



# Louisiana Board of Pharmacy

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July 6, 2022

Senator P. Page Cortez  
President, Louisiana Senate  
Via Email: [APA.SenatePresident@legis.la.gov](mailto:APA.SenatePresident@legis.la.gov)

## Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2022-5 ~ Pharmacy Operations

Dear Senator Cortez:

As we indicated in our first report to your office on April 8, the Board initiated this regulatory project to amend its rules for pharmacies to address concerns expressed by consumers, licensees and legislators. The rule changes address appropriate staffing levels in pharmacies and adequate rest breaks for pharmacy staff. The proposed rule changes also require pharmacy owners to develop plans, policies and procedures for business continuity as well as continuity of patient care in the event of a disaster or emergency.

Subsequent to the publication of our *Notice of Intent* in the April 2022 edition of the *Louisiana Register*, we conducted a public hearing on May 27 to receive comments and testimony on the proposed rule changes. We received no comments or testimony. The Board subsequently determined no revisions were warranted. During their June 29 meeting, the Occupational Licensing Review Commission authorized the Board to complete the promulgation process. In connection with this regulatory project, you should find the following documents in this package:

- *Notice of Intent*, as published in the April 2022 *Louisiana Register* Page 2
- Record from the May 27, 2022 Public Hearing Page 5
- Full text of proposed rule, as intended for publication in the *Louisiana Register* Page 6

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposed rule changes without amendment as a *Rule* in the August 20, 2022 edition of the *Louisiana Register* with an immediate effective date. If you have any questions about the enclosed information or our procedures, please contact me directly at [jfontenot@pharmacy.la.gov](mailto:jfontenot@pharmacy.la.gov) or 225.925.6481.

For the Board:

M. Joseph Fontenot Jr.  
Executive Director

cc: Chair, Senate Health & Welfare Committee – [APA.S-H&W@legis.la.gov](mailto:APA.S-H&W@legis.la.gov)  
Speaker, House of Representatives – [APA.HouseSpeaker@legis.la.gov](mailto:APA.HouseSpeaker@legis.la.gov)  
Chair, House Health & Welfare Committee – [APA.H-HW@legis.la.gov](mailto:APA.H-HW@legis.la.gov)  
Editor, *Louisiana Register* – [Reg.Submission@la.gov](mailto:Reg.Submission@la.gov)  
Reference File



## NOTICE OF INTENT

### Department of Health Board of Pharmacy

#### Pharmacy Operations (LAC 46:LI.1107)

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 Louisiana Board of Pharmacy hereby gives notice of its intent to amend §1107 of its rules relative to pharmacy operation to address consumer, licensee, and legislator complaints. The proposed changes in Subsection A address complaints from consumers and pharmacists in regards to adequate pharmacy staffing levels to provide for patient safety. The proposed changes in Subsection B, which are in response to requests from pharmacists and pharmacy permit holders, exempts specific pharmacy permit classifications from posting their hours of operation. The proposed change in Subsection C further enforces the requirement of a rest break for credentialed persons and is in response to complaints by pharmacists. The proposed new Subsection D, which is in response to consumer and legislator complaints, requires a pharmacy owner to develop plans, policies and procedures to ensure business continuity as well as continuity of patient care in the event of a disaster or emergency.

#### Title 46

### PROFESSIONAL AND OCCUPATIONAL STANDARDS

#### Part LI. Pharmacists

#### Chapter 11. Pharmacies

#### Subchapter A. General Requirements

#### §1107. Pharmacy Operations

A. The owner of the pharmacy shall employ an appropriate number of professional, technical and clerical personnel commensurate with the nature and scope of the pharmacy practice. The owner of the pharmacy shall ensure

there are a sufficient number of licensed personnel on site when the pharmacy is open to competently and safely perform patient care services and dispense prescriptions accurately.

#### B. Minimum Hours of Operation; Business Hours Posted

1. A pharmacy shall be open for business a minimum of 10 hours per week. A pharmacist shall be on duty at all times when the pharmacy is open for business, subject to the provision for the temporary absence of a pharmacist in Section 1109 of this Part.

2. The pharmacy shall post its hours of operation at the building entrance in full public view from outside the premises. Pharmacies holding permits classified as correctional, hospital, institutional, or nuclear shall be exempt from this posting requirement.

C. No person credentialed by the board may engage in the practice of pharmacy for a period of time longer than six hours without a rest break.

