NOTICE OF INTENT

Department of Health Board of Pharmacy

Prescription Drug Delivery (LAC 46:LIII.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 Section 2501 of its rules to address delivery of prescription drugs to patients. The proposed Rule changes add Section 2501.A.4, requiring pharmacies to implement safeguards to protect medication integrity when delivering prescriptions to patients or their authorized agents. These changes address standards, notification, packaging, and temperature control for prescription drug delivery, as well as possession and control of the prescription drug whether the pharmacy uses a common or contract carrier or a pharmacy employee. The proposed Rule changes also require pharmacies to replace any prescription drug that is compromised in any way during delivery.

Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS

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

A. - A.3.b. ...

- 4. Delivery. To complete the dispensing process, pharmacies may deliver prepared prescriptions to the patient or their authorized agent upon request, using a common carrier, contract carrier, or pharmacy employee. Proper safeguards shall be in place to ensure the integrity of the medication—preserving its safety, identity, strength, quality, and purity throughout the delivery process. The pharmacy is responsible for the safe and accurate delivery of prescription drugs and remains accountable for any issues that may arise during the process.
- a. Standards. The pharmacy shall ensure that all prescription drugs are delivered to the patient or their authorized agent in compliance with nationally recognized standards, including those established by the manufacturer or the United States Pharmacopeia (USP).
- b. Notification. The pharmacy shall notify the patient or their authorized agent of the delivery.
- c. Packaging. Prescription drugs delivered by a common or contract carrier shall be enclosed in tamper-evident packaging.
- d. Temperature Control. Throughout the delivery process, until the medication is received by the patient or their authorized agent, prescription drugs shall be maintained within the temperature range specified by the United States Pharmacopeia (USP) or as recommended by the manufacturer, with allowances for permitted excursions.
- e. Possession and Control. When a pharmacy relinquishes physical possession and control of a prescription drug during delivery, the drug shall not be returned to the pharmacy for reuse.
- i. Common or Contract Carrier. If there is no formal agreement in place with a common or contract carrier that ensures delivery integrity standards and grants the pharmacy control during transit, prescription drugs shall not be returned to the pharmacy for reuse.
- ii. Pharmacy Employee. When a pharmacy employee delivers a prescription drug, the pharmacy retains physical possession and control of the medication throughout the delivery process.
- f. Compromised Product. If it is determined a prescription drug is in any way compromised during delivery, the pharmacy shall replace the drug or arrange for the drug to be replaced, either by promptly delivering a replacement to the patient or by promptly contacting the prescriber to arrange for the drug to be dispensed to the patient by a pharmacy of the patient's or their agent's choice.

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), amended LR 52:

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 changes 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 changes 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 changes will have no effect on the functioning of the family.
- 4. The Effect on Family Earnings and Family Budget. The proposed Rule changes will have no effect on family earnings and family budget.
- 5. The Effect on the Behavior and Personal Responsibility of Children. The proposed Rule changes 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 changes 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 changes 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 changes 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 changes will have no effect on employment and workforce development.
- 4. The Effect on Taxes and Tax Credits. The proposed Rule changes 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 changes 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 changes 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 changes 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 changes 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 changes 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 changes.

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 changes will have no effect on the staffing level requirements 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 changes may increase the cost to the provider to provide the same level of service if the provider is currently delivering prescription medication to patients without proper safeguards in place to ensure the integrity of the medication. The amount of this increase is variable and indeterminate. However, the benefit to the patient of ensuring integrity of the medication outweighs the increased cost to the provider.
- 3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed Rule changes will have no impact 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 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 changes. The deadline for the receipt of all written comments is 12 p.m. on Wednesday, November 26, 2025.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule changes is scheduled for Wednesday, November 26, 2025 at 9 a.m. 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: Prescription Drug Delivery

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

Other than the cost of rulemaking, there are no estimated implementation costs or savings for state or local government units resulting from the promulgation of the proposed rule changes. The cost for the Louisiana Board of Pharmacy is approximately \$958 in FY 26 for the notice and rule publication in the *Louisiana Register*.

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

There is no estimated effect on 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 changes will benefit patients by ensuring safeguards are in place to maintain the integrity of prescription drugs delivered to patients. Pharmacies that are not currently following these safeguards, such as tamper-evident packaging, temperature control, and replacement of compromised products, may incur additional costs to comply with the new requirements. The magnitude of these costs cannot be determined, as they will vary depending on the extent to which a pharmacy's existing delivery practices already meet the new standards.

State-owned and parish-owned pharmacies deliver prescriptions using pharmacy employees rather than common or contract carriers. Because the staff of these pharmacies maintain possession and control of the medication throughout the delivery process, the proposed rule is not expected to impose additional costs on state-owned and parish-owned pharmacies.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes are not anticipated to impact competition and employment.

M. Joseph Fontenot, Jr. Executive Director 2510#041 Patrice Thomas Deputy Fiscal Officer Legislative Fiscal Office