

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 8, “Universal Practice Standards,” and to adopt new Chapter 13, “Telepharmacy Practice,” Iowa Administrative Code.

The amendments were approved at the _____, regular meeting of the Board of Pharmacy.

The proposed amendment to subrule 8.35(2) identifies a telepharmacy practice as a defined subset of a limited use pharmacy license type. The proposed rules in new Chapter 13 provide standards for the provision of pharmaceutical services to patients through the use of audio-visual technologies that link the telepharmacy site with a managing pharmacy, allowing a verifying pharmacist at the remote pharmacy to oversee and verify the dispensing processes performed by the technician at the telepharmacy site. The audio-visual technology also ensures that the patient and the pharmacist are able to converse, face-to-face over secure connections, about the patient’s drug treatment plan.

The proposed rules define terms used in the chapter and assign responsibilities for various aspects of the practices involved. The proposed rules require a written agreement between the managing pharmacy and the telepharmacy site, identifying specific required provisions and contents of the written agreement and what must occur in case the agreement is terminated or either pharmacy closes. The proposed rules identify the general requirements for a telepharmacy site, a managing pharmacy, a verifying pharmacist, and a telepharmacy technician, including addressing specific training and experience requirements for those personnel.

The required information to be provided with the initial application for a limited use pharmacy license as a telepharmacy site and the minimum information to be provided in a request for waiver of the minimum distance between a proposed telepharmacy site and an existing pharmacy that dispenses prescription drugs to outpatients are identified. Specific application and notification requirements in the case of a change of telepharmacy site or managing pharmacy name, location, ownership, or pharmacist in charge are identified. The proposed rules provide that the opening of a new pharmacy within 10 miles of an existing telepharmacy site does not force the closing of the telepharmacy site.

Subjects to be addressed by policies and procedures to be adopted and implemented by both the telepharmacy site and the managing pharmacy are listed and information and reports required of a telepharmacy site or managing pharmacy are identified. The proposed rules identify specific records that must be maintained by and available at a telepharmacy site including the monthly inspection of the telepharmacy site by a pharmacist from the managing pharmacy.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34. Requirements for waiver of the specific restrictions regarding location of a telepharmacy site within 10 miles of another pharmacy that dispenses prescription drugs to outpatients are identified in subrule 13.16(8).

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on _____, 2017. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by email to terry.witkowski@iowa.gov.

A public hearing was held on August 30, 2016, during a regularly held meeting of the Board. Numerous written and oral comments, objections, and suggestions were received both by persons attending the hearing and other interested persons. The Board considered all of those comments when composing these rules.

After analysis and review of this rulemaking, the Board has been unable to determine whether the adoption of these rules will have an impact on jobs or the net result of any possible impact. The establishment of telepharmacy sites where a pharmacy currently does not exist may create jobs for pharmacy technicians and also for verifying pharmacists. However, the establishment of a telepharmacy site in place of an existing pharmacy that intends to close, as a means of preserving the availability of pharmacy services in a community or area, may still result in the overall reduction in the number of jobs in that area.

These amendments are intended to implement Iowa Code sections. These rules are intended to implement Iowa Code sections 124.301, 147.107, 155A.3, 155A.6A, 155A.13, 155A.14, 155A.19, 155A.28, 155A.31, 155A.33, and 155A.41.

The following amendments are proposed.

Item 1. Amend subrule 8.35(2) as follows:

8.35(2) Limited use pharmacy license. Limited use pharmacy license may be issued for nuclear pharmacy practice, correctional facility pharmacy practice, telepharmacy practice, and veterinary pharmacy practice. Applications for limited use pharmacy license for these and other limited use practice settings shall be determined on a case-by-case basis.

Item 2. Adopt new 657—Chapter 13, Telepharmacy Practice, as follows:

Chapter 13

Telepharmacy Practice

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 audio-visual technologies that link the telepharmacy site with a managing pharmacy and one or more verifying pharmacists. The telepharmacy site and the managing pharmacy shall be located within Iowa and shall maintain appropriate licensure by the board.

657—13.2(155A) Definitions. For purposes of this chapter, the following definitions shall apply.

“Board” means the board of pharmacy.

“CSA” or *“CSA registration”* means a registration issued pursuant to Iowa Code section 124.303 and 657—Chapter 10.

“DEA” means the Drug Enforcement Administration of the U. S. Department of Justice.

“Managing pharmacy” means a licensed pharmacy located in Iowa that oversees the activities of one or more telepharmacy sites.

“Telepharmacy” means the practice of pharmacy where pharmaceutical care services are provided using audio-visual technologies linking a telepharmacy site with the managing pharmacy.

