

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 155A.13 and 155A.33.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 155A.13 and 155A.33.

Purpose and Summary

These amendments are the result of an overall five-year review of Chapter 13 as required by Iowa Code section 17A.7(2) and comments solicited by the Board from interested stakeholders in advance of the Board’s review. The amendments:

- Reduce the notification period to terminate a written agreement between a managing pharmacy and a telepharmacy site from 90 days to 45 days,
- Authorize the practice of pharmacy support persons (PSP) at a telepharmacy site and establish requirements for PSP registration and training,
- Remove duplicated rules which are required in other Board chapters, and
- Authorize the Board to establish a committee to consider requests for exemption to the technician practice experience requirements in exceptional circumstances that may otherwise result in the closure of 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 December 15, 2021, as **ARC 6083C**.

A public hearing was held on January 5, 2022, at 10:00 am at the Iowa Board of Pharmacy office as well as by Zoom. A total of 13 individuals attended the public hearing via Zoom with no individuals providing oral comments.

The board received two written comments. One commenter sought clarification relating to the possible presence of a pharmacy support person (PSP) in a telepharmacy in the absence of a certified pharmacy technician (CPhT) or pharmacist, expressing concern that the PSP would be authorized to engage in technical functions, as well as the elements identified in paragraph 13.3(1)"e" relating to the requirement to close a telepharmacy. The board's rules articulate the nontechnical functions that PSPs are authorized to engage in which continue to dictate the authorized functions within a telepharmacy; a PSP is not, under any circumstances, authorized to engage in technical functions in any pharmacy setting, including a telepharmacy site. Paragraph 13.3(1)"e" provides that all three identified elements of a telepharmacy site and its connection with a managing pharmacy must be in place for the telepharmacy site to be open; if any one of the three elements are not available or functioning, the telepharmacy site must close until all three are available and operational. The second comment was in support of the rulemaking.

The rulemaking is identical to that which was noticed.

Adoption of Rule Making

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

Fiscal Impact

This rule making has no fiscal impact to the state of Iowa.

Jobs Impact

A minimal increase in PSP positions in telepharmacies may result in any of the 23 licensed telepharmacy locations in the state.

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 action is adopted:

ITEM 1. Amend rule 657—13.1(155A) as follows:

657—13.1(155A) Purpose and scope. The purpose of this chapter is to provide standards for the provision of telepharmacy services to patients. These rules provide for pharmaceutical care services at a telepharmacy site utilizing audiovisual technologies that link the telepharmacy site with a managing pharmacy and one or more verifying pharmacists, but does not include remote pharmacist verification occurring in or on behalf of a hospital pharmacy. The telepharmacy site and the managing pharmacy shall be located within Iowa and shall maintain appropriate licensure by the board.

ITEM 2. Adopt the following **new** definitions of “ACPE” and “Telepharmacy personnel” in rule **657—13.2(155A)**:

“ACPE” means the Accreditation Council for Pharmacy Education.

“Telepharmacy personnel” means one or more registered certified pharmacy technicians or registered pharmacy support persons who have met the general requirements for telepharmacy site practice and who work at a telepharmacy site under the remote supervision of a verifying pharmacist.

ITEM 3. Amend rule **657—13.2(155A)**, definition of “Telepharmacy site,” as follows:

“Telepharmacy site” means a licensed pharmacy that is operated by a managing pharmacy and staffed by ~~one or more~~ telepharmacy ~~technicians~~ personnel where pharmaceutical care services, including the storage and dispensing of prescription drugs, drug utilization review, and patient counseling, are provided by a licensed pharmacist through the use of technology.

ITEM 4. Amend rule 657—13.3(124,155A) as follows:

657—13.3(124,155A) Written agreement. The managing pharmacy and the telepharmacy site shall execute and maintain a current written agreement between the pharmacies. If there is no current written agreement between the pharmacies, the telepharmacy site shall immediately

notify the board and shall discontinue operations as a telepharmacy site until a current written agreement between the managing pharmacy and the telepharmacy site is executed.

