

Final Rule

**Department of Health and Hospitals
Board of Pharmacy**

Telepharmacy Services Permit (LAC 46:LIII.2421 *et seq.*)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy has amended *Chapter 24 – Limited Service Providers* of its rules by drafting a new *Subchapter C – Telepharmacy Services*, to create a new classification of pharmacy permit that will enable the establishment of telepharmacy dispensing sites.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 24. Limited Service Providers

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Subchapter C. Telepharmacy Services

§2421. Purpose

- A. As market forces continue to adversely impact community pharmacies, some pharmacies have or will close permanently. In certain parts of the state, such closures create critical access issues for citizens in need of pharmacy services.
- B. As the pharmacy workforce continues to evolve, with changing patterns of distribution of the workforce, certain parts of the state have experienced a shortage of pharmacists, which can adversely impact access to pharmacist care.
- C. In an effort to improve access to pharmacist care and pharmacy services, the board has determined it appropriate to establish standards for the operation and regulation of telepharmacy services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2149 (October 2015).

§2423. Definitions

- A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:
 - Central pharmacy* – a permitted pharmacy in Louisiana that supervises a telepharmacy dispensing site.
 - Still image capture* – a specific image captured electronically from a video or other image capture device.
 - Store and forward* – a video or still image record which is saved electronically for future review.
 - Telepharmacy dispensing site* – a permitted pharmacy supervised by a central pharmacy that offers pharmacy services using a telepharmacy system.
 - Telepharmacy system* – a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:
 - a. Audio and video;
 - b. Still image capture; and
 - c. Store and forward.

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§2425. Telepharmacy Dispensing Site

- A. General Requirements
 1. At the time of its opening, there shall be no other pharmacies licensed by the board within 20 miles (driving distance) of the location of the telepharmacy dispensing site.
 2. A telepharmacy dispensing site permit shall authorize the permit holder to procure and possess prescription and non-prescription drugs and devices, and:
 - a. hold such items for immediate administration directly to a patient pursuant to an order from a lawful prescriber;
 - b. dispense such items to a patient for later use upon the order of a practitioner with prescriptive authority; or
 - c. distribute such items to another entity with lawful authority to procure and possess such items.

3. In the event the telepharmacy dispensing site intends to procure and possess any controlled substances, that pharmacy shall first obtain a Louisiana Controlled Dangerous Substance license as well as the federal registration from the U.S. Drug Enforcement Administration.
 4. The telepharmacy dispensing site shall operate using a telepharmacy system under the control of its supervising central pharmacy.
 5. A central pharmacy may supervise no more than two telepharmacy dispensing sites, and all such sites must be located within the state of Louisiana.
 6. The minimum staffing requirement for a telepharmacy dispensing site shall be a Louisiana-licensed certified pharmacy technician with at least two years of experience as a Louisiana-licensed certified pharmacy technician and with demonstrated proficiency in operating the telepharmacy system used in the telepharmacy dispensing site.
 7. A pharmacist shall approve each prescription before it is taken away from the telepharmacy dispensing site.
- B. Licensing Procedure
1. A person or other entity intending to operate a telepharmacy dispensing site shall complete the application form supplied by the board, and then submit it with any required attachments and the application fee to the board.
 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
 3. A person or other entity who submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2) and shall be subject to disciplinary action by the board.
 4. If determined appropriate by the board, the applicant may be required to meet with a committee of the board or an agent of the board prior to the issuance of the permit.
 5. Regardless of the date issued, the pharmacy permit shall expire on December 31 of every year. No person or other entity may operate a telepharmacy dispensing site with an expired permit; the continued operation of a telepharmacy dispensing site with an expired permit shall substantiate a violation of R.S. 37:1241(A)(12).
 6. In the event a new community pharmacy opens at a location within 20 miles (driving distance) of the telepharmacy dispensing site, then the board shall not renew the telepharmacy dispensing site's pharmacy permit. The board shall notify the central pharmacy supervising the telepharmacy dispensing site of the new pharmacy operating within 20 miles (driving distance) of the telepharmacy dispensing site, and of the requirement for the telepharmacy dispensing site to close permanently on or before the expiration date of the telepharmacy dispensing site's current renewal of its pharmacy permit. The closure shall be accomplished in compliance with the provisions of Section 1133 of the board's rules. In lieu of permanent closure, the telepharmacy dispensing site may elect to apply for and complete the conversion of its permit to a community pharmacy permit prior to the expiration date of the telepharmacy permit.
- C. Maintenance of Permit
1. A telepharmacy dispensing site permit shall be valid only for the person or other entity to whom it is issued, and it shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the physical location for which it was issued.
 2. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall be marked as such, and it shall not serve or be used as an additional or second permit.
- D. Closure of Permit
1. When the owner of the permit intends to close the telepharmacy dispensing site permanently, the owner's managing officer and the pharmacist-in-charge shall be accountable to the board for the proper closure of the pharmacy in compliance with Section 1133 of the board's rules.
 2. Unless approved by the board in advance, all remaining inventory and records shall be transferred to the central pharmacy supervising that telepharmacy dispensing site.
- E. Standards of Practice
1. Environmental Standards
 - a. The prescription department shall consist of an area at least 300 square feet in size; this space shall be restricted to authorized personnel only and not accessible to the general public.
 - b. The prescription department shall contain sufficient fixtures, equipment, and supplies commensurate with the nature and scope of practice for that pharmacy.
 - c. The prescription department shall include a sink with a hot and cold water supply, exclusive of restroom facilities, with approved sewage disposal.