“Telepharmacy site” means a licensed pharmacy that is operated by a managing pharmacy and staffed by one or more telepharmacy technicians 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.

“Verifying pharmacist” means a remote Iowa-licensed pharmacist or pharmacists who

perform any step in the prescription verification and dispensing process including but not limited to: verification of data entry; product selection, packaging, and labeling; drug utilization review; and patient counseling.

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 staffing, verifying pharmacist staffing and availability, and on-site pharmacist staffing as needed.

b. Hours of operation of the telepharmacy site and hours of availability of pharmacists at the managing pharmacy.

c. Emergency contact information for the managing pharmacy and the telepharmacy site.

d. Complete description of the audio-visual technology to be utilized to link the managing pharmacy and the telepharmacy site.

e. A provision that, in the event that the telepharmacy technician is not available at the telepharmacy site, that a verifying pharmacist is not available, or that the audio-visual communication connection between the telepharmacy site and the managing pharmacy is not available, the telepharmacy site shall close pending the availability of the technician, the verifying pharmacist, and the communication link or pending the arrival at the telepharmacy site

of a pharmacist to provide onsite pharmacy services.

f. Activities and services to be provided by the managing pharmacy at the telepharmacy site.

g. Identification of contact persons to receive, on behalf of the managing pharmacy and the telepharmacy site, notifications and official communications regarding the written agreement. Identification of contact persons shall include delivery addresses and preferred methods of delivery of the written communications required by this rule and any other communications affecting the written agreement between the managing pharmacy and the telepharmacy.

h. Pharmacy locations, other than the managing pharmacy, where verifying pharmacists may be based or located.

13.3(2) Termination of agreement. A managing pharmacy shall provide written notice to the Board and to the telepharmacy site 90 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 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 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 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) Closing of telepharmacy site. A telepharmacy site that intends to close the telepharmacy site shall provide written notification to the managing pharmacy and the board as provided in 13.3(2). In addition, the telepharmacy site shall provide written notification to the DEA and to patients and shall comply with all requirements for closing a pharmacy as provided in subrule 657—8.35(7).

13.3(4) Closing of managing pharmacy. A managing pharmacy that intends to close the managing pharmacy shall provide written notification to the telepharmacy site and the board as provided in 13.3(2). In addition, the managing pharmacy shall provide written notification to the DEA and to patients and shall comply with all requirements for closing a pharmacy as provided in subrule 657—8.35(7). A telepharmacy site that has been managed by the closing pharmacy shall comply with the provisions of subrules 13.3(2) and 13.3(3), as applicable.

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 and to staff pharmacists, including verifying pharmacists. A telepharmacy technician shall share responsibility with the pharmacist in charge, 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.

657—13.5 to 13.7 Reserved.

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.

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 telepharmacy site shall be the pharmacist in charge of the managing pharmacy.

13.8(3) 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. Electronic keypad or other electronic entry system into the telepharmacy site or the pharmacy department that requires and records the unique identification of the individual accessing the pharmacy, including the date and time of access. Complete access records shall be maintained for a minimum two years beyond the date of access.

b. Secure storage such as a safe.

c. Controlled access to computer records.

d. A continuous system of video surveillance and recording of the pharmacy department that includes maintenance of recordings for a minimum 60 days following the date of the recording.

13.8(4) Telepharmacy site signage. In addition to the patient counseling sign required pursuant to subrule 13.8(5), 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) Patient counseling. Patient counseling as required by rule 657—6.14(155A) shall be provided utilizing the audio-visual 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) Label requirements. In addition to the label requirements identified in subrule 657—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. The name, telephone number, and address of the telepharmacy site;
- b. The name and telephone number of the managing pharmacy.

13.8(7) 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.
- b. Advising patients regarding OTC products unless that advice is communicated directly by a pharmacist to the patient.
- c. Dispensing or delivering prescription medications packaged by a technician into patient med paks unless an onsite pharmacist has verified the drugs in the patient med paks.
- d. Tech-check-tech practice.

e. Compounding, unless an onsite pharmacist has verified the accuracy and completeness of the compounded drug product.

f. All judgmental activities identified in rule 657—3.23(155A) that a pharmacy technician 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) Technology failure. If the audio-visual 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) Perpetual controlled substances inventory. A telepharmacy site that dispenses controlled substances shall maintain a perpetual inventory record of those controlled substances.

a. The perpetual inventory record requirement shall apply to all controlled substances maintained and dispensed by the telepharmacy site and shall not be limited only to Schedule II controlled substances.

b. The perpetual inventory record format and other requirements provided in rule 657—10.33(124,155A) shall apply to the telepharmacy site's perpetual inventory record of controlled substances, with the following exceptions:

(1) The perpetual inventory record shall contain records for all controlled substances, not just Schedule II controlled substances, and

(2) Audit of the perpetual inventory record shall be completed and the physical and perpetual inventories shall be reconciled pursuant to the requirements of subrule 10.33(4) each month as

part of the inspection of the telepharmacy site.

