

PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby amends Chapter 13, “Telepharmacy Practice,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted 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 amendments 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 require the display at the telepharmacy site of the 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 of any pharmacist who may provide counseling to patients at the telepharmacy site.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on August 14, 2019, as **ARC 4593C**.

The Board received three comments for this rulemaking. One comment proposed a change to subrule 13.9(4) to not require the pharmacist in charge of the managing pharmacy to ensure the audiovisual connection is functional but rather any pharmacist who is on duty. The Board declined this suggestion as the Board’s expectation for the pharmacist in charge to ensure the functionality is not intended to mean that only the pharmacist in charge can do this. The Board recognizes that the pharmacist in charge is not physically in the pharmacy at all times and expects the pharmacist in charge to ensure a legal operation through the establishment and implementation of policies and procedures. The second comment related to the proposed amendment which directs the pharmacist in charge at the managing pharmacy to designate a pharmacist in charge for the telepharmacy site, but which allows the pharmacist in charge to oversee both sites if desired. The commenter suggested changing “shall” to “may,” but the Board declined the suggestion as it did not want to cause confusion by thinking having a pharmacist in charge at the telepharmacy site was optional. The third comment was in support of the rulemaking with no recommended changes. The board made no changes in response to the comments. The board added one amendment in subrule 13.8(7)

to amend the phrase “tech-check-tech practice” to “technician product verification activities” for consistency in the board’s rules.

Adoption of Rule Making

This rule making was adopted by the Board on _____, 2019.

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.

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 _____, 2019.

The following rule-making action is adopted:

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 of each respective pharmacy and to staff pharmacists, including verifying pharmacists. A telepharmacy technician shall share responsibility with the pharmacist in charge of the telepharmacy site, 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 of the telepharmacy site pursuant to subrule 13.9(3).

ITEM 3. Amend paragraph **13.8(7)“d”** as follows:

d. ~~Tech check tech practice~~ technician product verification activities.

ITEM 4. Adopt the following **new** subrule 13.8(11):

13.8(11) Display of pharmacist license. A telepharmacy site shall display, in a position visible to the public, the 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, the current license renewal certificate, which may be a photocopy of an original renewal certificate, of the pharmacist in charge of the telepharmacy site and of 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 5. 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 ~~be~~ designate a 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 of the managing pharmacy 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 of the telepharmacy site 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 6. 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 onsite pharmacist.

ITEM 7. 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, and 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 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 8. 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)~~ 657—10.9(124).

13.17(1) Change of pharmacist in charge. A change of pharmacist in charge at either the managing pharmacy or telepharmacy site 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) and rule 657—13.16(124,155A).

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

ITEM 9. 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 respective pharmacist in charge shall be maintained. Policies and procedures shall address, at a minimum, the following:

a. to k. No change.