2404#062

POTPOURRI

Department of Health
Board of Pharmacy

Public Hearing—Substantive Changes to Proposed Rule:
Product Integrity (LAC 46:LIII.1103 and 2501)

The Board of Pharmacy published a Notice of Intent to amend §1103 and §2501 of its rules relative to prescription department requirements and prescription drugs in the

November 20, 2023 edition of the *Louisiana Register*, volume 49, pages 1969-1971. Pursuant to the board's consideration of comments and testimony received during the December 28, 2023 public hearing, the board proposes to amend the original proposed Rule in order to specifically address drug product storage and remove references to drug product delivery as part of this regulatory project.

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:

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:

Public Hearing

A public hearing to solicit comments and testimony on the substantive changes to the proposed Rule is scheduled for 9:00 a.m. on Tuesday, May 28, 2024 at the Board office. During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

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Executive Director