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-incharge 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 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. 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.

§1105. Pharmacist-in-Charge

An initial and renewal pharmacy permit application shall designate and identify the licensed A. It does not say on pharmacist-in-charge. duty, it says В. Authority and Accountability. The pharmacist-in-charge shall be ultimately responsible for complete always. 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. C. 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. D. 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. E. 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. F. Recall. The pharmacist-in-charge shall be responsible for the implementation of a recall procedure that can be readily activated to assure patient safety. G. 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. H. Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacistin-charge designation for a pharmacy has changed. 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.
- I. 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.
- J. 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.

§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.

Also known as the lunch clause

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

believe is a tricky word. Good one here though.

- 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

Interesting! Especially all of you student pharmacist out there

- 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. Availability and Inspection

- A. Pharmacy records shall be available and readily retrievable upon request for board inspection and review.
- B. All records required by the laws and regulations of the board shall be provided to the board, or its agent, within seventy-two (72) hours of request, unless a shorter period is required, as determined by the board or its agent.

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.

§1121. General Record Keeping

- A. Requirements. A pharmacy shall maintain complete, accurate, and readily retrievable prescription drug records. All prescription drug records shall be available for board review upon request.
- 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 prescription orders dispensed or drugs sold, and
 - 3. inventory records drugs in current possession.
- C. Retention. All records required in this section and by Louisiana law shall be retained for a minimum of two years.

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.

§1123. Records

- A. Acquisition Records. Prescription drug acquisition records shall be required, and shall consist of documented invoices from manufacturers, wholesalers, distributors, brokers, or other sources of supply.
- B. Inventory Records. Accurate and readily retrievable records regarding prescription drug acquisition invoices, distribution, and inventories shall be maintained and available for accountability and retained at the pharmacy premises. Inventories of controlled dangerous substances shall be required, where
 - applicable, and maintained at the pharmacy.
- C. Prescription Records.
 - 1. Dispensing Prescription Files. Dispensed prescription orders shall be required and maintained for a minimum of two years from the last transaction/fill date by the pharmacy, constituting proof of dispensing by adequate prescription files properly documented with the proper medical practitioner's authority and the following information:
 - a. patient's name, address, and telephone number;
 - b. prescriber's name, address, telephone number, and if applicable, the Drug Enforcement Administration (DEA) registration number and signature;
 - c. drug name, dosage form, strength, and quantity prescribed, as well as quantity dispensed when in variance with the original order;
 - d. number of prescription refills authorized by the prescriber;
 - e. prescription number;
 - f. original dispensing date; and
 - g. pharmacist's name or initials.
 - 2. Prescription Refill Records. The following information shall be readily retrievable from the electronic record keeping system:
 - a. date of refill;
 - b. quantity dispensed when in variance with original order; and
 - c. pharmacist's name, initials, or identification code.
- D. Electronic Record Keeping System. An electronic record keeping system shall be utilized in a pharmacy and shall be a complete, accurate, readily retrievable prescription record keeping and storage system. An electronic record keeping system shall meet the following requirements:
 - 1. Retrieval. The system shall provide on-line retrieval via screen or hard-copy printout of original prescription order information for those prescription orders that are currently authorized for refilling.
 - 2. Summary. The system shall be capable of producing a daily hard-copy summary of controlled dangerous substance transactions.
 - 3. Refills. The system shall be capable of recording and providing the dates of prescription refills and the identity of the pharmacist refilling those prescriptions.
 - 4. Patient Profile. The system shall be capable of producing a patient profile that shall contain the following minimum information: patient's name and address/location, name of drug, dosage form, strength, route and frequency of administration, and pharmacist's identification.
 - 5. Original Prescription Records. The prescription hard copy shall represent the original written order or original oral prescription reduced to written form manually or electronically produced by the pharmacist, and shall meet the record keeping requirements of this chapter.

Should look familiar

Don't see many	
states mandating 6.	Maintenance. The original written prescription, or the written form of an oral prescription,
daily backups, we	shall be retained on file, in numerical order, for a minimum of two years from the date of
do here.	dispensing or the date of the last refill dispensed.
7.	Prescription Refill Information. Records of refills shall be entered into the electronic record
	keeping system.
8.	Record. A report of all original or refilled prescriptions dispensed shall be maintained, and
	shall include the following:
	a. prescription number;
	b. date of initial dispensing of the original prescription and the date(s) of refilling;
	c. total number of prescription refills dispensed to date or retrievable refill history on
	a visual mode of display as an alternative to appearing on the hard-copy printout;
	d. patient's name;
	e. patient's address, if required;
	f. the authorized prescriber's name;
	g. authorized prescriber's address, if required;
	h. the name, strength, dosage form, and quantity of the drug dispensed; andi. the last name and initial of the dispensing pharmacist.
0	Backup Support System. The electronic record keeping system shall be capable of being
У.	reconstructed in the event of an electronic or computer malfunction or unforeseen accident
\checkmark	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.
E. Digital	Imaging of Prescriptions
	In lieu of filing the actual original hard-copy prescription, a pharmacy may use an electronic
	imaging recordkeeping system, if:
	a. the system is capable of capturing, storing, and reproducing the exact image of a
Added in 2010	prescription, including the reverse side of the prescription
Added III 2010	b. 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;
	c. the prescription image and any associated notes of clarification to or alterations to
	a prescription are retained for a period not less than two years from the date the
	prescription is last dispensed;
	d. policies and procedures for the use of an electronic imaging recordkeeping system
	are developed, implemented, reviewed, and available for board inspection; and
	e. the prescription is not for a Schedule II controlled dangerous substance.
2.	In this capacity the pharmacy may retain the hard copy prescriptions in order of date scanned
	in lieu of numerical order.

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).

§1125. Security

A. The electronic record keeping system shall provide adequate safeguards against improper, illegal, or unauthorized manipulation or alteration.

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.

§1127. Register

A. The pharmacy shall maintain 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.

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.

§1129. Confidentiality

Think of a translator by phone service here.

Know the steps

A. 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 communication device, the confidential health information may not be accessed, maintained, or altered by the operator of the data communication 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 29:2091 (October 2003), effective January 1, 2004.

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;

Know what must – be posted and who is responsible if not posted.

- 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.

Similar to the CDS protocol

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 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 of physical transfer of drugs.

Remote Dispenser – a Louisiana permitted pharmacy which provides centralized prescription dispensing services for another permitted pharmacy in Louisiana.

Remote Processor – a permitted pharmacy in Louisiana 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).

§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.

Allows for the off site RX processing that was tried by one company.

- 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. With respect to hospital pharmacies and institutional pharmacies, 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 within the hospital or institutional facility. The activities authorized by this Section are intended to supplement hospital and institutional pharmacy services when the pharmacy is not operating and are not intended to eliminate the need for an on-site pharmacy or pharmacist.
- 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.

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