13.3(1) Contents of agreement. The written agreement between the managing pharmacy and a telepharmacy site shall include, but may not be limited to, the following:

a. Staffing, to include telepharmacy ~~technician~~ personnel staffing, verifying pharmacist staffing and availability, and on-site pharmacist staffing as needed.

b. to d. No change.

e. A provision that, in the event that the telepharmacy ~~technician~~ personnel is not available at the telepharmacy site, that a verifying pharmacist is not available, or that the audiovisual communication connection between the telepharmacy site and the managing pharmacy is not available, the telepharmacy site shall close pending the availability of ~~the technician~~ telepharmacy personnel, the verifying pharmacist, and the communication link or pending the arrival at the telepharmacy site of a pharmacist to provide on-site pharmacy services.

f. to h. No change.

13.3(2) Termination of agreement. A managing pharmacy shall provide written notice to the board and to the telepharmacy site ~~90~~ 45 days in advance of the managing pharmacy's intent to terminate the agreement between the telepharmacy site and the managing pharmacy. A telepharmacy site shall provide written notice to the board and to the managing pharmacy ~~90~~ 45 days in advance of the telepharmacy site's intent to terminate the agreement between the managing pharmacy and the telepharmacy site.

a. New agreement. A new written agreement between a managing pharmacy and the telepharmacy site, including the filing of a new pharmacy license application identifying the new pharmacist in charge, shall be executed within the ~~90-day~~ 45-day advance notification period.

b. No new agreement. If the telepharmacy site is unable to contract with a new managing pharmacy, the telepharmacy site shall, 30 days prior to the expiration of the ~~90-day~~ 45-day advance notification period, implement the prior notification requirements for closing a telepharmacy site as provided in subrule 13.3(3). The telepharmacy site shall cease operations and close at the end of that 30-day closing notification period unless a new written agreement is executed.

13.3(3) and 13.3(4) No change.

ITEM 5. Rescind and reserve rule ~~657—13.4(155A)~~.

ITEM 6. Amend rule 657—13.8(124,155A) as follows:

~~657—13.8(124,155A) General requirements for telepharmacy site. The telepharmacy site shall maintain a pharmacy license issued by the board. If the telepharmacy site plans to dispense controlled substances, the telepharmacy site shall also maintain a CSA registration and a DEA registration.~~ In addition to applicable requirements for pharmacies located in Iowa, a telepharmacy site shall also ensure compliance with the requirements identified herein.

~~13.8(1) Located in Iowa. A telepharmacy site shall be located within the state of Iowa.~~

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

~~13.8(3) 13.8(1) Security.~~ A telepharmacy site shall employ methods to prevent unauthorized access to prescription drugs, devices, and pharmacy and patient records. Such methods may include an alarm system and shall include other security systems and methods as provided by these rules. Alarm systems and entry system locks should be disarmed when the telepharmacy site is staffed and open for business. Minimum security methods shall include:

a. to d. No change.

~~13.8(4) 13.8(2) Telepharmacy site signage.~~ In addition to the patient counseling sign required pursuant to ~~subrule 13.8(5) rule 657—6.14(155A)~~, one or more signs, prominently posted in every prescription pick-up area and clearly visible to the public, shall inform the public that the location is a telepharmacy site supervised by a pharmacist at a remote location. Signage shall include the name, location, and telephone number of the managing pharmacy. The telepharmacy site shall also prominently post the days and times that the telepharmacy is open for business.

~~13.8(5) 13.8(3) Patient counseling.~~ Patient counseling as required by rule 657—6.14(155A) shall be provided utilizing the audiovisual technology employed between the telepharmacy site and the managing pharmacy. ~~Every telepharmacy site shall post in every prescription pickup area, in a manner clearly visible to patients, a notice that Iowa law requires the pharmacist to discuss with the patient any new prescriptions dispensed to the patient. The board shall provide a telepharmacy site with the required signage.~~

~~13.8(6) 13.8(4) Label requirements.~~ In addition to the label requirements identified in 657—subrule 6.10(1), the label affixed to or on the dispensing container of any prescription drug or device dispensed by a telepharmacy site pursuant to a prescription drug order shall include, on

the primary label or affixed by use of an auxiliary label, the following:

a. and *b.* No change.

