

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

Subchapter A. General Requirements

§1101. Pharmacy

- A. Qualification. Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.
- B. Appearance. The applicants, including the pharmacist-in-charge, may be required to personally appear before the board prior to a board decision on the permit application.
- C. Pharmacy Permit.
 1. The initial pharmacy permit application shall be completed and signed by the pharmacist-in-charge and the owner of the pharmacy and submitted to the board for approval. An application for a pharmacy permit shall expire one year after the date of receipt in the board office.
 2. Renewal. A pharmacy permit that has not been renewed by December 31 of each year shall expire and be null and void.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007).

§1103. Prescription Department Requirements

- A. A prescription department of a pharmacy shall provide sufficient floor space allocated to ensure that drugs are compounded and dispensed in a well lighted, ventilated, climate controlled, and safely enclosed structure.
- B. Restricted. A prescription department is a restricted area.
- C. Square Footage. A prescription department that is new or remodeled on or after January 1, 2004 shall be not less than three hundred (300) total square feet, and shall be inaccessible to the public.
- D. Prescription Counter. A prescription counter on which to compound or dispense medications shall have a working surface of not less than a minimum of twenty-four (24) total square feet. The minimum unobstructed free working surface shall be kept clear at all times for the compounding or dispensing of prescriptions.
- E. Prescription Aisle Space. The aisle space behind the prescription counter shall be not less than thirty (30) inches in width.
- F. Prescription Department Plumbing. A sink equipped with hot and cold running water shall be located within the prescription department. A sink located in a pharmacy restroom shall not be sufficient to satisfy this requirement.
- G. Electronic Record Keeping System. An electronic record keeping system shall be utilized in a pharmacy department and shall be a complete, accurate, and readily retrievable prescription record keeping and storage system.
- H. Drug Inventory.
 1. Storage. The pharmacy shall provide sufficient space on-site for proper storage of labels, prescription containers, and an adequate prescription inventory in order to compound and dispense prescription orders. Drugs that require special storage shall be properly stored.
 2. Missing or Damaged Inventory. When significant drug inventory is missing or damaged for any reason, the pharmacy owner or pharmacist-in-charge shall file with the board a signed statement of the circumstances of such occurrence and evidence that the appropriate law enforcement authorities were notified as required by law.

3. Equipment. The pharmacy shall provide sufficient fixtures, equipment, and utensils to ensure that drugs are properly compounded and dispensed.
- I. Pharmacy Security. The prescription department or the premises housing the prescription department shall be adequately secured by the installation of partitions and secured entrances, which shall be locked by a pharmacist and made inaccessible when the prescription department is closed. The prescription department or any premises housing a prescription department shall be adequately secured by an alarm system.
- J. Emergency Access. An additional key to the prescription department may be maintained in a secure location outside the prescription department for use during an emergency. A log shall be maintained with the key, indicating the name of each non-pharmacist using this key, the date and time of entry, and the nature of the emergency.
- K. References. A printed copy of the *Louisiana Board of Pharmacy Laws and Regulations* shall be maintained and readily available within the prescription department of a pharmacy. The pharmacy shall maintain access to current and appropriate reference materials pertinent to the pharmacy practice, including but not limited to, pharmacology, drug interactions, dosing, toxicity, and patient counseling.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, amended LR 39:315 (February 2013).

§1105. Pharmacist-in-Charge

- A. The opportunity to accept an appointment as the pharmacist-in-charge (PIC) of a pharmacy is a professional privilege. The following requirements are attached to a PIC privilege.
 1. The acquisition of the PIC privilege shall require:
 - a. Possession of an active Louisiana pharmacist license;
 - b. Active pharmacy practice for a minimum of two years under the jurisdiction of any board of pharmacy in the United States; and
 - c. The completion of the Affidavit of Responsibility and Duties described below.
 2. The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 20 hours per week the PIC shall be present and practicing at least 50 percent of the normal business hours.
- B. An initial and renewal pharmacy permit application shall designate and identify the licensed pharmacist-in-charge.
- C. Authority and Accountability. The pharmacist-in-charge shall be ultimately responsible for complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.
- D. Policy and Procedure Manual. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures regarding quality pharmacy services including drug control, distribution, patient compliance accountability, inspection, and record keeping.
- E. Circumvention. It is a violation of the pharmacy permit for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department in the compliance of federal and state pharmacy laws and regulations.
- F. Records. The pharmacist-in-charge shall be responsible for the proper maintenance of all prescription records. This necessarily includes electronic prescription records and the system's compliance and capacity to produce the required records.
- G. Recall. The pharmacist-in-charge shall be responsible for the implementation of a recall procedure that can be readily activated to assure patient safety.
- H. Discontinued and Outdated Drugs. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures to ensure that discontinued or outdated drugs, or containers with worn, illegible, or missing labels are withdrawn from the pharmacy inventory.
- I. Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacist-in-charge designation for a pharmacy has changed.
 1. The permit holder shall notify the board within ten days of the prior pharmacist-in-charge's departure date. The permit holder shall designate a new pharmacist-in-charge within ten days of the departure of the prior pharmacist-in-charge.

