Louisiana Board of Pharmacy

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September 27, 2013

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 January 29, 2013 meeting, the Board approved a *Declaration of Emergency*, and further, adopted an *Emergency Rule ~ Compounding for Prescriber's Use*. At the same time, the Board initiated the formal rulemaking process to render a final rule. During two subsequent public hearings, the Board received comment and testimony prompting the Board to develop alternative content which represents a substantive change from the original proposal. In the interim, the Emergency Rule is scheduled to expire on September 29. The Board has determined it appropriate to re-issue the Declaration of Emergency and Emergency Rule.

During their May 29 meeting, the Board voted to re-issue the *Declaration of Emergency* as well as the *Emergency Rule ~ Compounding for Prescriber's Use*, as may become necessary during the promulgation process. As directed by the Board, we now re-issue those documents, effective today. 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:

Malcolm J 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

Compounding for Prescriber Use – LAC 46:LIII.2535

The Louisiana Board of Pharmacy is exercising the emergency provisions of the Administrative Procedure Act, specifically at R.S. 49:953.B, to amend certain portions of its rules permitting pharmacists to compound medications intended for administration by practitioners 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. 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 drug products as opposed to compounding medications pursuant to patient-specific prescriptions.

The preparation of drug products intended for use in the general population in the United States is governed by federal laws and rules administered by the federal Food and Drug Administration (FDA). Drug manufacturers are credentialed and regulated by that federal agency, and their manufacturing activities are required to comply with a set of quality and safety standards generally known as current Good Manufacturing Practices (cGMP). There are provisions within the federal laws and rules that permit state licensed pharmacies to prepare drug products in response to patient specific prescriptions. Louisiana-licensed pharmacies engaged in the compounding of drug preparations in response to such prescriptions are required to comply with the set of quality and safety standards published in the United States Pharmacopeia (USP). By comparison, the USP standards are less stringent than the cGMP standards.

The Board's current rule permitting pharmacies to compound products for prescriber use without a patient-specific prescription contain no limits on products prepared by pharmacies intended for that general use. As evidenced by the tragedies referenced earlier, there are risks associated with pharmacies engaged in manufacturing activities while adhering to compounding standards. In an effort to mitigate that risk for Louisiana residents, the Board proposes to limit a pharmacy's product preparation intended for general use (including prescriber use) to ten percent of its total dispensing and distribution activity. With respect to a pharmacy's total dispensing and distribution activity for Louisiana residents, the Board proposes a minimum of ninety percent be accomplished in response to patient-specific prescriptions and no more than ten percent for prescriber use in response to purchase orders.

The Board has determined this emergency rule is necessary to prevent imminent peril to the public health, safety, and welfare. The original declaration of emergency was effective January 31, 2013, was re-issued on May 29, and is scheduled to expire September 29. Although the Board has initiated the promulgation process necessary to finalize the proposed rule, it is necessary to re-issue the emergency rule to provide the necessary time to complete the promulgation process. Therefore, the Board has re-issued the declaration of emergency, effective September 27, 2013. The emergency rule 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.

For the Board:

Malcolm J. Broussard

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

...

§2535. General Standards

A – C ...

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

1 – 3 ...

4. A pharmacy may prepare such products not to exceed ten percent of the total number of drug dosage units dispensed and distributed by the pharmacy on an annual basis.

E. ...

F. 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:

1 Products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health-System Pharmacists (ASHP).

2 Products temporarily unavailable from distributors, as documented by invoice or other communication from the distributor.

G. Labeling of Compounded Products.

1 – 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 23:1316 (October 1997), amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR 39: