



Louisiana Board of Pharmacy

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Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov



December 17, 2012

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

Certified Mail – Return Receipt Requested

Re: Notice of Emergency Rule

Dear Governor Jindal:

In compliance with the provisions of La. R.S. 49:953(B), this will serve notice of the Board's adoption of an Emergency Rule on December 13, 2012. Copies of the Declaration of Emergency and the Rule are enclosed. In the event you desire any further information about this topic, please contact my office directly at 225.925.6481 or mbroussard@pharmacy.la.gov.

For the Board:

Malcolm J Broussard
Executive Director

Encls.

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Board of Pharmacy

Compounding for Prescriber's Use – 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 repeal certain portions of its rules permitting pharmacists to compound medications intended for administration by practitioners without the necessity of a patient-specific prescription.

The statutory definition of *compounding* at La. R.S. 37:1164(5) embodies three concepts – the necessity of a patient-specific prescription issued in the context and course of a legitimate physician-patient relationship, the inclusion of anticipatory preparation based on routine prescribing patterns, and the exclusion of preparation of copies of commercially available products. There is no statutory authority for the compounding of medications in the absence of a patient-specific prescription. The administrative code currently contains provisions for the preparation and labeling of practitioner administered compounds without the necessity of a patient-specific prescription.

The Board has taken note of the recent tragedies associated with fungal meningitis traced to a compounding pharmacy in Massachusetts. That pharmacy was licensed to do business in Louisiana, although none of the cases to date have been located within the state. Further, the Board has learned there are other similar types of pharmacies operating across the country that are licensed to do business in Louisiana. Some of these pharmacies specialize in the large-scale preparation of practitioner administered compounds as opposed to compounding medications pursuant to patient-specific prescriptions. Further, the Board has recently learned that other state boards of pharmacy may have resource limitations that restrict their ability to inspect such facilities on a sufficiently regular basis.

The preparation of compounds in the absence of a patient-specific prescription is construed as manufacturing as opposed to compounding. Compounding by pharmacies is regulated by the Board. Manufacturing is regulated by the federal Food and Drug Administration (FDA). In an abundance of caution for the health, safety and welfare of Louisiana citizens, the Board seeks to repeal the rule which allows the compounding of preparations without the necessity of a patient-specific prescription. The business entity that wishes to continue the preparation of such products will be able to apply for a manufacturer's registration from the federal Food and Drug Administration and then continue their same activities.

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 13, 2012, 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. In recognition of the necessity for practitioners to develop alternative business procedures to acquire needed medications for their patients, the Board has instructed its compliance officers to delay their assessment of compounding pharmacies for compliance with this emergency rule until January 14, 2013.

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

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§2533. Definitions

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

...

~~*Practitioner Administered Compounds*—products compounded by a licensed pharmacist, upon the medical order of a licensed prescriber for administration by a prescriber for diagnostic or therapeutic purposes.~~

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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

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- ~~D.—Compounding for Prescriber's Use. Pharmacists may prepare practitioner administered compounds for a prescriber's use with the following requirements:~~

- ~~1.—an order by the prescriber indicating the formula and quantity ordered to be compounded by the pharmacist;~~
- ~~2.—the product is to be administered by the prescriber and not dispensed to the patient; and~~
- ~~3.—the pharmacist shall generate a label and sequential identification number for the compounded drug.~~

E. ...

- F. Labeling of Compounded Products.

1. ...

- ~~2.—All practitioner administered compounds shall be packaged in a suitable container with a label containing, at a minimum, the following information:~~

- a. ~~pharmacy's name, address, and telephone number;~~
- b. ~~practitioner's name;~~
- e. ~~name of preparation;~~
- d. ~~strength and concentration;~~
- e. ~~lot number;~~
- f. ~~beyond use date;~~
- g. ~~special storage requirements, if applicable;~~
- h. ~~assigned identification number; and~~
- i. ~~pharmacist's name or initials.~~

G. Manufacturing Activities. No pharmacy shall engage in the manufacturing of drugs or drug products within the prescription department.

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 of Sterile Products

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G. Labeling.

1. ~~All practitioner administered sterile compounds shall be packaged in a suitable container, and shall bear a label with the following minimum information:~~

- a. ~~pharmacy's name, address, and telephone number;~~
- b. ~~preparation name;~~
- e. ~~strength and concentration;~~
- d. ~~lot number;~~
- e. ~~beyond use date;~~
- f. ~~practitioner's name;~~
- g. ~~assigned identification number;~~
- h. ~~special storage requirements, if applicable; and~~
- i. ~~pharmacist's name or initials.~~

2. ...

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, amended LR.