2. The new pharmacist-in-charge shall afford the board written notice of his newly designated pharmacist-in-charge status within ten days of the departure of the prior pharmacist-in-charge.
 3. A pharmacist-in-charge who voluntarily leaves a pharmacy shall give written notice to the board and the owner of the permit at least ten days prior to this voluntary departure, unless replaced in a shorter period of time.
- J. Affidavit of Responsibility and Duties. The designated pharmacist-in-charge shall sign an affidavit on a form supplied by the board indicating his understanding and acceptance of the duties and responsibilities of a pharmacist-in-charge. This notarized document shall be submitted to the board for inclusion in the pharmacy's record in the board office.
- K. A pharmacist shall not hold a pharmacist-in-charge position at more than one pharmacy permit, unless approved by the board.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004, amended LR 38:1239 (May 2012).

§1107. Pharmacy Operation

- A. A pharmacist shall be on duty at all times during regular open hours of the pharmacy.
- B. A pharmacy shall be open for business a minimum of 10 hours per week, with said business hours posted at the building entrance in full public view from outside the premises.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004, amended LR 34:1408 (July 2008).

§1109. Pharmacist Temporary Absence

- A. A pharmacist shall be considered to be temporarily absent from the prescription department when not within the confines of the prescription department but remains on-site.
- B. The pharmacist may be temporarily absent from the prescription department for breaks and meal periods without closing the prescription department and removing pharmacy personnel providing the following conditions are met:
 1. at least one certified pharmacy technician or pharmacy intern remains in the prescription department;
 2. the pharmacist is available for emergencies;
 3. the temporary absence does not exceed thirty minutes at a time and a total of sixty minutes in a twelve hour period;
 4. the pharmacist reasonably believes that the security of the prescription department will be maintained in his absence; and
 5. a notice is posted that includes the following information:
 - a. the fact that the pharmacist is taking a break; and
 - b. the time the pharmacist will return.
- C. If the pharmacist, in his professional judgment, determines it necessary, all personnel shall be removed from the pharmacy and the pharmacy shall be secured for the duration of the temporary absence, and notice shall be posted indicating the pharmacy is closed.
- D. During a temporary absence, certified pharmacy technicians or pharmacy interns may continue to process prescription orders, provided that no orders processed during the pharmacist's temporary absence be removed from the prescription department prior to the final check by the pharmacist.
- E. If the pharmacist is absent less than five minutes from the prescription department, this absence is not considered a "temporary absence" within the meaning of this chapter and will not require a posted notice, provided the prescription department's security is not compromised.
- F. If at any time the pharmacist deems it necessary to leave the on-site facility, the pharmacy shall be closed in accordance with §1111.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 27:2237 (December 2001) effective January 1, 2002, amended LR 29:2088 (October 2003), effective January 1, 2004.

§1111. Pharmacist Absence

- A. A pharmacist is considered absent from the prescription department when he is not in the prescription department and is off-site.
- B. When a pharmacist is absent from the prescription department, the prescription department must be securely closed and made inaccessible. A sign shall be displayed in a conspicuous position in front of the prescription department giving notice of closure. The sign shall be at least 8½ x 11 inches with the following wording in black letters at least one inch high: PRESCRIPTION DEPARTMENT CLOSED.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 24:692 (April 1998), amended LR 29:2089 (October 2003), effective January 1, 2004.

§1113. Mechanical Drug Dispensing Devices

- A. Dispensing of prescription drugs directly to a patient or caregiver by mechanical devices or machine is prohibited. This prohibition shall not apply to automated medication systems as defined and provided for in Chapter 12 of these regulations.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004.