657—13.9(155A) General requirements for managing pharmacy.

13.9(1) Distance to telepharmacy site. The managing pharmacy shall be located in Iowa and within a 200-mile radius of a telepharmacy site, to ensure that the telepharmacy site is sufficiently supported by the managing pharmacy and that necessary personnel or supplies may be delivered to the telepharmacy site within a reasonable period of time of an identified need.

13.9(2) Emergency preparedness plan. A managing pharmacy shall develop and include in both the managing pharmacy's and the telepharmacy site's policies and procedures a plan for continuation of pharmaceutical services provided by the telepharmacy site in case of an emergency interruption of the telepharmacy site's services. The plan shall address the timely arrival at the telepharmacy site of necessary personnel or the delivery to the telepharmacy site of necessary supplies within a reasonable period of the identification of an emergency need. The plan may provide for alternate methods of continuation of the services of the telepharmacy site including, but not limited to, personal delivery of patient prescription medications from an alternate pharmacy location or onsite pharmacist staffing at the telepharmacy site.

13.9(3) Pharmacist in charge. The pharmacist in charge of the managing pharmacy shall be the pharmacist in charge of the telepharmacy site.

13.9(4) Adequate audio-visual connection. The pharmacist in charge shall ensure adequate audio-visual 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 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.** Audit and reconciliation of controlled substances perpetual and physical inventories;
- b.** Audit of electronic entry system and records;
- c.** Verification that the video recording system is functioning properly and that the recordings are maintained and available for at least 60 days past the date of the recording;
- d.** Compilation of a record of the number of prescriptions filled, the number of onsite pharmacist hours, and the number of hours the pharmacy site was open for business during the preceding month.
- e.** Review of written policies and procedures and verification of compliance with those policies and procedures;
- f.** Ensuring compliance with and review of records in the continuous quality improvement program, following up with responsible personnel to address issues identified by incident reports to prevent future incidents;
- g.** Review of records of the receipt and disbursement of prescription drugs, including controlled substances, to ensure compliance with recordkeeping requirements;
- h.** Inspection of drug supplies and storage areas to ensure removal and quarantine of outdated drugs;
- i.** Inspection of stock drug supplies and storage areas to ensure drugs are maintained in a

manner to prevent diversion and maintain the integrity of the drugs, verifying that the temperatures of storage areas are appropriate for the stored drugs and equipment,

j. Inspection of pharmacy and storage areas and shelves to ensure areas and shelves are clean and free of pests and other contaminants.

13.9(6) Onsite pharmacist staffing. In an effort to promote public health, the telepharmacy site shall be staffed by a pharmacist for at least 16 hours per month. While on site, the pharmacist shall make available to the community general health care services which may include, but not necessarily be limited to, immunizations, medication therapy management, or health screenings, as deemed necessary and appropriate by the pharmacist in charge and as provided by policies and procedures.

a. If a pharmacist will be available at the telepharmacy site to provide in-person patient services, a consistent schedule of the pharmacist's availability shall be established and published.

b. Signage identifying the days and times when a pharmacist is onsite and available to patients shall be conspicuously posted at the telepharmacy site and may be published by other means, as deemed appropriate.

c. Notice that the pharmacist will not be present at the telepharmacy site during any routinely scheduled and posted onsite availability shall be provided to the public in advance of the absence except as provided in the emergency preparedness plan.

d. If the average number of prescriptions dispensed per day by the telepharmacy site exceeds 150 prescriptions, the telepharmacy site shall provide onsite pharmacist staffing 100% of the time the pharmacy is open for business and shall, within 10 business days, apply to the Board for licensure as a general pharmacy. The average number of prescriptions dispensed per day shall

be determined by averaging the number of prescriptions dispensed per day over the previous 90-day period.

657—13.10(155A) General requirements for verifying pharmacist. A verifying pharmacist shall maintain a current and active license to practice pharmacy in Iowa.

13.10(1) Location of verifying pharmacist. The verifying pharmacist who is performing patient counseling shall be physically located within the managing pharmacy or another pharmacy licensed to operate a pharmacy in Iowa.

