

ITEM 3. Adopt the following **new** subrule 8.35(9):

8.35(9) *License verification fee.* The board may require a nonrefundable fee of $15 to complete a request for written license verification of any pharmacy license.

ITEM 4. Amend rule 657—13.16(124,155A) as follows:

657—13.16(124,155A) Telepharmacy site—initial application.

13.16(1) *License application.* A telepharmacy site shall complete and submit to the board a limited use/telepharmacy license application and nonrefundable fee as provided in rule 657—8.35(155A). In addition to the application and fee, the telepharmacy site shall include the additional information identified in this rule.

13.16(2) *CSA registration application.* If controlled substances will be dispensed from the telepharmacy site, the telepharmacy site shall complete and submit, with the limited use/telepharmacy license application and fee, the CSA registration application and nonrefundable fee as provided in rule ~~657—10.1(124)~~ 657—10.5(124).

13.16(3) No change.

13.16(4) *Distance to nearest ~~general~~ pharmacy that dispenses prescription drugs to outpatients.* The telepharmacy site application shall identify the nearest licensed pharmacy that dispenses prescription drugs to outpatients and shall provide evidence identifying the total driving distance between the proposed telepharmacy site and the nearest currently licensed ~~general~~ pharmacy that dispenses prescription drugs to outpatients.

a. If the distance between the proposed telepharmacy site and the nearest currently licensed ~~general~~ pharmacy that dispenses prescription drugs to outpatients is less than ten miles, the telepharmacy site shall submit a request for waiver of the distance requirement. The process and requirements for a request for waiver are identified in subrule 13.16(8).

b. No change.

13.16(5) through **13.16(7)** No change.

13.16(8) *Request for distance waiver.* The board shall consider a request for waiver of the distance requirement between the proposed telepharmacy site and the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients if the petitioner can demonstrate to the

board that the proposed telepharmacy site is located in an area where there is limited access to pharmacy services and that there exist compelling circumstances that justify waiving the distance requirement.

a. No change.

b. In addition to the requirements of 657—Chapter 34, the request for waiver shall include evidence and specific information regarding each of the following, if applicable. If an item identified below does not apply to the proposed telepharmacy site, the request for waiver shall specifically state that the item does not apply.

(1) to (2) No change.

(3) That access to the nearest currently licensed ~~general~~ pharmacy that dispenses prescription drugs to outpatients is limited. A description of how the proposed telepharmacy site will improve patient access to pharmacy services shall be included.

(4) to (7) No change.

c. The board shall consider a request for waiver of the distance requirement during any open session of a meeting of the board. One or more representatives of the parties to the waiver request, including representatives of the proposed telepharmacy site, the managing pharmacy, and the nearest currently licensed ~~general~~ pharmacy that dispenses prescription drugs to outpatients, shall be invited and encouraged to attend the meeting at which the waiver request is scheduled for consideration to be available to respond to any questions.

d. No change.