§1115. Advertising

- A. False, fraudulent, deceptive, or misleading advertising as prohibited by R.S. 37:1241 of the Pharmacy Practice Act and this section shall include, but is not limited to, any public misrepresentation done or made with the knowledge, whether actual or constructive, that is untrue or illegal, or is said to be done falsely when the meaning is that the party is in fault for its error. Actual or constructive knowledge as used in this context shall include intentionally, negligently, mistakenly, or accidentally representing an untrue fact.
- B. No person shall carry on, conduct, or transact business under a name which contains a part thereof the words "pharmacist", "pharmacy", "apothecary", "apothecary shop", "chemist's shop", "drug store", "druggist", "drugs", or any word or words of similar or like import, or in any manner by advertisement, circular, poster, sign, or otherwise describe or refer to a place of business by the terms of "pharmacy", "apothecary", "apothecary shop", "chemist's shop", "drug store", "drugs", or any word or words of similar or like import, unless the place of business is a pharmacy validly permitted by the board.
- C. Pharmacies and pharmacists are prohibited from advertising professional ability, experience, integrity, or professional qualifications, or soliciting professional practice by means of providing prescribers of prescriptions with prescription forms imprinted with any material referring to a pharmacy or pharmacist.
- D. No advertising shall include any reference, direct or indirect, to any controlled dangerous substance as provided for in Schedules II, III, IV, or V of RS. 40:964. The provision of coupons or vouchers for controlled substances through authorized prescribers, which accompany legitimate prescriptions for such controlled substances issued to patients, shall not be prohibited by this section.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007).

§1117. Centralized Prescription Processing

Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, repealed LR 33:1131 (June 2007).

Subchapter B. Pharmacy Records

§1119. Definitions

- A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:
- “*Department*” means the Louisiana Department of Health and Hospitals or its successor.
- “*Password*” means a private identification that is created by a user to obtain access to an electronic pharmacy information system.
- “*Personal identifier*” means a unique user name or number for identifying and tracking a specific user’s access to a pharmacy information system such as social security number, user identification number, or employee number.
- “*Positive identification*” means a method of identifying an individual who prescribes, administers, or dispenses a prescription drug.
- a. A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:
 - i. A manual signature on a hard copy record;
 - ii. A magnetic card reader;
 - iii. A bar code reader;
 - iv. A thumbprint reader or other biometric method;
 - v. A proximity badge reader;
 - vi. A register in which each individual pharmacist dispensing a prescription shall sign a log each day, attesting to the fact that the information entered into the electronic record keeping system has been reviewed that day, and is correct as stated.
 - vii. A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the prescription drug. The printout must be maintained for two years and made available on request to an agent of the board.
 - b. A method relying on a magnetic card reader, a bar code reader, or a proximity badge reader must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR 40:2252 (November 2014), effective January 1, 2015.

§1121. General Requirements

- A. Requirements.
1. All records relating to the practice of pharmacy shall be uniformly maintained for a period of two years, be readily available, and promptly produced upon request for inspection by an agent of the board during regular business hours.
 2. All records required by the laws and regulations of the board shall be provided to the board, or its agents, within seventy-two (72) hours of request, unless a shorter period is required, as determined by the board or its agent.
 3. The failure to produce any pharmacy records requested by the board or its agent within seventy-two (72) hours of such request shall substantiate a violation of R.S. 37:1241(A)(22).
- B. Accountability. The holder of the pharmacy permit and the pharmacist-in-charge shall account for all prescription drug transactions, consisting of:
1. Acquisition records – invoice receipts of drugs acquired;
 2. Disposition records – drugs dispensed pursuant to prescription orders, administered pursuant to medical orders, or distributed pursuant to purchase orders, and
 3. Inventory records – drugs in current possession.
- C. Retention. Except as provided in Section 1123, all records required by this Chapter and by Louisiana law shall be retained for a minimum of two years from the most recent transaction. The failure to retain such records for at least two years shall substantiate a violation of R.S. 37:1229.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR 40:2252 (November 2014), effective January 1, 2015.

