Wyoming Administrative Rules

Pharmacy, Board of

Pharmacy, Board of

Chapter 14: Telepharmacy

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TFLFPHARMACY

CHAPTER 14

Section 1. Authority.

These rules are promulgated as authorized by the Wyoming Pharmacy Act, W.S. § 33-24-101 through -301.

Section 2. Purpose.

To describe procedures for operating a telepharmacy.

Section 3. Scope.

Applies to parent pharmacies and telepharmacies licensed in Wyoming.

Section 4. Definitions.

- (a) "Adequate Supervision" means oversight by the parent pharmacy by which they maintain visual supervision and auditory communication with the telepharmacy and full supervisory control of the automated system, if applicable, and shall not be delegated to another person or entity.
- (b) "Automated Dispensing Device" means a mechanical system which performs operations relative to distributing individual unit of issue packages, and which collects, controls, and maintains all transaction information.
- (c) "Parent Pharmacy" means a pharmacy licensed by the Board which is authorized by the Board to operate a telepharmacy site via real-time data, video, and audio links.
- (d) "Real-time" means that the transmission of information through data, video and audio links is so rapid that the information is available to the parent pharmacy and telepharmacy sites simultaneously.
- (e) "Telepharmacy" means a site where prescription drugs are stored and dispensed that is remote from but under the active control and supervision of a parent pharmacy and a licensed pharmacist, and that is subject to the requirements of W.S. § 33-24-156.
 - (f) "Single Unit Dose" means a package that contains one unit of medication.
- (g) "Traditional Dispensing" means a drug package system in which individual doses are not packaged in single unit dose packages or unit of use packages.

(h) "Unit of Use package" means a package that provides multiple units of doses separated in a medication card or other similarly designed container.

Section 5. Licensing of Facilities.

- (a) An application for licensure to establish, operate or maintain a telepharmacy shall be made on an application provided by the Board and submitted to the Board no less than sixty (60) days prior to opening the telepharmacy.
- (b) A set of blueprints shall be provided to the Board with the initial application for licensure.
- (c) Prior to opening a telepharmacy site, the Board shall inspect the telepharmacy for minimum standards of this Chapter.
- (d) The Board shall be notified with every change of pharmacist-in-charge (PIC).
- (e) Every telepharmacy license shall expire on June thirty (30) of each year and shall be renewed annually by filing an application provided by the Board together with a fee set by the Board, postmarked no later than June thirty (30).
- (f) Initial and renewal telepharmacy license fee shall be \$150.00. Any application for renewal postmarked after June thirty (30) shall be subject to a late fee of \$200.00 in addition to the renewal fee.
- (g) A telepharmacy license shall not be renewed by the Board if a retail pharmacy opens for business within ten (10) miles of the telepharmacy site. A telepharmacy may continue to operate until the end of the current licensure year. The Board shall notify the telepharmacy's parent pharmacy when a retail pharmacy license has been issued to a site within ten (10) miles of the licensed telepharmacy, and shall include the last date the telepharmacy may remain open for business. This ten (10) mile restriction does not apply:
- (i) In counties with a city of fifty thousand (50,000) or more persons as shown in the most recent federal census; or
- (ii) To any facility owned or leased by the state or any subdivision of the state; or
 - (iii) To any facility located in a hospital or clinic setting.

- **Section 6.** Minimum Structural, Security and Equipment Requirements to Operate a Telepharmacy.
- (a) All telepharmacies operating in Wyoming shall meet the following structural requirements:
- (i) Shall consist of an area of no less than 150 square feet exclusive of the patient consulting room;
 - (ii) Shall have a means of delivering a private, secure consultation;
- (iii) Shall include a sink with a hot and cold water supply, exclusive of restroom facilities, with approved sewage disposal;
- (iv) Shall be properly lighted and ventilated. The temperature of the telepharmacy shall be maintained within a range compatible with the proper storage of pharmaceuticals; and
- (v) Shall have adequate shelving and counter space on which to work and the working surface shall be kept clear and uncluttered at all times.
- (b) All telepharmacies operating in Wyoming shall meet the following security requirements:
- (i) Shall be secured with solid core or metal doors with a deadbolt and a locking doorknob;
- (ii) Shall have in place dedicated intrusion detectors, which provide coverage throughout the telepharmacy;
- (iii) Shall have telepharmacy walls which extend to the roof or adjoining floor if a multistory building, or provide security acceptable to the Board;
- (iv) Shall meet all other applicable federal or state regulations concerning security access; and
- (v) Shall store controlled substances in a lockable cabinet which is securely fastened to the structure.
- (c) All telepharmacies operating in Wyoming shall meet the following equipment requirements:
- (i) A computer, scanner, and printer which meet the following requirements:

