



Louisiana Board of Pharmacy

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December 3, 2014

Office of the Governor
PO Box 94004
Baton Rouge, LA 70804-9004

Re: Re-issuance of Emergency Rule

Electronic Mail – Delivery Receipt Requested

Dear Governor Jindal:

During their August 6, 2014 meeting, the Board approved a *Declaration of Emergency*, and further, adopted an *Emergency Rule ~ Pharmacy Compounding* with an effective date of August 8, 2014. At the same time, the Board initiated the formal rulemaking process to render a final rule. We held a public hearing and received no comments and testimony, and we have filed our second report with the legislative oversight committee. During their August 6 meeting, the Board also voted to re-issue the *Declaration of Emergency* as well as the *Emergency Rule ~ Pharmacy Compounding* as may become necessary to give the Board time to complete the promulgation process.

As directed by the Board, we now re-issue those documents and they will become effective on December 5, 2014. Copies of both documents are attached. In the event you have any questions or need further information, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

A handwritten signature in blue ink that reads "Malcolm Broussard".

Malcolm J Broussard
Executive Director

cc: Office of the President, Louisiana Senate
Office of the Speaker, Louisiana House of Representatives
Office of the Attorney General
Office of the Director, *Louisiana Register*

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Board of Pharmacy

Pharmacy Compounding – LAC 46:LIII.Chapter 25

The Louisiana Board of Pharmacy is exercising the emergency provisions of the Administrative Procedure Act, specifically at R.S. 49:953.B, to amend its rules governing the compounding of drugs by pharmacies, especially certain portions of that rule permitting pharmacists to compound medications intended for administration by practitioners without the necessity of a patient-specific prescription.

The U.S. Congress passed the Drug Quality & Security Act (DQSA) in November 2013. The first portion of that law amended several portions of the federal Food, Drug and Cosmetic Act. Subsequent to the effective date of that new law on November 27, 2013, the federal Food and Drug Administration (FDA) issued preliminary and final guidance to compounding pharmacies. Within the final guidance issued by the FDA on July 1, 2014, there are a number of requirements that compounding pharmacies must comply with in order to be eligible for an exemption to all of the other provisions applicable to the manufacturing of drugs. Among other provisions, the new law established a clear definition of compounding that requires the necessity of a patient-specific prescription. There is no authority for the compounding of medications in the absence of a patient-specific prescription.

New language in the DQSA includes the creation of a new category of provider known as outsourcing facilities. These facilities are registered and regulated by the federal FDA, and they are permitted to prepare products for practitioners without a patient-specific prescription, using quality guidelines that are more stringent than the quality guidelines used by pharmacies for their compounding activities.

The preparation of compounds in the absence of a patient-specific prescription is now construed as manufacturing as opposed to compounding. Compounding by pharmacies is regulated by the Board. Manufacturing is regulated by the federal FDA. In an abundance of caution for the health, safety and welfare of Louisiana citizens, the Board seeks to repeal the current rule which allows the compounding of preparations without the necessity of a patient-specific prescription.

The Board has determined this emergency rule is necessary to prevent imminent peril to the public health, safety, and welfare. The declaration of emergency is effective December 5, 2014 and shall remain in effect for the maximum time period allowed under the Administrative Procedure Act or until adoption of the final rule, whichever shall first occur.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

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

§2533. Definitions

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

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

§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, 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

§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