§1123. Records

- A. There shall be positive identification of the pharmacist, intern, technician, or technician candidate responsible for performing all activities related to the practice of pharmacy including, but not limited to:
 - 1. Prescription information entered into the pharmacy information system;
 - 2. Prospective drug utilization review;
 - 3. Prescription dispensing;
 - 4. Administration of immunizations.
- B. A pharmacy may use one of the following types of pharmacy information systems:
 - 1. A system that utilizes the original hard copy prescription to document the initial dispensing of a prescription, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system shall require the manual signature or initials of a pharmacist on a hard copy record as specified in Paragraph E of this Section.
 - 2. An electronic recordkeeping system that complies with the provisions of 21 CFR 1311 and documents the positive identification of the pharmacist responsible for the practice of pharmacy. Such systems shall provide for routine backups at least once per day.
- C. All pharmacy information systems shall be capable of providing immediate retrieval (via display and hard copy printout or other mutually agreeable transfer media) of patient profile information for all prescriptions dispensed within the previous two years. This information shall include the following minimum data:
 - 1. The original prescription number;
 - 2. Date of issuance of the original prescription order by the prescriber;
 - 3. Date of dispensing by the pharmacist;
 - 4. Full name and address of the patient;
 - 5. Full name and address of the prescriber;
 - 6. Directions for use;
 - 7. The name, strength, dosage form, and quantity of the drug prescribed;
 - 8. The quantity dispensed if different from the quantity prescribed;
 - 9. The pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in §515 of these rules, and the pharmacist responsible for dispensing;
 - 10. The total number of refills authorized by the prescriber; and
 - 11. The refill history of the prescription as defined in Paragraph D of this Section.
- D. The refill history of the prescription record maintained in the pharmacy information system shall include, but is not limited to:
 - 1. The prescription number;
 - 2. The name and strength of the drug dispensed;
 - 3. The date of the refill or partial fill;
 - 4. The quantity dispensed;
 - 5. The pharmacist responsible for prospective drug utilization review as defined in §515 of these rules, and the pharmacist responsible for dispensing each refill;
 - 6. The total number of refills or partial fills dispensed to date for that prescription order
- E. The hard copy documentation required pursuant to Paragraph (B)(1) of this Section shall be provided by each individual pharmacist who makes use of such system by signing a statement attesting to the fact that the prescription information entered into the computer is correct as displayed.
- F. Backup Support System
 - 1. The pharmacy information system shall be capable of being reconstructed in the event of an electronic or computer malfunction or unforeseen accident resulting in the destruction of the system or the information contained therein. To prevent the accidental loss of electronic records, an adequate backup system shall be maintained. Backup support systems shall be updated at least once daily.
 - 2. In the event the pharmacy information system experiences down time, a record of all refills dispensed during such time shall be recorded and then entered into the pharmacy information system as soon as it is available for use. During the time the pharmacy information system is

not available, prescriptions may only be refilled if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.

- G. A pharmacy purging a pharmacy information system of prescription records shall develop a method of recordkeeping capable of providing retrieval (via display, hard copy printout, or other mutually agreeable transfer media) of prescription order information for all prescriptions filled or refilled within the previous two years. This information shall include, at a minimum, the following data:
1. Pharmacy name and address;
 2. Original prescription number;
 3. Date of issuance of the original prescription order by the prescriber;
 4. Date of original dispensing by the pharmacist;
 5. Full name and address of the patient;
 6. Full name and address of the prescriber;
 7. Directions for use;
 8. Name, strength, dosage form, and quantity of the drug prescribed;
 9. Quantity dispensed if different from the quantity prescribed;
 10. Total number of refills authorized by the prescriber;
 11. Total number of refills dispensed to date for that prescription order;
 12. Date of each refill;
 13. Name or initials of each individual dispensing pharmacist.
- H. A log shall be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. At a minimum, the log shall contain the following information:
1. Date and time of change;
 2. Change(s) made;
 3. Pharmacist making the change.
- I. Prescriptions entered into a pharmacy information system but not dispensed shall meet all of the following requirements:
1. The complete prescription information shall be entered in the computer system;
 2. The information shall appear in the patient's profile; and
 3. There is positive identification, in the pharmacy information system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system.
- J. With respect to oral prescriptions received in the pharmacy and then transcribed to written form in the pharmacy, or written prescriptions received by facsimile in the pharmacy, or written prescriptions presented to the pharmacy, a pharmacy may use an electronic imaging system to preserve such prescriptions, but only if:
1. The system is capable of capturing, storing, and reproducing the exact image of a prescription, including the reverse side of the prescription form;
 2. Any notes of clarification of and alterations to a prescription shall identify the author and shall be directly associated with the electronic image of the prescription form;
 3. The image of the prescription form and any associated notes of clarification to or alterations to a prescription are retained for a period of not less than two years from the date the prescription is last dispensed;
 4. Policies and procedures for the use of an electronic imaging system are developed, implemented, reviewed, and available for board inspection; and
 5. The prescription is not for a controlled dangerous substance listed in Schedule II
- K. Filing and Retention of Prescription Forms
1. Written prescription forms (including transcriptions of verbal prescriptions received in the pharmacy, prescriptions received by facsimile in the pharmacy, as well as written prescription forms presented to the pharmacy) shall be assembled and stored in prescription number sequence. Prescriptions for controlled dangerous substances listed in Schedule II shall be filed separately from all other prescriptions. Where multiple medications are ordered on a single prescription form and includes one or more controlled dangerous substances listed in Schedule II, then such forms shall be filed with other Schedule II prescriptions. These original hard copy prescription forms shall be retained in the prescription department for a minimum of two years following the most recent transaction.
 2. For those pharmacies utilizing an electronic imaging system as described in Paragraph J of this Section, written prescription forms may be assembled and stored in prescription number sequence, or in the alternative, a date scanned sequence. Further, these original hard copy

