

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 time following 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 on-site pharmacist staffing at the telepharmacy site.

13.9(3) *Pharmacist in charge.* The pharmacist in charge of the managing pharmacy shall 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. 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 on-site 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 record-keeping 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) *On-site 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 on site 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 on-site 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 on-site pharmacist staffing 100 percent of the time the pharmacy is open for business and shall, within ten 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.

[ARC 3236C, IAB 8/2/17, effective 9/6/17; ARC 4798C, IAB 12/4/19, effective 1/8/20]