



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



April 8, 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. 1 of 3 for Regulatory Project 2022-5 ~ Pharmacy Operations

Dear Senator Cortez:

The Board seeks 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.

The Occupational Licensing Review Commission approved the initiation of this project during their March 10, 2022 meeting. In connection with this regulatory project, the following items are appended:

- Notice of Intent Page 2
- Fiscal & Economic Impact Statement Page 6

As indicated in the solicitation, we will convene a public hearing on May 27, 2022 to receive public comments and testimony on these proposed rule changes. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information about this project, please contact me directly at [mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov) or 225.925.6481.

For the Board:

Malcolm J. Broussard  
Executive Director

cc: Chair, Senate Health & Welfare Committee  
Via Email: [APA.S-H&W@legis.la.gov](mailto:APA.S-H&W@legis.la.gov)  
Speaker, House of Representatives  
Via Email: [APA.HouseSpeaker@legis.la.gov](mailto:APA.HouseSpeaker@legis.la.gov)  
Chair, House Health & Welfare Committee  
Via Email: [APA.H-HW@legis.la.gov](mailto:APA.H-HW@legis.la.gov)  
Director, Community Competitiveness & Small Business Services, La. Economic Development  
Via Email: [Witty@la.gov](mailto:Witty@la.gov)  
Editor, *Louisiana Register*  
Via Email: [Reg.Submission@la.gov](mailto:Reg.Submission@la.gov)  
Reference File

## NOTICE OF INTENT

### 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 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 LIII: Pharmacists

#### Chapter 11. Pharmacies

#### Subchapter A. General Requirements

#### §1107. Pharmacy Operations

A. ~~A pharmacist shall be on duty at all times during regular open hours of the pharmacy.~~ 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. ~~with said business hours posted at the building entrance in full public view from outside the premises.~~ 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~~ shall be required to 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

### **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**

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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.

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### **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 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. 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 GOVERNMENTAL 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 NON-GOVERNMENTAL 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 to competently and safely practice, 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.

**FISCAL AND ECONOMIC IMPACT STATEMENT  
WORKSHEET**

Person Preparing Statement:	Joe Fontenot Executive Director-Designate	Dept.: Dept. of Health Office: Board of Pharmacy
Telephone:	225.925.6481	Title: Pharmacy Operations
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809	Effective Date of Rule: Upon promulgation Aug. 20, 2022 (est.)

**SUMMARY**  
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

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**Joe Fontenot**

Digitally signed by Joe Fontenot  
DN: cn=Joe Fontenot, o=Louisiana Board of Pharmacy, ou=Executive  
Director, email=jfontenot@pharmacy.la.gov, c=US  
Date: 2022.04.07 16:36:41 -0500

Signature of Agency Head or Designee

**Joe Fontenot, Executive Director-Designate**

Typed Name and Title of Agency Head

**Evan Brassfield, Interim Deputy**

Legislative Fiscal Officer or Designee

**4/8/22**

Date of Signature

*Fiscal Officer*

FISCAL AND ECONOMIC IMPACT STATEMENT  
WORKSHEET

April 7, 2022  
Date of Signature

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The proposed changes in Subsection 1107(A) addresses complaints from consumers and pharmacists in regards to adequate pharmacy staffing levels to provide for patient safety. The proposed changes in Subsection 1107(B) are in response to requests from pharmacists and pharmacy permit holders and exempt specific pharmacy permit classifications from posting their hours of operation. The proposed change in Subsection 1007(C) further enforces the requirement of a rest break for credentialed persons and was developed in response to complaints by pharmacists. The proposed new Subsection 1107(D), developed in response to consumer and legislator complaints, requires a pharmacy owner to develop plans, policies and procedures to ensure both business continuity and continuity of patient care in the event of a disaster or emergency. A copy of the notice of intent is appended.

- B. Summarize the circumstances which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

In response to consumer, pharmacists, and legislator complaints, the Board of Pharmacy determined it appropriate to amend Section 1107 of its rules relative to pharmacy operations.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

LBP has allocated \$1,000 for printing the Notice of Intent and the Rule. LBP operates on self-generated funds.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

- (a) \_\_\_\_\_ Yes. If yes, attach documentation.  
(b) No NO. If no, provide justification as to why this rule change should be published at this time

LBP operates on self-generated funds, and they have determined the proposed rule changes are in the public's best interest.

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 22	FY 23	FY 24
Personal Services			
Operating Expenses	\$500	\$500	
Professional Services			
Other Charges			
Equipment			
Major Repairs & Constr.			
TOTAL	\$500	\$500	None
POSITIONS (#)	None	None	None

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase

FISCAL AND ECONOMIC IMPACT STATEMENT  
WORKSHEET

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 22	FY 23	FY 24
State General Fund			
Agency Self-Generated	\$ 500	\$500	
Dedicated			
Federal Funds			
Other (Specify)			
TOTAL	\$500	\$500	None

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

LBP has sufficient self-generated funds available to implement the proposed rule changes.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.
2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

SOURCE	FY 22	FY 23	FY 24
State General Fund			
Agency Self-Generated			
Dedicated			
Federal Funds			
Other (Specify)			
TOTAL	None	None	None

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. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

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

REVENUE INCREASE/DECREASE	FY 22	FY 23	FY 24
State General Fund			
Agency Self-Generated			
Dedicated Funds*			
Federal Funds			
Local Funds			
TOTAL	None	None	None

\*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

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



## FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

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 costs 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 to competently and safely practice, there would be a cost to the owner, the amount of which 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 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.

- B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

The proposed rule changes will not impact a licensee's receipts or revenue.

### IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

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.

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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 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. 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 GOVERNMENTAL 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 NON-GOVERNMENTAL 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 to competently and safely practice, 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.