prescriptions shall be retained in the prescription department for a minimum of one year following the most recent transaction.

3. Prescription forms received as an electronic image or electronic facsimile directly within the pharmacy information system shall be retained within the information system for a minimum of two years following the most recent transaction. Further, the pharmacy may produce a hard copy of the prescription form but shall not be required to do so merely for recordkeeping purposes.
4. Electronic prescriptions – those generated electronically by the prescriber, transmitted electronically to the pharmacy, and then received electronically directly into the pharmacy information system – shall be retained within the information system for a minimum of two years following the most recent transaction. The pharmacy may produce a hard copy of the prescription, but shall not be required to do so merely for recordkeeping purposes.

L. Patient Profiles

All pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from that pharmacy.

1. The dispensing pharmacist shall be responsible for ensuring that a reasonable effort has been made to obtain, document, and maintain at least the following records:
 - a. The patient's data record, which should consist of, but is not limited to, the following information:
 - i. Full name of the patient for whom the drug is intended;
 - ii. Residential address and telephone number of the patient;
 - iii. Patient's date of birth;
 - iv. Patient's gender;
 - v. A list of current patient specific data consisting of at least the following:
 - (a) Known drug related allergies,
 - (b) Previous drug reactions,
 - (c) History of or active chronic conditions or disease states,
 - (d) Other drugs and nutritional supplements, including nonprescription drugs used on a routine basis, or devices.
 - vi. The pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug.
 - b. The patient's drug therapy record, which shall contain at least the following information for all the prescriptions that were filled at the pharmacy:
 - i. Name and strength of the drug or device;
 - ii. Prescription number;
 - iii. Quantity dispensed;
 - iv. Date dispensed;
 - v. Name of the prescriber;
 - vi. Directions for use.
 - c. Any information that is given to the pharmacist by the patient or caregiver to complete the patient data record shall be presumed to be accurate, unless there is reasonable cause to believe the information is inaccurate.

M. Exceptions

The provisions of this Section shall not apply to the following:

1. Pharmacies permitted as hospital pharmacies by the board shall comply with the provisions of Chapter 15 of these rules.
2. Other pharmacies providing medications and services to patients within facilities other than hospitals licensed by the department shall comply with the provisions of Section 1124 of these rules for those activities.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR 36:755 (April 2010), amended LR 40:2253 (November 2014), effective January 1, 2015.

§1124. Records of Pharmacy Services for Patients in Licensed Healthcare Facilities Other than Hospitals

A. Definitions

Dispensing of a drug pursuant to an inpatient prescription – the professional review by a pharmacist required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a prescriber. In the case of an automated medication system meeting the requirements of Chapter 12 of these rules, the final association with the name of a particular inpatient will be deemed to have occurred when the pharmacist has given the final approval to the patient specific order in the system.

Electronic drug record keeping system – a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.

Inpatient – a person receiving health care services within a healthcare facility other than a hospital licensed by the department.

Inpatient Prescription – a written, electronic or oral order for a drug for use in treating a patient within a healthcare facility other than a hospital licensed by the department.

Password – a private identification that is created by a user to obtain access to an electronic drug record keeping system.

