



Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov



November 8, 2023

Senator P. Page Cortez
President, Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2023-09 ~ Product Integrity

Dear Senator Cortez:

The Board seeks 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.

In connection with this regulatory project, the following items are appended:

- Notice of Intent
- Fiscal & Economic Impact Statement

As indicated in the solicitation, we will convene a public hearing at 9:00 a.m. on Thursday, December 28, 2023 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 jfontenot@pharmacy.la.gov or 225.925.6481.

For the Board:

M. Joseph Fontenot Jr.
Executive Director

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

NOTICE OF INTENT

Department of Health Board of Pharmacy

Product Integrity (LAC 46:LIII.1103 and 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 §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, ventilated, 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. ~~Drugs that require special storage shall be properly stored.~~

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

* * *

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

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 9:00 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 GOVERNMENTAL 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 NON-GOVERNMENTAL 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.

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

Person Preparing Statement:	<u>M. Joseph Fontenot Jr. Executive Director</u>	Dept.:	<u>Dept. of Health</u>
Phone:	<u>225.925.6481</u>	Office:	<u>Board of Pharmacy</u>
Return Address:	<u>3388 Brentwood Drive Baton Rouge, LA 70809</u>	Rule Title:	<u>Product Integrity</u>
		Date Rule Takes Effect:	<u>Upon promulgation May 20, 2024 (est.)</u>

**SUMMARY
(Use complete sentences)**

In accordance with Section 961 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.

**I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL 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.

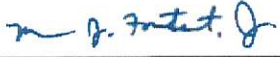
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To the extent a pharmacy is not currently storing and/or delivering medication in appropriate environmental conditions, there could be additional costs to the pharmacy to ensure appropriate storage conditions prior to transferring possession of the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



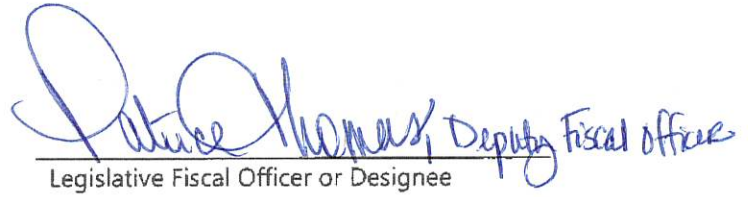
Signature of Head or Designee

M. Joseph Fontenot Jr., Executive Director

Typed Name & Title of Agency Head or Designee

November 07, 2023

Date of Signature



Legislative Fiscal Officer or Designee

11/08/2023

Date of Signature

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

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 rule change in §1103.A adds a requirement for a prescription department to be maintained in a clean and orderly condition. The proposed rule change in §1103.E and §2501.A 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.

- 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 recent reports of prescription departments not being maintained in a clean condition and prescriptions being shipped to patients with no means to protect the drugs from extreme temperatures and to ensure the integrity of the drug, LBP determined it appropriate to amend Sections 1103 and 2501 of its rules relative to prescription department requirements and prescription drugs.

- 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) X_____ 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 change is in the public's best interest.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

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 24	FY 25	FY 26
PERSONAL SERVICES	\$0	\$0	\$0
OPERATING EXPENSES	SEE BELOW	SEE BELOW	SEE BELOW
PROFESSIONAL SERVICES	\$0	\$0	\$0
OTHER CHARGES	\$0	\$0	\$0
EQUIPMENT	\$0	\$0	\$0
MAJOR REPAIR & CONSTR.	\$0	\$0	\$0
TOTAL	SEE BELOW	SEE BELOW	SEE BELOW
POSITIONS (#)	0	0	0

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

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 state 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.

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

SOURCE	FY 24	FY 25	FY 26
STATE GENERAL FUND	SEE BELOW	SEE BELOW	SEE BELOW
AGENCY SELF-GENERATED	SEE BELOW	SEE BELOW	SEE BELOW
DEDICATED	SEE BELOW	SEE BELOW	SEE BELOW
FEDERAL FUNDS	SEE BELOW	SEE BELOW	SEE BELOW
OTHER (Specify)	\$0	\$0	\$0
TOTAL	SEE BELOW	SEE BELOW	SEE BELOW

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 change.

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.

To the extent a local 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.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

The proposed rule change will not impact sources of funding of local governmental units.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

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

REVENUE INCREASE/DECREASE	FY 24	FY 25	FY 26
STATE GENERAL FUND	\$0	\$0	\$0
AGENCY SELF-GENERATED	\$0	\$0	\$0
DEDICATED	\$0	\$0	\$0
FEDERAL FUNDS	\$0	\$0	\$0
LOCAL FUNDS	\$0	\$0	\$0
TOTAL	\$0	\$0	\$0

*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.

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

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

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

- A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule change will benefit consumers by requiring that drugs be stored in an appropriate environment which ensures the integrity of the drug prior to receipt by 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.

- 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 change 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 change will have no effect on competition or employment.