D. The owner of the pharmacy shall develop plans, policies and procedures to ensure business continuity in the event of natural or other disasters or emergencies. Such plans, policies and procedures shall include provisions for continuity of patient care in the event the pharmacy is unable to open for business. The pharmacy shall provide access to such plans, policies and procedures when requested by the board.

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 29:2088 (October 2003), effective January 1, 2004, LR 34:1408 (July 2008), amended by the Department of Health, Board of Pharmacy, LR 47:1643 (November 2021), LR 48:

#### 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 in §1107.A will require the pharmacy owner to hire an appropriate number of licensed personnel to safely operate the pharmacy. To the extent a pharmacy needs to hire additional personnel to meet the safety standard, there could be a positive impact on employment.

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. The proposed changes in §1107.B.2 establish a less stringent requirement for specific pharmacy permit classifications.

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 in §1107.A establishes operational standards to safely perform patient care services and dispense prescriptions accurately.

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

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed rule changes 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 Joe Fontenot, Executive Director-Designate, 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.

### Public Hearing

A public hearing to solicit comments and testimony on the proposed rule changes is scheduled for 9:00 a.m. on Friday, May 27, 2022. 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. noon that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

Joe Fontenot

Executive Director-Designate

## FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

### RULE TITLE: Pharmacy Operations

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

The proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in printing expenses of \$500 in FY 2022 and \$500 in FY 2023. There will be no additional expenditures or cost savings for LBP.

To the extent a local governmental unit operates a pharmacy, and to the extent that pharmacy needs to hire additional licensed personnel to safely operate the pharmacy, there could be additional costs to the pharmacy. The amount of such costs would vary and is indeterminable.

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

The proposed rule changes will not affect revenue collections for 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 in Subsection 1107(A) will benefit consumers and pharmacists by addressing adequate pharmacy staffing levels to safely perform patient care services and dispense prescriptions accurately. There will be no cost to pharmacy owners if they are currently staffing a sufficient number of personnel to meet the objective of patient safety. If the pharmacy owner is not staffing a sufficient number of personnel, then there would be a cost to the owner but that amount is indeterminable. The proposed rule changes in Subsection 1107(B) will benefit pharmacy owners of specific pharmacy classifications by removing a signage requirement, the cost of which is negligible. The proposed rule change in Subsection 1107(C) will benefit pharmacy personnel by providing for rest breaks in pharmacies. The proposed new Subsection 1107(D) will benefit consumers during disasters and emergencies by requiring pharmacies to develop plans, policies and procedures to provide for continuity of patient care. If a pharmacy owner does not have current plans, policies and procedures to ensure business continuity in the event of a disaster or emergency there could be a cost to develop such plans, but that amount is indeterminable. Requests by LBP on individual pharmacy preparedness for emergencies may be informational and will not pose a significant burden on individual pharmacies.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will have minimal effect on competition or employment. While this rule change codifies expectations for appropriate staffing levels, appropriateness beyond pre-existing requirements will be determined by individual pharmacies. To the extent pharmacies determine their staffing levels are below that which is necessary to provide a standard of high-quality care, pharmacy staff employment may rise.

Joe Fontenot  
Executive Director-Designate  
2204#060

Evan Brasseaux  
Interim Deputy Fiscal Officer  
Legislative Fiscal Office



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Summary of Testimony & Public Comments  
re  
Regulatory Project 2022-5 ~ Pharmacy Operations  
at  
May 27, 2022 Public Hearing

*No comments or testimony received.*

## **RULE**

### **Department of Health Board of Pharmacy**

#### **Pharmacy Operations (LAC 46:LIII.1107)**

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 Louisiana Board of Pharmacy has amended §1107 of its rules relative to pharmacy operations to address consumer, licensee, and legislator complaints. The changes in Subsection A address complaints from consumers and pharmacists in regards to adequate pharmacy staffing levels to provide for patient safety. The changes in Subsection B, which are in response to requests from pharmacists and pharmacy permit holders, exempt specific pharmacy permit classifications from posting their hours of operation. The change in Subsection C further enforces the requirement of a rest break for credentialed persons and is in response to complaints by pharmacists. The new Subsection D, which is in response to consumer and legislator complaints, requires a pharmacy owner to develop plans, policies and procedures to ensure business continuity as well as continuity of patient care in the event of a disaster or emergency. 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**

##### **§1107. Pharmacy Operations**

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M. Joseph Fontenot, Jr.

Executive Director