Personal identifier – a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as social security number, user identification number, or employee number

Positive identification –

- a. has the same meaning as defined in Section 1119 of these rules, except that a specific facility having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for the prescribing and administration of a drug, provided the pharmacist-in-charge has determined:
 - i. adequate audit controls are in place to detect and deter drug diversion;
 - ii. adequate access controls are in place to assure the identity of the user and to assign accountability of the user for any drug transaction;
 - iii. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;
 - iv. an ongoing quality assurance program is in place to ensure that (a) through (c) of this term are being fulfilled and reviewed; and
 - v. appropriate policies and procedures are in place to address items (a) through (d) of this term.
- b. All of the above notwithstanding, however, positive identification as defined in Section 1119 of these rules shall always be used to document the:
 - i. Dispensing, compounding, or prepackaging of a drug;
 - ii. Removal and possession of a controlled substance to administer to a patient; and
 - iii. Waste of a controlled substance.

B. Drug Distribution and Control

The pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs.

1. Procedure Manual. The pharmacist-in-charge shall maintain defined procedures for the safe and efficient distribution of medications and pharmacy care. A current copy of the manual shall be available for board inspection upon request.
2. Inventories. The pharmacist-in-charge shall be responsible for the performance of an annual inventory of all controlled dangerous substances within his span of control, in compliance with the provisions of Section 2733 of these rules.
3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:
 - a. A record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured.
 - b. All drug orders and records relating to the practice of pharmacy.
 - i. Records of drugs dispensed shall include, but are not limited to:
 - (a) The name, strength, and quantity of drugs dispensed;
 - (b) The date of dispensing;

- (c) The name of the inpatient to whom, or for whose use, the drug was dispensed; and
 - (d) Positive identification of all pharmacists involved in the dispensing.
 - ii. All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:
 - (a) The name of the inpatient to whom, or for whose benefit, the activity was performed;
 - (b) The nature of the pharmacy practice activity performed;
 - (c) The results of the activity, if applicable; and
 - (d) Positive identification of all pharmacists involved in the activity; identifying the function performed by each pharmacist.
 - iii. Records of drugs dispensed to patients for use outside the facility shall be maintained in compliance with Section 1123 of these rules.
- c. A record of all drugs compounded or prepackaged for use only within that facility, which shall include at least the following:
 - i. Name of drug, strength, quantity, and dosage form;
 - ii. Manufacturer's or distributor's control number (except for patient-specific sterile compounded preparations);
 - iii. Manufacturer's or distributor's name, if a generic drug is used;
 - iv. Pharmacy control number;
 - v. Manufacturer's or distributor's expiration date (except for patient-specific sterile compounded preparations);
 - vi. Pharmacy's expiration date or beyond-use date;
 - vii. Identification of the licensed person responsible for the compounding or prepackaging of the drug.
- d. A record of the distribution of drugs to patient care areas and other areas of the facility held for administration, which shall include at least the following:
 - i. The name, strength, dosage form, and amount of the drug distributed;
 - ii. The area receiving the drug;
 - iii. The date distributed;
 - iv. Identification of the individual receiving the drug if it is a controlled dangerous substance;
 - v. The area of the facility receiving the controlled dangerous substance shall make a record of all such drugs administered to patients. Such records shall include at least the following:
 - (a) Name of the patient;
 - (b) Name, dosage form, and strength when applicable of the drug;
 - (c) Date and time the drug was administered;
 - (d) Quantity administered;
 - (e) Positive identification of the personnel administering the drug.
- e. A log that shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:
 - i. Date and time of change;
 - ii. Changes made;
 - iii. Person making the change.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 40:2255 (November 2014), effective January 1, 2015.

§1125. Security and Confidentiality

- A. The holder of the pharmacy permit shall provide adequate safeguards against improper, illegal, or unauthorized manipulation or alteration of any records in the pharmacy information system.
- B. A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential information. If confidential health information is not transmitted directly between a pharmacist and a practitioner, but is transmitted through a data communications device, the

confidential health information may not be accessed, maintained, or altered by the operator of the data communications device. Confidential information is privileged and may be released only subject to federal privacy laws and regulations, and subject to applicable Louisiana statutes.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23.1312, (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, amended LR 40:2256 (November 2014), effective January 1, 2015.

§1127. Register

Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, repealed LR 40:2256 (November 2014), effective January 1, 2015.

§1129. Confidentiality

Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004, repealed LR 40:2256 (November 2014), effective January 1, 2015.

