



# Louisiana Board of Pharmacy

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May 31, 2024

To: Attorney General Liz Murrill  
Attn: Department of Justice, Occupational Licensing Review Program

From: Joe Fontenot, Executive Director  
Louisiana Board of Pharmacy

Subject: **Regulatory Project 2023-09 ~ Product Integrity**

The Louisiana Board of Pharmacy seeks to amend Sections 1103 and 2501 of its rules relative to prescription department requirements and prescription drugs. The proposed rule change in Section 1103.A adds a requirement for a prescription department to be maintained in a clean and orderly condition. The proposed rule changes in Section 1103.E and Section 2501 add environmental condition requirements for all areas where drugs are stored.

To facilitate the Department of Justice's review of the proposed rule, the Louisiana Board of Pharmacy provides answers to the following questions.

1. Describe any relevant factual background to the occupational regulation and the purpose of the occupational regulation?

*In response to reports of prescription departments not being maintained in a clean condition, the Board of Pharmacy determined it appropriate to amend Sections 1103 and 2501 of its rules to require a pharmacy to provide an appropriate environment to ensure the integrity of drugs.*

2. Is the occupational regulation within the scope of the occupational licensing board's general authority to regulate in a given occupation or industry? If so, identify the law that provides the authority for the rule and describe how the occupational regulation is within the scope.

*Yes. LA R.S. 37:1182 details the powers and duties of the Board and states the Board shall be responsible for the control and regulation of the practice of pharmacy and shall establish minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, compounding, and dispensing of drugs or devices. Requiring an appropriate environment for the storage of drugs falls within this scope.*

3. Check all of the following that apply as reasons the occupational regulation is subject to review

- Creates a barrier to market competition
- Fixes prices, limits price competition, or results in high prices for a product or service provided by or to a license holder.
- Reduces competition or excludes present or potential competitors from the occupation regulated by the board
- Limits output or supply in this state of any good or service provided by the members of the regulated occupation.
- Reduces the number of providers that can serve a particular set of customers
- Other activity (please describe)

*The Public Hearing held pursuant to the Notice of Intent received comments from several entities objecting to the delivery aspect of the proposal. The entities did not express an issue with the storage of drugs. Recognizing the necessity to have a regulation, the Board decided to remove the delivery component and focus the regulatory project on the storage component. After this project is complete, the Board plans to begin another project which will be focused only on the delivery aspect.*

4. Identify the clearly articulated state policy (e.g., health, safety, welfare, or consumer protection) in state statute, or any supporting evidence of the harm the action/proposed action is intended to protect against?

*LA R.S. 40:616(2) states that a drug is considered adulterated if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health. LAC 46:LIII.2501.C.1 states that it is unlawful to possess or dispense adulterated drugs.*

*The United States Pharmacopeia (USP), manufacturers, distributors, and FDA-approved labeling provide storage requirements for drug products to be followed to ensure integrity of the drug product. Storage outside of the required conditions may result in changes to the product that could be harmful to the patient.*

*The purpose of the Louisiana Pharmacy Practice Act, as stated in LA R.S. 37:1163, is to promote, preserve, and protect the public health, safety, and welfare. Requiring drug products to be stored appropriately protects the public.*

5. Do any less restrictive alternatives to the occupational regulation exist for addressing the same harm? If so, include a comparison of the occupational regulation to the alternatives and a justification for not pursuing a less restrictive alternative. If no less restrictive alternatives exist, explain why.

*No, less restrictive alternatives do not exist. Storage requirements are determined by USP, the manufacturer of the drug, or both.*

6. Describe the process that the occupational licensing board followed in developing the proposed rule, including any public hearings held, studies conducted, and data collected or analyzed.

**07-18-2023** – The Regulation Revision Committee of the Board held a public meeting to consider the regulatory draft proposal and voted to recommend to the Board their approval.

**08-16-2023** – The Board approved, during its quarterly meeting, the draft proposal for promulgation.

**10-10-2023** – Impact statements submitted to Legislative Fiscal Office for approval.

**11-08-2023** – The Legislative Fiscal Office approved the fiscal and economic impact statement.

**11-08-2023** – The 1st Report submitted to Joint Legislative Oversight Committee on Health & Welfare.

**11-20-2023** – The Board distributed electronic Notice of Rulemaking Activity.

**11-20-2023** – The Notice of Intent was published in the Louisiana Register.

**12-28-2023** – A Public Hearing was conducted at the Board office to receive comments and testimony.

**01-24-2024** – The committee reviewed the comments and testimony from the public hearing, received stakeholder input during the meeting, and developed Draft # 2. The committee then voted to recommend to the Board their approval of Draft #2.

**02-21-2024** - The Board approved, during its quarterly meeting, the draft proposal for continuation of the promulgation process.

**03-08-2024** - Impact statements submitted to Legislative Fiscal Office for approval due to the substantive change to the original notice.

**04-09-2024** – The Legislative Fiscal Office approved fiscal and economic impact statement.

**04-20-2024** - Potpourri Notice published in the April 2024 edition of the Louisiana Register because of a substantive change to the original Notice of Intent.

**04-20-2024** - The Board distributed electronic Notice of Rulemaking Activity.

**05-28-2024** - A Public Hearing was conducted at the Board office.

7. Does the occupational regulation relate to a matter on which there is pending litigation or a final court order? *No*

8. Please identify the board members voting in favor of this rule, and state whether the member is an active market participant.

*On February 21, 2024, 15 members were present and two members (Richard Mannino and Rhonny Valentine) were absent. The vote in favor of the proposed rule was unanimous (14-0, with President McKay not voting as Chair). Members present: Robert Cloud, David Darce, Jennifer Dupree, Jacqueline Hall, Richard Indovina, Jr., Charles Jones, Kevin LaGrange, Robert LeBas, Marty McKay, Chris Melancon, Troy Menard, Anthony Mercante, Blake Pitre, Don Resweber, and Raymond Strong. All members voting are active market participants except for Mr. Resweber, the public member.*

9. Is there anything else that the occupational licensing board would like the Department to know about the proposed rule? *No.*