Louisiana Board of Pharmacy

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September 21, 2015

Office of the Governor
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Kendal.Melvin@la.gov

Electronic Mail – Delivery Receipt Requested

Re: Notice of Re-Issuance 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 re-issuance of an Emergency Rule. The initial emergency rule was effective on June 1, 2015, and although the Board has made progress in the formal rulemaking process, the emergency rule will expire before that process can be completed. The Board has directed the re-issuance of the emergency rule, effective today, September 21, 2015. 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 mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

cc: Office of the Attorney General – executive@ag.state.la.us
President, Louisiana Senate – apa.senatepresident@legis.la.gov
Speaker, Louisiana House of Representatives – apa.housespeaker@legis.la.gov
Director, Office of the State Register – reg.submission@la.gov

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Board of Pharmacy

Compounding for Office Use for Veterinarians – 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 its rules governing the compounding of drugs by pharmacies, to restore the capability of pharmacies to compound preparations intended for administration by veterinarians without the necessity of a patient-specific prescription.

Pursuant to the adoption of the Drug Quality & Security Act (DQSA) by the U.S. Congress in November 2013, the Board amended its rules to remove the capability of pharmacies to compound drug preparations intended for administration by practitioners without the necessity of a patient-specific prescription. With the further clarification from the federal Food and Drug Administration that the DQSA only applied to compounding of drugs for human use, and further, did not apply to the compounding of drugs for veterinary use, in combination with requests from veterinarians for the restoration of the authority for pharmacies to compound drugs for office use by veterinarians, the Board has determined it appropriate to restore the authority for pharmacies to compound drugs for office use by veterinarians.

The Board now seeks to amend its rules to authorize pharmacies to compound drugs for office use for veterinarians only and not for human use. In their petition to the Board, the veterinarians presented examples of medications that are needed for emergency use in the veterinarian's office. Since the time required to promulgate the rule change is of such duration that a veterinarian may not be able to obtain a compounded medication necessary to save an animal's life, the Board proposes to enable the temporary authority for pharmacies to compound medications for office use by veterinarians through an emergency rule.

The initial emergency rule was made effective June 1, 2015. Since that time, the Board has published the Notice of Intent and conducted a public hearing on August 26 to receive comments and testimony on the proposed rule. The Board will consider those comments during their next meeting on November 18. Since the emergency rule will expire before that time, the Board has directed the re-issuance of the emergency rule, with no changes to the content of the proposed rule.

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 September 21, 2015 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

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§2535. General Standards

A. – D. …

E. Veterinarian Administered Compounds, also referred to as Pharmacy-Generated Drugs
   1. Upon receipt of a valid non-patient-specific medical order from a licensed veterinarian, the pharmacy may compound a preparation intended for administration to an animal patient by the veterinarian.
   2. These preparations may not be distributed to any other third party by the pharmacy, nor may these preparations be further re-sold or distributed by the veterinarian ordering the preparation from the pharmacy.
   3. This authorization is primarily intended to facilitate the preparation of medications needed for emergency use in a veterinary office practice. Given the limited application of this authorization, which allows these products to be prepared using less rigorous standards applicable to compounding as opposed to the more rigorous standards applicable to manufacturing processes, the compounding pharmacy preparing these products shall be limited in the amount of such products they can prepare.
      a. No Louisiana-licensed pharmacy may distribute any amount of practitioner administered compounds in excess of five percent of the total amount of drug products dispensed and/or distributed from their pharmacy.
      b. The five percent limitation shall be calculated on a monthly basis and shall reference the number of dosage units.
      c. For those Louisiana-licensed pharmacies located outside Louisiana, the total amount distributed and/or dispensed shall reference the pharmacy's total business within the state of Louisiana.

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 manufacturers, as documented by invoice or other communication from the distributor or manufacturer.

G. Labeling of Compounded Preparations.
   1. For patient-specific compounded preparations, the labeling requirements of R.S. 37:1225, or its successor, as well as §2527 of this Chapter, or its successor shall apply.
   2. For veterinarian administered compounds, the label shall contain, at a minimum, the following data elements:
      a. pharmacy's name, address, and telephone number;
      b. veterinarian's name;
      c. name of preparation;
      d. strength and concentration;
      e. lot number;
      f. beyond use date;
      g. special storage requirements, if applicable;
      h. identification number assigned by the pharmacy; and
      i. name or initials of pharmacist responsible for final check of the preparation.

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), amended LR

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