

NOTICE OF INTENT

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 hereby gives notice of its intent to amend §1103 and §2501 of its rules relative to prescription department requirements and prescription drugs. The proposed rule change in §1103.A. adds a requirement for a prescription department to be maintained in a clean and orderly condition. The proposed rule changes in §1103.E. and §2501 add environmental condition requirements for all areas where drugs are stored or located prior to the transfer of possession of the drug to the patient or the patient's agent.

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 or located 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 labeling, prior to the transfer of possession of the drug to the patient or the patient's agent.

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

§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 or located 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 labeling, prior to the transfer of possession of the drug to the patient or the patient's agent.

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:

Family Impact Statement

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the Rule proposed for adoption, repeal, or amendment. The following statements will be published in the *Louisiana Register* with the proposed agency Rule.

1. The Effect on the Stability of the Family. The proposed rule amendment will have no effect on the stability of the family.

2. The Effect on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed rule amendment will have no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The Effect on the Functioning of the Family. The proposed rule amendment will have no effect on the functioning of the family.

4. The Effect on Family Earnings and Family Budget. The proposed rule amendment will have no effect on family earnings and family budget.

5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule amendment will have no effect on the behavior and personal responsibility of children.

6. The Ability of the Family or a Local Government to Perform the Function as Contained in the Proposed Rule. The proposed rule amendment will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.

Poverty Impact Statement

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the Rule proposed for adoption, repeal, or amendment.

1. The Effect on Household Income, Assets, and Financial Security. The proposed rule amendment will have no effect on household income, assets, or financial security.

2. The Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed rule amendment will have no effect on early childhood development or preschool through postsecondary education development.

3. The Effect on Employment and Workforce Development. The proposed rule amendment will have no effect on employment and workforce development.

4. The Effect on Taxes and Tax Credits. The proposed rule amendment will have no effect on taxes or tax credits.

5. The Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. The proposed rule amendment will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

Small Business Analysis

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses:

1. The Establishment of Less Stringent Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment will have no effect on reporting requirements for small business.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment will have no effect on schedules or deadlines for compliance or reporting requirements for small business.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment will have no effect on consolidation or simplification of compliance or reporting requirements for small business.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed rule amendment will have no effect on establishment of performance standards for small businesses to replace design or operational standards for small business.

5. The Exemption of Small Businesses from All or Any Part of the Requirements Contained in the Proposed Rule. There are no exemptions for small businesses in the proposed rule amendment.

Provider Impact Statement

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

1. The effect on the staffing level requirements or qualifications required to provide the same level of service. The proposed rule amendment will have no effect on the staffing level requirements or qualifications required to provide the same level of service.

2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed rule amendment will have an indeterminate effect on the cost to the provider to provide the same level of service. There may be increased shipping costs for those pharmacies that mail or deliver prescriptions to patients.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed rule amendment will have no effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to M. Joseph Fontenot Jr., Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding the proposed Rule amendment. The deadline for the receipt of all written comments is 12 p.m. on Thursday, December 28, 2023.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule changes is scheduled for 9 a.m. on Thursday, December 28, 2023 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.

M. Joseph Fontenot Jr.
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Product Integrity

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule change will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in estimated printing expenses of \$1,000 in FY 24. Other than publication costs, which are included in the LBP's annual operating budget, the proposed rule change is not anticipated to result in any additional expenditures or cost savings for LBP.

To the extent a government-operated pharmacy is not currently storing and/or delivering medication in appropriate environmental conditions, there could be additional costs to the pharmacy to ensure appropriate storage conditions prior to transferring possession of the medication to the patient. These costs are indeterminable.

The proposed rule change adds a requirement for the prescription department of a pharmacy to be maintained in a clean and orderly condition. The proposed rule change also adds environmental condition requirements for all areas where drugs are stored or located prior to the transfer of possession of the drug to the patient or the patient's agent.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule change will not affect revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

The proposed rule change will benefit consumers by ensuring that drugs are stored under environmental conditions which ensure the integrity of the drug prior to delivery to the patient.

To the extent a pharmacy is not currently storing and/or delivering medication in appropriate environmental conditions, there could be additional costs to the pharmacy to ensure

appropriate storage conditions prior to transferring possession of the medication to the patient. These costs are indeterminable.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT
(Summary)

The proposed rule change will have no effect on competition or employment.

M. Joseph Fontenot Jr.
Executive Director
2311#021

Patrice Thomas
Deputy Fiscal Officer
Legislative Fiscal Office