- d. All areas where drugs and devices are stored shall be dry, well-lighted, well ventilated, and maintained at temperatures which will ensure the integrity of drugs prior to their dispensing as stipulated by the United States Pharmacopeia and/or manufacturer's or distributor's product labeling unless otherwise indicated by the board;
 - e. The prescription department shall be secured by a physical barrier with suitable locks and a monitored alarm system capable of detecting unauthorized entry.
 - f. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information; and
 - g. The dispensing site shall be configured and equipped to sustain optimal operation of all the technological components of the telepharmacy system.
2. Minimum Staffing Requirements.
- a. The pharmacist-in-charge of the supervising central pharmacy shall be the pharmacist-in-charge of the telepharmacy dispensing site, and this requirement shall operate as an exception to the provisions of Section 1105.A.2 and Section 1105.K of the board's rules. However, the pharmacist-in-charge shall comply with the remaining provisions of Section 1105 of the board's rules.
 - b. The telepharmacy dispensing site does not require the personal presence of a pharmacist, but it is permissible for a pharmacist to practice in that site.
 - c. In the absence of a pharmacist, the site shall be staffed by one – and only one – Louisiana-licensed certified pharmacy technician. The technician present at the telepharmacy dispensing site shall be included with the other personnel at the supervising central pharmacy when calculating the ratio of pharmacists to technicians.
 - d. A pharmacy intern may not practice at a telepharmacy dispensing site.
 - e. Additional clerical personnel may also be present at the site.
3. Operational Standards
- a. The telepharmacy dispensing site shall comply with the provisions of Chapters 11, 25, 27, and 29 of the board's rules except when this Subchapter grants exceptions or imposes more stringent requirements.
 - b. The telepharmacy dispensing site shall be connected to its supervising central pharmacy using the telepharmacy system.
 - c. In the event of an interruption in the proper operation of the telepharmacy system, the telepharmacy dispensing site must immediately cease operations. No prescription shall be dispensed during the interruption, and further, the staff shall post a sign at the entrance advising the public of an estimated date or time of resumption of services.
 - d. The dispensing of prescriptions shall be construed as completed at the central pharmacy; therefore, the telepharmacy dispensing site shall use the central pharmacy's dispensing information system.
 - e. The telepharmacy system shall permit prescription labels to be generated from the central pharmacy or the telepharmacy dispensing site.
 - i. New prescriptions may be received and entered at the central pharmacy with a label printed at the telepharmacy dispensing site; or
 - ii. New prescriptions received at the telepharmacy dispensing site may be entered by the technician with all verification, utilization review, and final check the responsibility of the pharmacist at the central pharmacy.
 - f. As part of the final check, the pharmacist shall verify the source container, prescription medication, and prescription label against the prescription form, using the technology in the telepharmacy system.
 - g. A pharmacist shall counsel the patient or patient's agent for all new prescriptions and refills, using the technology in the telepharmacy system.
 - h. The pharmacist-in-charge shall be responsible for routine inspections of the telepharmacy dispensing site. The policies and procedures shall identify the inspection criteria to be monitored. Each inspection shall be conducted no later than 30 days after the previous inspection. The inspection reports detailing the findings of each inspection shall be retained for at least two years, and further, shall be readily retrievable upon request by the board or its agent.
4. Recordkeeping Requirements
- a. The dispensing information system shall be capable of recording the names or initials of the pharmacist responsible for final verification of the prescription as well as the technician assisting in the dispensing process, and to print those identities on the prescription label.

- b. Prescriptions filled at the telepharmacy dispensing site shall be distinguishable on records from those filled at the central pharmacy
- c. Records of activities at the telepharmacy dispensing site shall be distinguishable from the records of activities at the central pharmacy.
- d. Telepharmacy dispensing sites holding controlled substances shall maintain a perpetual inventory of controlled dangerous substances and drugs of concern.

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