

STATE OF LOUISIANA

DEPARTMENT OF JUSTICE OFFICE OF THE ATTORNEY GENERAL P.O. Box 94005 BATON ROUGE, LA 70804-9005

To: Mr. Joe Fontenot

Executive Director

Louisiana State Board of Pharmacy

Farra Mughal From:

Louisiana Department of Justice

Occupational Licensing Review Program

Date: May 19, 2025

Subject: Louisiana State Board of Pharmacy

Proposed Amendment to LAC 46: LIII.1711

Regulatory Project 2024-06 ~ Emergency Drug Kit Permit

I. **SUMMARY**

The Louisiana State Board of Pharmacy (the "Board") proposes amending LAC 46: LIII.1711 (the "Proposed Amendment"), relative to Emergency Drug Kit (EDK) permits. The Proposed Amendment (i) removes the requirement for the administrator of the applicant facility to sign the application for an EDK permit, and (ii) requires the online permit verification to be readily retrievable, since the Board no longer issues paper permits.²

The Board published a Notice of Intent to promulgate the Proposed Amendment on February 20, 2025.³ The Notice invited public comments and testimony on this Proposed Amendment on March 31, 2024 and received no written or oral public comments.⁴

Pursuant to La. R.S. 49:260, the Board submitted the Proposed Amendment to the Louisiana Department of Justice's Occupational Licensing Review Program ("OLRP") on March 31, 2025. The OLRP invited public comments on the Proposed Amendment on April 2, 2025 through April 10, 2025 and received no comments.

As set forth below, the OLRP has determined the Board's Proposed Amendment to LAC 46: LIII.1711 adheres to clearly articulated state policy and is within the Board's statutory authority. Therefore, the Board may proceed with promulgation of the Proposed Amendment as drafted.

¹ 2024-06 1stReport Pkg 2025-0210

² Id. at pg. 2

³ Louisiana Register, Vol. 51, No. 2, at pgs. 307-309

⁵ <u>LABP</u> Regulatory Project 2024-06~ Emergency Drug Kit Permit

II. ANALYSIS

The Board proposes amending LAC 46: LIII.1711 to (i) remove the requirement for obtaining the signature of the facility administrator on applications for pharmacies to acquire or renew an EDK permit, and (ii) requires the online permit verification to be readily retrievable. The Louisiana Pharmacy Practice Act ("LPPA"), La. R.S. 37:1161 et seq., subjects the practice of pharmacy in the State of Louisiana to the regulation of the Board to promote, preserve, and protect the public health, safety, and welfare through effective control of the regulation of the pharmaceutical practice and the licensure, permitting, certification, registration, control and regulation of all persons or sites in or out of this state that sell drugs or devices within this state.⁶

Specifically, the Board is responsible for issuing and renewing permits deemed necessary to engage in the practice of pharmacy. Currently LAC 46:LIII.1711(B)(1) requires the signature of the administrator of a long-term care facility, institutional facility without an institutional pharmacy, or other board-approved site, other than a hospital on an application for an Emergency Drug Kit permit. The Board proposes the removal of the requirement to obtain the facility administrator's signature on an application for an EDK permit because the pharmacy permit and the pharmacist-in-charge are accountable for the EDK permit. Pursuant to LAC 46: LIII.1105, the pharmacist-in-charge is ultimately responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. Additionally, the pharmacist-in-charge of the provider pharmacy is the pharmacist-in-charge of the emergency drug kit and is at all times responsible for the maintenance of the emergency drug kit. The Board's proposal to remove the requirement for the facility administrator's signature on an application for an EDK permit would eliminate an unnecessary requirement and would simplify the permit's application process.

Permitting requirements function as a barrier to market entry by reducing the pool of eligible practitioners, imposing mandatory qualifications, fees, and procedural requirements that may limit the ability of individuals to enter into a profession. However, by removing the requirement for the administrator of the applicant facility to sign the application for the EDK permit and simplifying the process, the Board is reducing these barriers to entry. Emergency drug kits contain emergency drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients or residents because of delay resulting from obtaining such medications from such other source. ⁹ It is the policy of the state to promote, preserve, and protect the public health, safety, and welfare through the licensure, permitting,

⁶ LA R.S. 37:1163

⁷ LA R.S. 37:1182 (A)(8)

⁸ LAC 46: LIII.1711 (C)

⁹ LAC 46: LIII.1709 (A)

certification, registration, control, and regulation of all persons or sites in or out of this state that sell drugs within the state. 10

By removing a barrier to a facility's ability to obtain an EDK, it increases the likelihood a facility would have available emergency drugs, thus adhering to a state policy of promoting public health and safety.

The Board further proposes amending LAC 46: LIII.1711 (B)(6) to require a copy of the online permit verification to be readily retrievable. The current rule requires the original EDK permit to be in the same room as the EDK. The Board indicates this proposal seeks to amend an outdated rule since the Board is no longer issuing paper permits. The Board has the statutory authority to issue and renew licenses and permits deemed necessary to engage in the practice of pharmacy. LAC 46: LIII.1711 (B)(6) governs the practice of pharmacy. While this rule may govern the practice of pharmacy, it is not an occupational regulation with reasonably foreseeable anti-competitive effects and, therefore does not require input from the OLRP. However, the Proposed Amendment to LAC 46: LIII.1711 is within the Board's statutory authority and adheres to clearly articulated state policy. Therefore, the Board may proceed with promulgation of the Proposed Amendment.

III. DETERMINATION

The Board is a state regulatory body created by the LPPA to "promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy; the licensure of pharmacists; and the licensure, permitting, certification, registration, control, and regulation of all persons or sites in or out of this state that sell drugs or devices to consumers and/or patients or assist in the practice of pharmacy within the state." The Board is responsible for the control and regulation of the practice of pharmacy ¹³ and holds the statutory authority to issue and renew licenses, permits, certifications and any other designations necessary. Because the proposed rule is within the Board's statutory authority and the Proposed Amendment to LAC 46: LIII.1711 adheres to clearly articulated state policy, this Amendment is approved as submitted by the Attorney General and may be adopted by the Board.

¹⁰ LA R.S. 37:1163

¹¹ LA R.S. 37:1182 (A)(8)

¹² LA R.S. 37:1163, LA R.S. 37:1171

¹³ LA R.S. 37:1182

¹⁴ LA R.S. 37:1182 (A)(8)

OFFICE OF THE ATTORNEY GENERAL OCCUPATIONAL LICENSING REVIEW PROGRAM

Farra Mughal, OLRP- Assistant Attorney General

Public Protection Division

Louisiana Department of Justice

Sana Cylal

olrp@ag.louisiana.gov