2408#007

RULE

Department of Health
Board of Pharmacy

Product Integrity (LAC 46:LIII.1103 and 2501)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et. seq.), the Board of Pharmacy amended §1103 and §2501 of its rules relative to prescription department requirements and prescription drugs. The Rule change in §1103.A. adds a requirement for a prescription department to be maintained in a clean and orderly condition. The Rule changes in §1103.E. and §2501 add environmental condition requirements for all areas where drugs are stored. This Rule is hereby adopted on the day of promulgation.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 11. Pharmacies
Subchapter A. General Requirements
§1103. Prescription Department Requirements

A. A prescription department of a pharmacy shall be maintained in a clean and orderly condition and shall provide sufficient floor space, fixtures, equipment and supplies commensurate with the nature and scope of the pharmacy's practice to ensure that drugs are compounded and dispensed in a dry, well-lighted, climate controlled, and safely enclosed structure.

B. - D. …

E. Drug Inventory

1. Storage. The pharmacy shall provide an adequate prescription inventory in order to compound and dispense prescription orders. All areas where drugs are stored shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product information or labeling.

E.2. - J. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, LR 39:315 (February 2013), amended by Department of Health, Board of Pharmacy, LR 46:579 (April 2020), LR 47:1642 (November 2021), LR 48:497 (March 2022), LR 49:1556 (September 2023), amended LR 50:1156 (August 2024).

Chapter 25. Prescriptions, Drugs, and Devices
Subchapter A. General Requirements
§2501. Prescription Drugs and Devices

A. - A.2. …

3. Storage

a. Prescription drugs or devices shall be stored in a permitted pharmacy under the immediate control and responsibility of a pharmacist.

b. All areas where drugs are stored shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product information or labeling.

B. - E.3. …

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 29:2101 (October 2003), effective January 1, 2004, amended LR 50:1156 (August 2024).

M. Joseph Fontenot Jr.
Executive Director