13.10(2) Adequate audio-visual connection. The verifying pharmacist shall ensure adequate audio-visual connection with the telepharmacy site during all periods when the pharmacist is responsible for verifying telepharmacy site activities and practices including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.10(3) Verifying pharmacist training. A verifying pharmacist shall be adequately trained on the use of the technology to ensure accurate verification and patient counseling and shall review and understand the policies and procedures of the managing pharmacy and the telepharmacy site.

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 audio-visual communication. A technician may not accept and communicate a refusal of patient counseling from the patient or patient's caregiver to the pharmacist.

13.10(5) Reference library. A verifying pharmacist shall have access to all required references applicable to the telepharmacy services provided at the telepharmacy site.

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

technician shall maintain current national certification and registration in good standing with the board as a certified pharmacy technician.

13.11(1) Practice experience. Before practicing in a telepharmacy site, a telepharmacy technician shall have completed a minimum of 2,000 hours 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.

13.11(2) 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. 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 technician rules, 657 – Chapter 3.
- e. Understanding of the operation of the audio-visual technologies to be utilized at both pharmacies.
- f. Training at the telepharmacy site under the direct supervision of an onsite verifying pharmacist. Training shall include operation and use of the audio-visual technology and other means of communication between the telepharmacy site and the managing pharmacy and all daily operations from unlocking and opening the telepharmacy site to closing and locking the telepharmacy site at the end of the business day. If the telepharmacy site is protected by one or more alarm systems, training shall include how to disarm and engage the alarm system or

systems.

13.11(3) 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 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. Patient safety/medication errors.
- b. Pharmacy law.

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(4) Adequate audio-visual connection. The telepharmacy technician shall ensure adequate audio-visual 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.

657—13.12 to 13.15 Reserved.

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 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 fee as provided in rule 657—10.1(124).

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.

13.16(4) Distance to nearest general pharmacy. 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.

a. If the distance between the proposed telepharmacy site and the nearest currently licensed general pharmacy 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. The distance requirement shall not apply under any of the following circumstances:

(1) The telepharmacy site was approved by the board and operating as a telepharmacy site

prior to July 1, 2016.

(2) The proposed telepharmacy site is located within a hospital campus and services will be limited to inpatient dispensing.

(3) The proposed telepharmacy site is located on property owned, operated, or leased by the state.

13.16(5) 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) Key personnel. The telepharmacy site application shall identify key personnel including the pharmacist in charge of the managing pharmacy and 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.

13.16(7) Audio-visual technology. A description of the audio-visual 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. Prior to authorizing the telepharmacy site's system to print a prescription label and prior to filling the prescription at the telepharmacy site, requiring a verifying pharmacist to review and compare the electronic image of any new prescription presented to the telepharmacy technician

for filling with the data entry record of the prescription.

b. Requiring the technician to use barcode technology at the telepharmacy site to verify the accuracy of the drug to be dispensed.

c. Requiring remote visual confirmation by a verifying pharmacist of the drug stock bottle and the drug to be dispensed prior to dispensing the prescription at the telepharmacy site.

d. Ensuring the telepharmacy site's system prevents a prescription from being sold and delivered to a patient prior to the verifying pharmacist performing a final verification of the accuracy of the prescription and releasing the prescription for sale and delivery at the telepharmacy site.

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. The request for waiver shall be prepared and shall include the elements of a request for waiver or variance identified in 657 Chapter 34.

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) That the nearest currently licensed pharmacy that dispenses prescription drugs to

outpatients is open for business for limited hours or fewer hours than the proposed telepharmacy site.

(2) That the proposed telepharmacy site intends to provide services not available from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

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

(4) That limited access to pharmacy services is affecting patient safety.

(5) That there are transportation barriers to services from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(6) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is closing.

(7) That the proposed telepharmacy site is located in an area of the state where there is limited access to pharmacy services.

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, 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. The board's decision to grant or deny the request for waiver of the distance requirement shall be a proposed decision and shall be reviewed by the director of the department of public

health.

(1) The director shall have the power to approve, modify, or veto the board's proposed decision regarding the waiver request.

(2) The director's decision on a waiver request shall be considered final agency action.

(3) The director's decision (final agency action) shall be subject to judicial review under Iowa Code chapter 17A.

657—13.17(124,155A) Telepharmacy site or managing pharmacy changes. 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).

13.17(1) Change of pharmacist in charge. A change of pharmacist in charge shall require submission of a pharmacy license application for the managing pharmacy and the telepharmacy site as provided by subrule 657—8.35(6).

