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To: Mr. M. Joseph Fontenot, Jr.
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Louisiana State Board of Pharmacy

From: Nicol Hebert, Deputy Director
Louisiana Department of Justice
Occupational Licensing Review Program

Date: July 30, 2024

Subject: Proposed Amendment to LAC 46:LIII.1103 and 2501
Board of Pharmacy's Regulatory Project 2023-09 Product Integrity

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I. Summary

The Louisiana State Board of Pharmacy (the "***Board***") submitted to the Louisiana Department of Justice's Occupational Licensing Review Program (the "***OLRP***") proposed amendments to the provisions of LAC 46:LIII.1103 and 2501 with respect to (i) maintaining prescription departments in a clean and orderly manner, and (ii) adding environmental condition requirements for all areas where drugs are stored (the "***Proposed Rules***").[1] The Board initially published a Notice of Intent to promulgate the Proposed Rules (with delivery-related requirements) in the Louisiana Register on November 20, 2023 (the "***Notice***").[2] The Notice invited comments and set a public hearing for December 28, 2023.[3] The Board received five comment letters,[4] and in response the Board removed the delivery-related requirements from the Proposed Rules.[5] The Board responded to each comment letter and provided a draft of the revised language which resulted in the current version of the Proposed Rules. On April 20, 2024, the Board posted notice of the amended Proposed Rules in the Louisiana Register (the "***New Notice***").[6] The New Notice invited comments and set a public hearing on May 28, 2024.[7] The Board received no further comments and submitted the Proposed Rules to the OLRP on May 31, 2024. The OLRP began review shortly thereafter and invited comments for a 14-day period ending July 2, 2024. The OLRP received no comments on the Proposed Rules.

Upon review and for the reasons set forth herein, the Louisiana Department of Justice has determined the Proposed Rules do not have "*reasonably foreseeable anti-competitive effects*" on the regulated profession, and as such, the Board may proceed with promulgation in accordance with the Louisiana Administrative Procedure Act[8] (the "***Louisiana APA***") without further input from the OLRP.

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[1] Louisiana Register, Vol. 49, No. 11 at pg. 1969
[2] Id. at pgs. 1969-1971.
[3] Id.
[4] 2023-09_2ndReport_PKG_2024-0603.pdf (la.gov) pgs. 10-22.
[5] Id. at pg. 1
[6] Louisiana Register, Vol. 50, No. 4, pgs. 609-610. April 20, 2024.
[7] Id. at pg. 610.
[8] LSA-R.S. 49:950 *et seq.*

II. Analysis

A. Background

In response to reports of pharmacy prescription departments not being maintained in a clean condition and prescriptions being shipped to patients with no means to protect drugs from extreme temperatures, the Board determined it appropriate to amend Sections 1103 and 2501 of its rules to add (i) a requirement that prescription departments be kept in clean condition, and (ii) environmental condition requirements for drug storage areas.[9] The Board indicated its purpose for the Proposed Rules is to ensure the integrity of pharmaceutical drugs and medicines to help reduce the risk of harm to patients.

B. The Proposed Rules

The Proposed Rules (i) require that pharmacy prescription departments "*be maintained in a clean and orderly condition*"[10] and (ii) replace the general requirement that "*[d]rugs that require special storage shall be properly stored*" with the following more specific language:

> "*All areas where drugs are stored 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 production information or labeling.***"[11]

All medications have storage requirements, such as specific temperature and humidity guidelines, protection from sunlight and other considerations.[12] Storage requirements help keep medications from becoming contaminated, ensure that medications maintain their potency and help reduce the risk of harm to patients.[13] Medication storage requirements may be found on the medication's label or from a third-party resource.[14] The United States Pharmacopeia (the "***USP***") is a federally recognized third-party resource that develops and disseminates public quality compendial standards for medicines in the United States.[15] Under Federal law, a drug with a name recognized in the USP must comply with the current version of drug standards deemed official by the USP, or risk being deemed adulterated.[16]

The Board has determined it prudent to (i) specify that all prescription departments need to be kept clean and orderly, and (ii) replace general storage requirements applicable to all prescription departments with specific language referencing compliance with the USP and/or the manufacturer's or distributor's production information or labeling – both approaches are widely recognized industry standards.[17]

C. OLRP Statutory Authority: Occupational Regulations

The OLRP has authority under LSA-R.S. 49:260 (the "***OLRP Statute***") to review *occupational regulations*.[18] The OLRP Statute defines an *occupational regulation* as a rule that has "*reasonably foreseeable anti-competitive effects.*"[19] Anti-competitive behavior is an act or series of acts that have the effect of harming the market or the process of competition among businesses, or a tendency to reduce or

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[9] Louisiana Register, Vol. 49, No. 11 at pg. 1969
[10] Id.
[11] Id.
[12] Pharmacy Times, May 2024, Vol. 90 No. 5, pp. 36-37
[13] Id.
[14] Id.
[15] https://en.wikipedia.org/wiki/United_States_Pharmacopeia
[16] 21 USC § 351; 21 CFR 299.5(A&B)
[17] Pharmacy Times, May 2024, Vol. 90 No. 5, pp. 36-37
[18] LSA-R.S. 49:260(B)
[19] LSA-R.S. 49:260(G)(4)

eliminate competition, with no legitimate business purpose.[20] The OLRP finds that the Proposed Rules have no reasonably foreseeable anti-competitive effects because they (i) apply to all pharmacies equally, (ii) do not harm the market or the process of competition, and (iii) do not have a tendency to reduce or eliminate competition. Further, the addition of requirements intended to ensure medicinal integrity in accordance with widely recognized industry standards is in keeping with the Louisiana Pharmacy Practice Act's clearly articulated purpose to "*promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.*"[21]

III. Determination

The OLRP has determined that the Proposed Rules do not have reasonably foreseeable anti-competitive effects and therefore the Board may proceed with promulgation in accordance with the Louisiana APA without further input from the OLRP.

LOUISIANA DEPARTMENT OF JUSTICE
OCCUPATIONAL LICENSING REVIEW PROGRAM

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[20] Black's Law Dictionary, 12th Edition, p. 116
[21] LSA-R.S. 37:1163