

657—13.8(124,155A) General requirements for telepharmacy site. 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) 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 of 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 of 60 days following the date of the recording.

13.8(2) Telepharmacy site signage. In addition to the patient counseling sign required pursuant to 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(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.

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. The name, telephone number, and address of the telepharmacy site;

b. The name and telephone number of the managing pharmacy.

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

a. Practice of pharmacist-interns at the telepharmacy site.

b. Advising patients regarding over-the-counter 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 on-site pharmacist has verified the drugs in the patient med paks.

d. Technician product verification program activities.

e. Compounding, unless an on-site 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.

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(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(7) 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—10.18(124) 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 657—subrule 10.18(4) each month as part of the inspection of the telepharmacy site.

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.

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