- (A) All prescription data shall be processed utilizing the aforementioned electronic data processing equipment;
- (B) All new prescriptions shall be scanned, sequentially numbered and the prescription labels shall be produced on site;
- (C) Scanned prescription shall be displayable on the computer terminal at both the telepharmacy and parent pharmacy. Scanned prescriptions must be available for review for every new and refill prescription processed at the telepharmacy;
- (D) All patient demographics, as well as all prescription information, shall be viewable at both the telepharmacy and parent pharmacy in a real time mode;
- (E) Prescriptions dispensed at the telepharmacy site shall be distinguishable from those dispensed at the parent pharmacy including a unique label with a unique identifier in the prescription data base. Furthermore, the initials of the pharmacist who releases the prescription from the parent pharmacy shall appear on the prescription label;
- (F) Video monitors used for the proper identification of and communication and consultation with persons receiving prescription drugs shall be a minimum of twelve inches (12") wide, be of high definition, and provided at both the telepharmacy and the parent pharmacy for direct visual contact between the pharmacist and the patient or the patient's agent; and
- (G) The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and HIPAA-compliant.
- (ii) A real time data, video, and audio link with the parent pharmacy at all times the telepharmacy is open for business;
 - (iii) Fax capability;
- (iv) Any automated dispensing device shall be approved by the Board prior to installation;
- (v) A separate refrigerator located in the telepharmacy, which is sufficient in capacity to serve the needs of the telepharmacy that is equipped with a thermometer and provides a storage temperature of 36-46 degrees Fahrenheit (2-8 degrees Centigrade). The use of such refrigerator shall be limited to the storage of drugs. If a freezer compartment is utilized, it must maintain a temperature of -13 to +14 degrees Fahrenheit (-20 to -10 degrees Centigrade); and

- (vi) Access to a current set of Wyoming pharmacy laws and Wyoming State Board of Pharmacy Newsletter by access to the Board's website.
- (d) Upon written request and for good cause, the Board may waive any of the requirements of this chapter. A waiver that is granted under this section shall only be effective when issued by the Board in writing.

Section 7. Daily Operations.

- (a) A telepharmacy site may not remain open for business if an interruption in data, video or audio link occurs. Whenever an interruption in data, video, or audio link occurs, no prescription shall be dispensed and a sign shall be posted noting the closure and an estimated time when resumption of services can be expected.
- (b) The telepharmacy shall be staffed by a pharmacy technician or a pharmacy intern, licensed by the Board, or by a pharmacist whenever a pharmacy technician or intern is not available. Under no circumstance may the telepharmacy remain open for business unless a pharmacy technician, pharmacy intern or a pharmacist is on duty.
- (c) A pharmacy technician may only perform those pharmacy functions as allowed in Chapter 10 of the Board's rules. Adequate supervision shall be provided by a pharmacist at the parent pharmacy utilizing the data, video and audio link.
- (d) A pharmacy intern may only perform those duties as allowed in Chapter 3 of the Board's rules. Adequate supervision shall be provided by a pharmacist at the parent pharmacy utilizing the data, video and audio link.
- (e) Data entry may be performed at the parent pharmacy or at the telepharmacy site. All entries performed at the telepharmacy site must be verified by a pharmacist at the parent pharmacy prior to dispensing of the prescription at the telepharmacy.
- (f) Verification of prescriptions entered and dispensed at the telepharmacy site shall include:
- (i) For a new prescription, the pharmacist at the parent pharmacy, utilizing the data/audio/video link, shall review the patient profile as required by the Board's rules, the original scanned prescription, the unit of use or stock package selected to be dispensed or the prescription vial that has been filled if traditional dispensing it utilized and the directions as entered by the pharmacy technician or intern. The pharmacist shall view the label affixed to the unit of use package or prescription container to assure accuracy using the image or video link. The offer to counsel shall be made by the pharmacist; or

