PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend 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 and 155A.13.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 155A.13.

Purpose and Summary

The proposed amendments would allow the pharmacist in charge of a managing pharmacy to designate another pharmacist to serve as pharmacist in charge of a telepharmacy site; require the pharmacist in charge of the telepharmacy site to be employed by the managing pharmacy and to be identified on the pharmacy license of the telepharmacy site; allow training of telepharmacy technicians at the managing pharmacy or at another pharmacy which uses the same audiovisual technology system; and requires the display of an original license to practice pharmacy in Iowa of the telepharmacy site pharmacist in charge and the current license renewal certificates of the telepharmacy site pharmacist in charge and any pharmacist who may provide counseling to patients at the telepharmacy site.

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, RPh Iowa Board of Pharmacy 400 SW 8th Street, Suite E Des Moines, IA 50309

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—13.4(155A) as follows:

657—**13.4(155A) Responsible parties.** The responsibilities identified and assigned pursuant to rule 657—8.3(155A) shall be assigned, as appropriate, to the managing pharmacy and the telepharmacy site, by and through their respective owners or license holders, to the pharmacist in charge <u>of each respective pharmacy</u> and to staff pharmacists, including verifying pharmacists. A telepharmacy technician shall share responsibility with the pharmacist in charge <u>of the telepharmacy site</u>, the telepharmacy site, and the verifying pharmacist, as assigned in rule 657—8.3(155A), for all functions assigned to and performed by the telepharmacy technician.

ITEM 2. Amend subrule 13.8(2) as follows:

13.8(2) *Pharmacist in charge*. The pharmacist in charge of the telepharmacy site shall be the pharmacist in charge of the managing pharmacy shall designate a pharmacist in charge at the telepharmacy site pursuant to subrule 13.9(3).

ITEM 3. Adopt the following <u>new</u> subrule 13.8(11):

13.8(11) *Display of pharmacist license*. A telepharmacy site shall display, in a position visible to the public, an original license to practice pharmacy in Iowa of the pharmacist in charge

of the telepharmacy site. The telepharmacy site shall display, in a position visible to the public, a current license renewal certificate, which may be a photocopy of an original renewal certificate, of the pharmacist in charge of the telepharmacy site and each pharmacist who may provide patient counseling to patients at the telepharmacy site. A pharmacist working on-site while the telepharmacy site is open to the public shall display an original license and current license renewal certificate pursuant to 657—subrule 8.4(1).

ITEM 4. Amend subrules 13.9(3) to 13.9(5) as follows:

13.9(3) *Pharmacist in charge.* The pharmacist in charge of the managing pharmacy shall designate a be the pharmacist in charge of the telepharmacy site who will be identified on the license of the telepharmacy site. The pharmacist in charge of the telepharmacy site shall be employed by the managing pharmacy. Nothing in this subrule shall prohibit the pharmacist in charge of the managing pharmacy from simultaneously serving as the pharmacist in charge of the telepharmacy site.

13.9(4) Adequate audiovisual connection. The pharmacist in charge <u>of the managing</u> <u>pharmacy</u> shall ensure adequate audiovisual connection with the telepharmacy site during all periods when the telepharmacy site is open for business including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.9(5) *Monthly inspection.* The pharmacist in charge <u>of the telepharmacy site</u> or delegate pharmacist shall be responsible for performing a monthly inspection of the telepharmacy site. Inspection reports shall be signed by the individual pharmacist who performed the inspection. Inspection records and reports shall be maintained at the telepharmacy site for two years following the date of the inspection. A copy of the inspection report shall be provided to and maintained at the managing pharmacy. The monthly inspection shall include, but may not be limited to, the following:

a. to *j*. No change.

ITEM 5. Amend subrule 13.11(1) as follows:

13.11(1) *Practice experience.* Before practicing in a telepharmacy site, a telepharmacy technician shall have completed a minimum of 2,000 hours of practice experience as a certified pharmacy technician, at least 1,000 hours of which shall be practicing in an Iowa-licensed pharmacy and 160 hours of which shall be practicing in a managing pharmacy, at another

pharmacy which uses the same audiovisual technology system, or at the telepharmacy site under the direct supervision of an on-site pharmacist.

ITEM 6. Amend subrules 13.16(3) and 13.16(6) as follows:

13.16(3) *Identification of managing pharmacy.* The telepharmacy site application shall include identification of the managing pharmacy, including pharmacy name, license number, address, telephone number, pharmacist in charge; and a statement from the managing pharmacy or pharmacist in charge indicating that the managing pharmacy has executed a written agreement to provide the required services and oversight to the telepharmacy site; and a statement from the pharmacist in charge of the managing pharmacy designating the pharmacist in charge of the telepharmacy designating the pharmacist in charge of the telepharmacy designating the pharmacist in charge of the telepharmacy site pursuant to subrule 13.9(3).

13.16(6) *Key personnel.* The telepharmacy site application shall identify key personnel including the pharmacist in charge of the managing pharmacy, and the pharmacist in charge of the telepharmacy site, and the telepharmacy technician or technicians at the telepharmacy site. Identification shall include the names, the license or registration numbers, and the titles of the key personnel. Telepharmacy technician identification shall also include a copy of the telepharmacy technician's current national certification or other verification of the telepharmacy technician's current national certification.

ITEM 7. Amend rule 657—13.17(124,155A) as follows:

657—**13.17**(**124,155A**) **Changes to telepharmacy site or managing pharmacy.** Except as specifically provided by these rules, a change to a telepharmacy site shall require compliance with the licensure and notification requirements of the specific type of change identified in 657—subrules 8.35(6) and 8.35(7). A change affecting the CSA registration shall comply with the appropriate requirements of rule 657—10.11(124) <u>657—10.9(124)</u>.

13.17(1) Change of pharmacist in charge. A change of pharmacist in charge <u>at either the</u> <u>managing pharmacy or telepharmacy site</u> shall require submission of a pharmacy license application for the managing pharmacy and the telepharmacy site respective pharmacy location as provided by 657—subrule 8.35(6) <u>and rule 657—13.16(124,155A)</u>.

13.17(2) and 13.17(3) No change.

ITEM 8. Amend subrule 13.21(1) as follows:

13.21(1) *Minimum requirements.* Policies and procedures shall define the frequency of review, and written documentation of review by the <u>respective</u> pharmacist in charge shall be maintained. Policies and procedures shall address, at a minimum, the following:

a. to *k*. No change.