13.17(2) Closing or selling pharmacy. A telepharmacy site or managing pharmacy that intends to close or sell the pharmacy practice shall comply with all requirements for closing or selling a pharmacy found at 657 subrules 8.35(6) and 8.35(7) regarding ownership change and closing a pharmacy, including all advance notification requirements. A purchaser of a telepharmacy site shall complete and submit applications and supporting information as provided in rule 657—13.16(124,155A). A closing pharmacy shall also comply with the requirements of subrule 13.3(3) or 13.3(4), as appropriate.

13.17(3) Location change. A telepharmacy site that intends to move to a new location that is

outside the community wherein the telepharmacy site has been located, if the telepharmacy site intends to provide telepharmacy services from the new location, shall comply with the requirements of subrule 13.17(2) for closing a pharmacy and shall submit applications and supporting information as provided in rule 657—13.16(124,155A). A managing pharmacy that intends to move to a new location shall comply with the requirements of 657 subrules 8.35(5), 8.35(6), and 8.35(7), as appropriate.

657—13.18(155A) Traditional pharmacy opening. If a pharmacy, licensed as a general, hospital, or limited use pharmacy, opens for business within 10 miles of an existing and operating telepharmacy site, the telepharmacy site may continue to operate as a telepharmacy site and shall not be required to close due to the proximity of the new pharmacy.

657—13.19 to 13.20 Reserved.

657—13.21(124,155A) Policies and procedures. In addition to policies and procedures required for the specific services provided and identified in other chapters of board rules, both the managing pharmacy and the telepharmacy site shall develop, implement, and adhere to written policies and procedures for the operation and management of the specific pharmacy's operations. Policies and procedures shall be available for inspection and copying by the board or the board's representative at the location to which the policies and procedures apply. Policies and procedures shall define the frequency of review and written documentation of review by the pharmacist in charge shall be maintained. Policies and procedures shall address, at a minimum, the following:

- Procedures ensuring a record is made and retained identifying the pharmacist who verified the accuracy of the prescription including the accuracy of the data entry, the selection of the correct drug, the accuracy of the label affixed to the prescription

container, and the appropriateness of the prescription container.

- Procedures ensuring a record is made and retained identifying the pharmacist who performed the drug utilization review as provided by rule 657—8.21(155A).
- Procedures ensuring a record is made and retained identifying the pharmacist who provided counseling to the patient or the patient’s caregiver pursuant to rule 657—6.14(155A).
- Procedures ensuring a record is made and retained identifying the technician who filled the prescription.
- Procedures ensuring adequate security to prevent unauthorized access to prescription drugs and devices and to confidential records.
- Procedures regarding procurement of drugs and devices, including who is authorized to order or receive drugs and devices, from whom drugs and devices may be ordered and received, and the required method for documentation of the receipt of drugs and devices.
- Procedures ensuring appropriate and safe storage of drugs at the telepharmacy site including appropriate temperature controls.
- Procedures identifying the elements of a monthly inspection of the telepharmacy site by the pharmacist in charge or designated pharmacist including requirements for documentation and retention of the results of each inspection.
- Procedures for the temporary quarantine of out-of-date and adulterated drugs from dispensing stock and the subsequent documented disposal of those drugs.
- Procedures and documentation required in the case of return to the telepharmacy of a drug or device.

- Procedures for drug and device recalls.

657—13.22(155A) Reports to the board. The board may periodically request information regarding the services provided by a telepharmacy site. A telepharmacy site shall complete and submit the requested information in a timely manner as requested by the board. The board shall allow a reasonable amount of time for a telepharmacy site to complete and submit the requested information. Information requested may include, but may not necessarily be limited to, the following:

13.22(1) Prescriptions dispensed. The number of prescriptions dispensed from the telepharmacy site over a specified period of time.

13.22(2) Pharmacist hours. The number of hours a pharmacist was physically present at the telepharmacy site over a specified period of time.

13.22(3) Telepharmacy site hours. The number of hours the telepharmacy site was open for business over a specified period of time.

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. Specific records required to be maintained by and available at a telepharmacy site shall include but are not limited to the following:

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

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) Onsite pharmacist staffing. A written or electronic record of the number of prescriptions filled, the number of onsite pharmacist hours, and the number of hours the telepharmacy site was open for business each month.

13.23(3) Pharmacy access. Records identifying, by unique identification of the individual accessing the pharmacy department including the date and time of access, shall be maintained for two years beyond the date of access.

13.23(4) Monthly inspection. Reports of the monthly inspection of the telepharmacy site 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 for two years following the date of the inspection.

These rules are intended to implement Iowa Code sections 124.301, 147.107, 155A.3, 155A.6A, 155A.13, 155A.14, 155A.19, 155A.28, 155A.31, 155A.33, and 155A.41.