

**Final Rule**

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

Pharmacy Compounding (LAC 46:LIII.Chapter 25)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy has amended *Chapter 25 - Prescriptions, Drugs and Devices*, and more specifically, *Subchapter C – Compounding of Drugs*, of its rules. The Rule changes are intended to harmonize the Board’s rules on this topic with recently enacted federal legislation, the Drug Quality & Security Act of 2013.

# Louisiana Administrative Code

## Title 46 – Professional and Occupational Standards

### Part LIII: Pharmacists

#### Chapter 25. Prescriptions, Drugs, and Devices

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#### Subchapter C. Compounding of Drugs

##### §2531. Purpose and Scope

- A. Purpose. The rules of this Subchapter describe the requirements of minimum current good compounding practices for the preparation of drug formulations by Louisiana-licensed pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates for dispensing and/or administration to patients.
- B. Scope. These requirements are intended to apply to all compounded preparations, sterile and non-sterile, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or practitioner's office.

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 29:2105 (October 2003), effective January 1, 2004, amended LR 41:97 (January 2015).

##### §2533. Definitions

- A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:

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*Preparation* – a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR 41:97 (January 2015).

##### §2535. General Standards

- A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.
  - 1. A pharmacy shall have written procedures as necessary for the compounding of drug preparations to assure that the finished preparations have the identity, strength, quality, and purity they are represented to possess.
  - 2. All compounding activities shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, as well as the Federal Food, Drug & Cosmetic Act of 1938 as subsequently amended, and most recently in November 2013 (FDCA), the 2014 edition of Title 21 of the Code of Federal Regulations (CFR), and all relevant chapters of the 2014 edition of the United States Pharmacopeia – National Formulary (USP 37 – NF 32).
    - a. The compounding of sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503A of the FDCA and USP Chapter 797.
    - b. The compounding of non-sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503A of the FDCA and USP Chapter 795.
    - c. The compounding of preparations for veterinary use shall comply with the

- provisions of Section 530 of Title 21 of the CFR.
- d. The compounding of positron emission tomography (PET) drugs shall comply with the provisions of Section 212 of Title 21 of the CFR.
3. Products or duplicates of products removed from the market for the purposes of safety shall not be used to compound prescriptions for human use.
- B. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the compounding of sterile preparations shall notify the board and shall receive approval from the board prior to beginning that practice.
- C. Training and Education. All individuals compounding sterile preparations shall:
1. Obtain practical and/or academic training in the compounding and dispensing of sterile preparations;
  2. Complete a minimum of one hour of Accreditation Council for Pharmacy Education (ACPE) accredited or board-approved continuing education, on an annual basis, related to sterile drug preparation, dispensing, and utilization;
  3. Use proper aseptic technique in compounding of all sterile preparations, as defined by the pharmacy practice site's policy and procedure manual;
  4. Qualify through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such persons will be assigned to use to make and dispense sterile preparations; and
  5. Maintain in the pharmacy practice site a written record of initial and subsequent training and competency evaluations. The record shall contain the following minimum information:
    - a. name of the individual receiving the training/evaluation;
    - b. date of the training/evaluation;
    - c. general description of the topics covered;
    - d. signature of the individual receiving the training/evaluation; and
    - e. name and signature of the individual providing the training/evaluation.
- D. Anticipated Use Preparations. The pharmacist shall label any excess compounded preparation so as to reference it to the formula used and the assigned lot number and estimated beyond use date based on the pharmacist's professional judgment and/or other appropriate testing or published data.
- E. Compounding Commercial Products Not Available  
A pharmacy may prepare a copy of a commercial product when that product is not available as evidenced by either of the following:
- a. Products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health-System Pharmacists (ASHP).
  - b. Products temporarily unavailable from manufacturers, as documented by invoice or other communication from the distributor or manufacturer.
- F. Labeling of Compounded Preparations.
- a. The labeling requirements of R.S. 37:1225, or its successor, as well as this Chapter, shall apply.

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 23:1316 (October 1997), amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR 41:97 (January 2015).

### **§2537. Requirements for Compounding Sterile Products**

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 14:708 (October 1988), effective January 1, 1989, amended LR 29:2106 (October 2003), effective January 1, 2004, repealed LR 41:98 (January 2015).