~~13.8(7)~~ **13.8(5)** *Prohibited activities.* In the physical absence of a pharmacist, the following activities are prohibited:

a. Practice of pharmacist-interns ~~or pharmacy support persons at the telepharmacy site,~~ except that a pharmacy support person may deliver prescriptions to patients outside the telepharmacy site but may not engage in prescription delivery or any other activities at the telepharmacy site.

b. to *f.* No change.

g. All judgmental and technical activities identified in rule 657—5.17(155A) that a pharmacy support person is prohibited from performing in the practice of pharmacy.

~~13.8(8)~~ *Continuous quality improvement.* A telepharmacy site shall implement and participate in a continuous quality improvement program pursuant to rule 657—8.26(155A).

~~13.8(9)~~ **13.8(6)** *Technology failure.* If the audiovisual technology between the telepharmacy site and the managing pharmacy or the verifying pharmacist is not operational, no prescriptions shall be dispensed from the telepharmacy site to a patient unless a pharmacist is physically present at the telepharmacy site.

~~13.8(10)~~ **13.8(7)** *Perpetual controlled substances inventory.* A telepharmacy site that dispenses controlled substances shall maintain a perpetual inventory record of those controlled substances.

a. and *b.* No change.

~~13.8(11)~~ **13.8(8)** *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).

13.8(9) *Adequate audiovisual connection.* The telepharmacy personnel shall ensure adequate audiovisual connection with the managing pharmacy during all periods when the telepharmacy

site is open for business, including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

ITEM 7. Amend subrule 13.10(4) as follows:

13.10(4) *Patient refusal of counseling.* If a patient or patient’s caregiver refuses patient counseling, the refusal shall be directly communicated by the patient or patient’s caregiver to the pharmacist through audiovisual communication. ~~A technician~~ Telepharmacy personnel may not accept and communicate a refusal of patient counseling from the patient or patient’s caregiver to the pharmacist.

ITEM 8. Amend rule 657—13.11(155A) as follows:

657—13.11(155A) General requirements for telepharmacy technician.

13.11(1) Registration and certification. A telepharmacy technician shall maintain current national certification and registration in good standing with the board as a certified pharmacy technician.

~~13.11(1)~~ **13.11(2) 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. The board may establish a committee to consider, on a case-by-case basis, requests for exceptions to the practice experience requirements in exceptional circumstances that may otherwise result in the closure of the telepharmacy site.

~~13.11(2)~~ **13.11(3) Training.** In addition to training required of all pharmacy technicians, a telepharmacy technician shall complete the following minimum training requirements before practicing in a telepharmacy site. Records of telepharmacy technician training shall be documented and maintained by the telepharmacy site.

a. to f. No change.

~~13.11(3)~~ **13.11(4) Continuing education.** Beginning with the first full two-year continuing education period for renewal of the technician’s national pharmacy technician certification after beginning practice as a telepharmacy technician, and for each subsequent renewal of national

certification for as long as the technician continues to practice as a telepharmacy technician, the technician shall complete two hours of ACPE-approved continuing education in each of the following activities. These continuing education requirements shall not be in addition to the total continuing education credits required to maintain national certification.

a. and b. No change.

~~**13.11(4) Identification.** The telepharmacy technician shall, at all times when the technician is practicing at the telepharmacy site and the telepharmacy site is open for business, wear a name badge or tag identifying the technician. The badge or tag shall include, at a minimum, the technician's first name and title. The name badge or tag shall be so designed and worn that the technician's name and title are clearly visible to the public at all times.~~

~~**13.11(5) Adequate audiovisual connection.** The telepharmacy technician shall ensure adequate audiovisual connection with the managing pharmacy during all periods when the telepharmacy site is open for business, including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.~~

ITEM 9. Adopt the following **new** rule 657—13.12(155A):

657—13.12(155A) General requirements for telepharmacy support person.

