

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 23. Out-of-State Pharmacy

§2301. Purpose

- A. Out-of-State Pharmacies shall comply with the provisions of this Chapter in order to be and remain permitted to operate in Louisiana as an out-of-state pharmacy.
- B. This Chapter applies to any place physically located outside the state of Louisiana that provides services in the state of Louisiana where prescription drugs are dispensed and/or pharmacy care is provided to residents of the state of Louisiana. This includes, but is not limited to, pharmacies providing goods and services via U.S. mail carrier, commercial carrier, the Internet, and/or directly to Louisiana residents.

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 18:1380 (December 1992) effective January 1, 1993, amended LR 29:2099 (October 2003), effective January 1, 2004.

§2303. Out-of-State Pharmacy Requirements

- A. The out-of-state pharmacy shall hold a current pharmacy permit in good standing in the state(s) in which it is located and/or practicing pharmacy.
- B. Each pharmacist dispensing drugs into Louisiana shall be licensed as a pharmacist in good standing in the state(s) where he practices.
- C. Every out-of-state pharmacy doing business in Louisiana by dispensing and delivering prescription drugs and devices to Louisiana residents shall designate a resident agent and a registered office in Louisiana for the service of process.

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 18:1380 (December 1992) effective January 1, 1993, amended LR 29:2100 (October 2003), effective January 1, 2004.

Truly the key, most important part of this rule. Pay the fee.

§2305. Out-of-State Pharmacy Permit Requirements

- A. The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board. The board may require such information as reasonably necessary to carry out the provisions of R.S. 37:1232, including, without limitation, the name, address, and position of each officer and director of a corporation or of the owners, if the pharmacy is not a corporation.
- B. The out-of-state pharmacy shall pay an annual permit fee as defined in R.S. 37:1184.

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 18:1380 (December 1992) effective January 1, 1993, amended LR 29:2100 (October 2003), effective January 1, 2004.

§2307. Pharmacist-in-Charge

- A. Designation. A pharmacist licensed by the Louisiana Board of Pharmacy shall be named in the application as the pharmacy's pharmacist-in-charge for the Louisiana permit and shall be responsible for the pharmacy permit's compliance.
- B. The pharmacist-in-charge shall have an active and current license in the state in which the pharmacy is located, and further, shall not have any restrictions that prohibit the position of pharmacist-in-charge.
- C. Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state

Wait a second, so the PIC must be registered in LA even if they never come here. Oh yeah, another fee.

This looks all too familiar, why re-spell it out instead of referring to Chap 11?

- D. **Policy and Procedure Manual.** The pharmacist-in-charge shall be responsible for the development and maintenance of policies 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** is 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 or Outdated Drugs.** The pharmacist-in-charge shall be responsible for the implementation of policies and procedures to ensure that discontinued drugs, outdated drugs, or drug 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.

Afford = tell

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 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2100 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

§2309. Applicable Laws and Regulations

- A. Louisiana pharmacy laws and regulations shall be applicable to regulate the practice of pharmacy for that portion of the out-of-state pharmacy's Louisiana pharmacy practice or operation.

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 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2100 (October 2003), effective January 1, 2004.

§2311. Inspection

- A. The facilities and records of the out-of-state pharmacy shall be subject to inspection by the board or its designated agent(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 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2313. Records

- A. Records shall be maintained for not less than two years.

So no different that a pharmacy in state

- B. The pharmacy shall maintain records of drugs dispensed to Louisiana residents in such a manner so as to be identifiable, readily retrievable, and available upon request. Said records shall be made available for inspection by the board. The pharmacy permit holder or the pharmacist-in-charge shall produce within seventy-two (72) hours any information, documentation, and/or records requested 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 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2315. Counseling Services

- A. The pharmacy shall maintain an incoming toll-free telephone number for use by Louisiana consumers during regular office hours. Readily available telephone counseling services shall be provided that are consistent with the reasonable standard of due care. This telephone number, plus other numbers available for use, shall be printed on each container of drugs dispensed to Louisiana residents. The toll-free telephone number shall have sufficient extensions to provide reasonable access to incoming callers.

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 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2317. Out-of-State Pharmacy Closure Procedures

- A. Notice. Notice shall be afforded the board not less than ten days prior to the anticipated closure date of an out-of-state pharmacy. Said notice shall include the location of all transferred prescription files for Louisiana residents.
- B. Permit. The out-of-state pharmacy permit holder shall surrender the pharmacy permit to the board upon closure.

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 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2319. Jurisdiction

- A. Out-of-state pharmacies soliciting, receiving, and dispensing and delivering prescription drugs and devices, including controlled dangerous substances as defined in 21 U.S.C. 1, et seq. and 21 CFR 1 et seq., or their successors, and delivered to residents in Louisiana constitutes doing business 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 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2101 (October 2003), effective January 1, 2004.

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