Subchapter C. Pharmacy Opening, Closing, Change of Ownership, and Change of Location Procedures

§1131. Pharmacy Opening Procedures

- A. The board has established the following procedures as a prerequisite to the opening of any pharmacy:
1. Application Form. The applicant shall obtain a Pharmacy Permit Application and Louisiana Controlled Dangerous Substance License Application from the board. The completed form(s) shall be signed by the pharmacist-in-charge and returned to the board office, with appropriate fees, not less than thirty days prior to the anticipated opening of the pharmacy.
 2. Inspection. After the board has reviewed and approved the application, a board compliance officer shall conduct an on-site inspection of the premises.
 3. Compliance. Upon receipt of satisfactory evidence that the applicant is in complete compliance, the board shall issue a pharmacy permit and, if requested, a Louisiana Controlled Dangerous Substance License.
 4. DEA Registration. If applicable, the applicant shall obtain the appropriate application from the DEA, and then return said form, with appropriate fees, to the DEA.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004.

§1133. Pharmacy Closing Procedures

- A. A pharmacy permit holder shall notify the public and the board prior to discontinuing a prescription department operation, or upon petitioning for bankruptcy.
1. Public Notice. The holder of a pharmacy permit shall post a closing notice in a conspicuous place in the front of the prescription department, and at all public entrance doors to the pharmacy. The closing notice to the public shall be posted not less than ten days prior to the anticipated date of closure, and the notice shall contain the following minimum information:
 - a. the anticipated date of closure of the prescription department;
 - b. the anticipated date of transfer or relocation of prescription files, if different than closure date;

- c. the name and address of the pharmacy to which the prescription files will be transferred; and
 - d. a statement that if a patient objects to the transfer of their prescription files to the intended recipient pharmacy, the patient shall make alternative arrangements for the transfer of their prescription files to another pharmacy prior to the anticipated file transfer date.
- 2. Board Notice. The holder of a pharmacy permit shall send written notice to the board not less than ten days prior to the anticipated date of closure, and the notice shall include the following minimum information:
 - a. the anticipated date of closure of the prescription department;
 - b. the name and address of the permitted pharmacy operating within a reasonably close proximity of the closing pharmacy that shall be the custodian of the transferred prescription files; and
 - c. any prescription drug sale or transfer, with a complete drug inventory including recipient's name and address and/or seizure action, sequestration, executory process, public auction, liquidation, creditor assignment, and bankruptcy.
- 3. Disposition of Inventory.
 - a. Drugs Listed in Schedule II. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by an executed DEA Form 222, or its successor. Alternatively, these drugs shall be inventoried on the DEA Form 41 (Registrants Inventory of Drugs Surrendered), or its successor, and then either returned to the regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board. The permit holder shall retain triplicate copies of returns, transfers, and/or destructions.
 - b. Drugs Listed in Schedules III, IV, or V. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by appropriate inventory records. Alternatively, these drugs shall be inventoried on the DEA Form 41, or its successor, and then either returned to the regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board.
 - c. All Other Prescription Drugs. These drugs shall be returned to the supplier, transferred to an authorized registrant, or destroyed.
- 4. Surrender of Pharmacy Permit and Louisiana Controlled Dangerous Substance License. The holder of the permit and license shall surrender same to the board upon closing, accompanied by written confirmation of the:
 - a. surrender of unused DEA order forms and the DEA registration certificate to the regional DEA office with a memorandum indicating the closing date of the prescription department;
 - b. location of applicable records of controlled dangerous substance and other prescription drugs, order forms, inventories, acquisitions, and purchase records, with commitment to store such records for not less than two years, and to make such records available for inspection by an agent of the board; and
 - c. removal of all pharmacy signage from the property.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004.

§1135. Pharmacy Change of Ownership Procedures

- A. The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises.
 - 1. A change of ownership of a pharmacy is evident under the following conditions:
 - a. sale of a pharmacy;
 - b. death of a sole proprietor;
 - c. the addition or deletion of one or more partners in a partnership;
 - d. bankruptcy sale, or
 - e. a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

2. The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.
3. Upon receipt of the new permit, the seller shall:
 - a. notify the board of the transaction, including the identity of the new owner(s); and
 - b. surrender the voided pharmacy permit and voided Louisiana Controlled Dangerous Substance License to the board.
4. Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2092 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007).