13.12(1) Registration. A telepharmacy support person shall maintain registration in good standing with the board as a pharmacy support person.

13.12(2) Training. In addition to training required of all pharmacy support persons, a telepharmacy support person shall complete the following minimum training requirements before practicing in a telepharmacy site. Records of telepharmacy support person training shall be documented and maintained by the telepharmacy site.

- a.* Review and understanding of the policies and procedures of the managing pharmacy.
- b.* Review and understanding of the policies and procedures of the telepharmacy site.
- c.* Review and understanding of these rules for telepharmacy practice.
- d.* Review and understanding of pharmacy support person rules, 657—Chapter 5.
- e.* Understanding of the operation of the audiovisual technologies to be utilized at both pharmacies.
- f.* Training at the telepharmacy site under the direct supervision of an on-site verifying pharmacist. Training shall include operation and use of the audiovisual technology and other

means of communication between the telepharmacy site and the managing pharmacy and the security of the telepharmacy site as identified in policies and procedures.

ITEM 10. Amend rule 657—13.16(124,155A) as follows:

657—13.16(124,155A) Telepharmacy site—initial 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) and, if controlled substances will be dispensed from the telepharmacy site, a CSA registration application and nonrefundable fee as provided in rule 657—10.5(124). As part of the limited use/telepharmacy license application, the telepharmacy site shall include the additional information identified in this rule.

~~**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—10.5(124).~~

~~**13.16(3)**~~ **13.16(1) 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; 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(4)**~~ **13.16(2) Distance to nearest pharmacy that dispenses prescription drugs to outpatients.** The telepharmacy site application shall identify the nearest currently 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 pharmacy that dispenses prescription drugs to outpatients.

a. If the distance between the proposed telepharmacy site and the nearest currently licensed

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)~~ 13.16(6).

b. No change.

~~13.16(5)~~ 13.16(3) *Written agreement.* The telepharmacy site application shall include the written agreement between the telepharmacy site and the managing pharmacy as described in subrule 13.3(1).

~~13.16(6)~~ 13.16(4) *Key personnel.* The telepharmacy site application shall identify key personnel including the pharmacist in charge of the managing pharmacy, the pharmacist in charge of the telepharmacy site, ~~and~~ the telepharmacy technician or technicians at the telepharmacy site, and the telepharmacy support person or persons 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~~ verification of the telepharmacy technician's current national certification ~~or other verification of the telepharmacy technician's current national certification.~~

~~13.16(7)~~ 13.16(5) *Audiovisual technology.* A description of the audiovisual technology system to be used to link the managing pharmacy and the telepharmacy site, including built-in safeguards relating to verification of the accuracy of the dispensing processes. Safeguards shall include but may not be limited to:

a. to d. No change.

~~13.16(8)~~ 13.16(6) *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. to d. No change.

ITEM 11. Rescind and reserve rule ~~657—13.17(124,155A)~~.

ITEM 12. Rescind and reserve rule ~~657—13.21(124,155A)~~.

ITEM 13. Rescind and reserve rule ~~657—13.22(155A)~~.

ITEM 14. Amend rule 657—13.23(124,155A) as follows:

657—13.23(124,155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124 and 155A or rules of the board shall be kept by the telepharmacy site and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record except as specifically identified by law or rule. Controlled substances records shall be maintained in a readily retrievable manner in accordance with federal requirements and 657—Chapter 10.

13.23(1) Dispensing record. ~~As provided in rule 657—13.21(124,155A),~~ a written or electronic record identifying the pharmacist who verified the prescription, the pharmacist who performed drug utilization review, the pharmacist who provided counseling to the patient or the patient’s caregiver, and the pharmacy technician who filled the prescription shall be maintained for every prescription fill dispensed by the telepharmacy site.

13.23(2) to 13.23(4) No change.

13.23(5) Policy and procedure review. A written or electronic record of the review of the policy and procedures by the pharmacist in charge shall be retained for two years following the date of the review.