

State of Louisiana

PARTMENT OF JUSTICE CIVIL DIVISION P.O. BOX 94005 BATON ROUGE 70804-9005

To:

M. Joseph Fontenot, Jr.

Executive Director

Louisiana Board of Pharmacy

From:

Terrence "Joe" Donahue, Jr.

Louisiana Department of Justice, Civil Division

Occupational Licensing Review Program

Date:

January 4, 2024

Subject:

OLRP File No. 23-10-OR-0020

Proposed LAC 46:LIII.1107 – Temporary Closure of Pharmacy

I. Summary

The Louisiana Board of Pharmacy (the "Board") proposes amending LAC 46:LIII.1107 to add Subsection (E), which authorizes delivery of prepared prescriptions to patients when a pharmacy is temporarily closed due to an emergency. The Board published a Notice of Intent for the proposed amendment on February 20, 2023, invited comments from the public, and conducted a public hearing on March 28, 2023. Three written comments and one verbal comment were received expressing concerns that the language of the proposed amendment was too broad. The Board provided a formal response to each of the comments on June 5, 2023, indicating that the proposed amendment to LAC 46:LIII.1107 was being referred back to the Board's Regulation Revision Committee to work with stakeholders on crafting language that would address the commenters' concerns.

On September 3, 2023, the Board sent additional correspondence to each of the commenters providing a revised version of the proposed amendment to LAC 46:LIII.1107 that was intended to alleviate the concerns previously expressed. On September 20, 2023 the Board published the revised language in the Louisiana Register, invited additional public comment, and conducted a second public hearing on October 30, 2023. No comments or testimony addressing the revised language of the proposed amendment to LAC 46:LIII.1107 were received.

Rules that regulate a market or profession, or which confer exclusive or shared rights to dominate a market, serve to limit competition, and LAC 46:LIII.1107 is therefore properly considered an occupational regulation with reasonably foreseeable anti-competitive

effects.¹ Pursuant to La. R.S. 49:260, the Board submitted the proposed amendment to LAC 46:LIII.1107 to the Louisiana Attorney General and a review of the regulation was initiated on October 31, 2023. The Attorney General invited public comments on the proposed amendments for a 17-day period ending on November 17, 2023, and received no comments. As set forth below, the Attorney General has determined the Board's proposed amendment to LAC 46:LIII.1107 adheres to clearly articulated state policy and therefore approves the amendment for adoption as drafted.

II. Analysis

The Louisiana Pharmacy Practice Act, La. R.S. 37:1161 *et seq.*, subjects the practice of pharmacy in the state of Louisiana to regulation by the Board for the purpose of promoting, preserving, and protecting the public health, safety and welfare.² In furtherance of these purposes, the legislature has authorized the Board to control and regulate all persons and sites that sell drugs or devices to consumers within the state.³ In particular, the Board is charged with establishing minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, compounding, and dispensing of drugs or devices.⁴

The filling, compounding, and dispensing of prescriptions may only be performed by a licensed pharmacist, or by certain other individuals under a licensed pharmacist's direct supervision.⁵ As a result, a pharmacy must have a licensed pharmacist on duty at all times.⁶ However, once a prescription has been properly prepared in compliance with applicable requirements, unlicensed clerical personnel may then deliver the prepared prescription to the patient, or the patient's agent or caregiver.⁷

The existing language of LAC 46:LIII.1107.D requires pharmacy owners to develop, plans, policies, and procedures to ensure continuity of patient care in the event the pharmacy is unable to open due to natural disasters or other emergencies. Information supplied by the Board indicates that during the COVID-19 public health emergency, some pharmacies were required to close due to the absence of a pharmacist on duty, resulting in patients being unable to obtain prescriptions, including those that had already been prepared by a pharmacist.⁸

The proposed addition of LAC 46:LIII.1107.E allows pharmacies to store prepared prescriptions in a secure location during emergencies so that these prescriptions may be

¹ La. R.S. 49:260(G)(4); see also N. Carolina State Bd. of Dental Examiners v. F.T.C₂, 574 U.S. 494, 503 (2015).

² La. R.S. 37:1163; La. R.S. 37:1171,

³ La. R.S. 37:1163,

⁴ La. R.S. 37:1182(A)(13).

⁵ La. R.S. 37:1224(A), see also La. R.S. 37:1164(12) (defining "dispense" as "the interpretation, evaluation, and implementation of a prescription drug order").

⁶ *Id.*; see also La. R.S. 1164(10) (defining "deliver" as "the actual, constructive, or attempted transfer of a drug or device from one person to another").

⁷ La. R.S. 37:1224(D).

⁸ October 31, 2023 Rule Submission Form at ¶ 1.

delivered to patients, thereby maintaining continuity of care. Both access to the prepared prescriptions and delivery of the prescriptions to patients must be authorized by the designated pharmacist-in-charge, but the prescriptions may be delivered when the pharmacy is closed and no pharmacist is on duty. 10

As addressed above, the legislature has required a pharmacist's participation in the filling, compounding, and dispensing of a prescription, but allows unlicensed clerical personnel to deliver the prescription once it has been properly prepared. The existing provisions of LAC 46:LIII.1107.D recognize that disruptions to pharmacy operations caused by natural disasters and similar emergencies pose a threat to the health, safety, and welfare of the public, and requires pharmacies to have plans in place to ensure continuity of patient care when such emergencies occur. The additional provisions of proposed Subsection (E) identify one acceptable method pharmacies have at their disposal to avoid disruptions to patient care when emergency conditions are present. At the same time, the proposed amendment provides greater flexibility to both pharmacies and pharmacists that will facilitate maintaining their patients' access to prescriptions when emergency conditions are present. As a result, the proposed amendment to LAC 46:LIII.1107 adheres to the clearly articulated state policies expressed in the Louisiana Pharmacy Practice Act.

III. Determination

As the Attorney General has determined the proposed amendment to LAC 46:LIII.1107 adheres to clearly articulated state policy, the amendment is approved and may be finally adopted by the Board.

JEFF LANDRY ATTORNEY GENERAL

Terrence J Donahue, Jr.

Assistant Attorney General

⁹ See February 20, 2023 Notice of Intent; September 20, 2023 Potpourri Notice of Revision.
¹⁰ Id