- (ii) For a refill prescription, the pharmacist at the parent pharmacy, utilizing the data/audio/video link, shall review the patient profile, the label, the filled prescription container to be dispensed and assure the label is affixed to the correct prescription container.
- (g) Verifications of prescriptions entered at the parent pharmacy and dispensed at the telepharmacy shall include:
- (i) The pharmacist shall perform a prospective drug use review of all new and refill prescriptions as outlined in the Board's rules.
- (ii) Utilizing the audio/video link, the pharmacist shall review the label, the stock medication container selected for dispensing, and assure the label is affixed to the correct prescription container at the telepharmacy site.

(h) Counseling.

- (i) All patients receiving a new prescription shall be counseled by a pharmacist in the consultation room or at a private, secure computer by audio/video link with the parent pharmacy or in person if the pharmacist is on duty at the telepharmacy;
- (ii) All patient questions regarding medication therapy or questions regarding over-the-counter products shall be answered by a pharmacist at the parent pharmacy utilizing an audio/video link in the consultation room, at a private, secure computer, or in person if the pharmacist is on duty at the telepharmacy;
- (iii) All counseling performed by the pharmacist shall be in accordance with the Board's rules; and
- (iv) A pharmacy intern may provide counseling at the telepharmacy site provided all counseling is performed under the supervision of a pharmacist at the parent pharmacy and is conducted in the consultation room or at a private, secure computer utilizing an audio/video link to the parent pharmacy.
- (i) Under no circumstance may a prescription be dispensed at the telepharmacy site until all verification required by this section has been fulfilled by a pharmacist at the parent pharmacy and the prescription has been released by the pharmacist. Release of the prescription by the pharmacist at the parent pharmacy shall be documented electronically for each prescription dispensed.
- (j) Under no circumstance shall prescription drug samples be stored or dispensed at the telepharmacy site.

Section 8. Recordkeeping Requirements.

- (a) All written prescriptions presented to the telepharmacy site shall be scanned into the electronic data processing equipment, such that on initial dispensing and each refill, the original prescription may be viewed on the monitor at both the telepharmacy and parent pharmacy site. All scanned prescriptions shall be retained electronically for at least two (2) years from the date scanned. All written prescriptions shall be delivered to the parent pharmacy for filing within 72 hours. Records shall be maintained at the parent pharmacy in files separate from the parent pharmacy files.
- (b) Controlled substance records shall be maintained at the telepharmacy unless specific approval is granted for central storage as permitted by state and federal law.
 - (c) Prescriptions required will be reported to WORx.
- (d) The establishment of minimum standards and practices necessary to ensure safety, accuracy, security, sanitation, recordkeeping, and patient confidentiality shall include:
- (i) Identification of personnel authorized to have access to the drug storage and dispensing areas at the telepharmacy and to receive drugs delivered to the telepharmacy;
- (ii) Procedures for the procurement of drugs and devices to the telepharmacy and into any automated dispensing device used, as applicable; and
- (iii) The criteria for monthly in-person pharmacist inspection of the telepharmacy and appropriate documentation on a form designated by the Board.

Section 9. Pharmacist-in-Charge (PIC) Responsibilities.

- (a) Unless an alternative PIC from the parent pharmacy is specifically designated in writing, the PIC of the parent pharmacy is the PIC for the telepharmacy.
- (b) The PIC and pharmacist-on-duty are responsible for ensuring that the parent pharmacy and telepharmacy are staffed in accordance with Board rules.

Section 10. Delivery and Storage of Drugs.

(a) Prescription drugs shall be delivered to the telepharmacy when a pharmacy technician or pharmacist is present to accept delivery and verify that the drugs were actually received;

- (b) An automated dispensing device shall be stocked with drugs only by a pharmacist licensed by the Board, a registered pharmacy technician or pharmacy intern under the supervision of a pharmacist; and
 - (c) Prescription drugs shall be stored in accordance with Board rules.