§1137. Pharmacy Change of Location Procedures

- A. The board has established the following procedures for changing the location of any pharmacy that does not involve a change of ownership or divestiture of that pharmacy:
 1. The permit holder shall notify the board in writing prior to relocating a prescription department operation.
 2. The proper notice procedures for the relocation shall include the notice requirements applicable to pharmacy closing procedures noted in this subpart. However, a permit cancellation is not required for a permit holder that is moving to a location in reasonably close proximity to the original location and planning to continue pharmacy operations without a transfer of ownership. The permit holder shall notify the board for the proper re-designation of permit address and re-issuance of that same permit.
 3. Inspection. A board compliance officer shall conduct an on-site inspection of the premises following receipt of written notice in the board office and prior to the opening of a prescription department in a new location.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2092 (October 2003), effective January 1, 2004.

Subchapter D. Off-Site Services

§1139. Definitions

- A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section, unless the context clearly indicates otherwise.
 - Centralized Prescription Dispensing* – the fulfillment by one permitted pharmacy of a request from another permitted pharmacy to fill or refill a prescription drug order.
 - On-Site Pharmacy* – a permitted pharmacy which utilizes centralized prescription dispensing services from a remote dispenser or remote processing services from a remote processor.
 - Remote Dispenser* – a Louisiana permitted pharmacy which provides centralized prescription dispensing services for another permitted pharmacy in Louisiana.
 - Remote Processing Services* – the processing of a medical order or prescription drug order by one permitted pharmacy on behalf of another permitted pharmacy, including:
 - a. receipt, interpretation, or clarification of an order;
 - b. data entry and information transfer;
 - c. interpretation of clinical data;
 - d. performance of drug utilization review; and
 - e. provision of drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation or physical transfer of drugs.
 - Remote Processor* – a Louisiana permitted pharmacy which provides remote processing services for another permitted pharmacy in Louisiana.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007), amended LR 39:313 (February 2013).

§1141. Centralized Prescription Dispensing

A. General Requirements

1. An on-site pharmacy may obtain centralized prescription dispensing services from a remote dispenser provided the pharmacies:
 - a. have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
 - b. share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.
2. All drugs dispensed to a patient that have been dispensed by a remote dispenser shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmacy primary care activities.

B. Policies and Procedures

1. On-site pharmacies and remote dispensers engaging in the acquisition or provision of centralized dispensing services shall maintain a policy and procedure manual for reference by all personnel; it shall be made available for inspection and copying by the board.
2. At a minimum, the manual shall include policies for:
 - a. a description of how the parties will comply with federal and state laws and regulations;
 - b. the maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling process;
 - c. the maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;
 - d. the maintenance of a mechanism to identify on the prescription label all pharmacies involved in the dispensing of the prescription drug order; and
 - e. the provision of adequate security to protect the confidentiality and integrity of patient information and to prevent its illegal use or disclosure.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007).

§1143. Remote Processing of Medical Orders or Prescription Drug Orders

A. General Requirements

1. An on-site pharmacy may obtain remote processing services from a remote processor provided the pharmacies:
 - a. have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
 - b. share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.
2. A contract or agreement for remote processing services shall not relieve the on-site pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services. The activities authorized by this Section are intended to supplement pharmacy services and are not intended to eliminate the need for an on-site pharmacy or pharmacist.
 - a. In the event the pharmacy soliciting remote processing services is located within a hospital with more than 100 occupied beds, there shall be at least one pharmacist on duty at that hospital at all times, and any remote processing services provided to that pharmacy shall be supplemental in nature.
 - b. Repealed.

B. Access to Patient Information

1. The pharmacist at the remote processor shall have secure electronic access to the on-site pharmacy's patient information system and to all other electronic systems directly involved with the preparation of prescriptions that the on-site pharmacist has access to when the on-site pharmacy is operating. The pharmacist at the remote processor shall receive training in the use of the on-site pharmacy's electronic systems.

2. If an on-site pharmacy is not able to provide remote electronic access to the remote processor, both pharmacies shall have appropriate technology to allow access to the required patient information.
- C. Policies and Procedures
1. On-site pharmacies and remote processors engaging in the acquisition or provision of remote processing services shall maintain a policy and procedure manual for reference by all personnel; it shall be available for inspection and copying by the board.
 2. At a minimum, the manual shall include policies and procedures for:
 - a. identification of the responsibilities of each of the pharmacies;
 - b. protection of the integrity and confidentiality of patient information; and
 - c. maintenance of appropriate records to identify the name, initials, or unique identification code of each pharmacist performing processing functions, the specific services performed, and the date of such 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 33:1132 (June 2007), amended LR 38:1240 (May 2012), amended LR 39:313 (February 2013), amended LR 41:2148 (October 2015).