

- To: Mr. M. Joseph Fontenot, Jr. Executive Director Louisiana State Board of Pharmacy
- From: Jessica Weimer Louisiana Department of Justice Occupational Licensing Review Program

Date: November 15, 2024

Subject: Louisiana State Board of Pharmacy Proposed Amendment to LAC 46:LIII.2403 Regulatory Project 2024-06 ~ Durable Medical Equipment (DME) Permit Change of Ownership

I. <u>SUMMARY</u>

The Louisiana State Board of Pharmacy (the "*Board*") proposes amending LAC 46:LIII.2403 (the "*Proposed Amendment*"), relative to Durable Medical Equipment ("*DME*") permit change of ownership.¹ The Proposed Amendment (i) removes language regarding a duplicate or replacement permit, and (ii) establishes the change of ownership procedures.²

The Board published a Notice of Intent to promulgate the Proposed Amendment on July 20, 2024.³ The Notice invited public comments and testimony on this Proposed Amendment on August 26, 2024 and received no written or oral public comments.⁴

No person or other entity shall sell, rent or provide, directly or indirectly, to consumers in this state, any durable medical equipment (DME) without obtaining a permit from the Board.⁵ Licensing and permitting requirements are barriers to market competition and the Proposed Amendment to §2403 is therefore properly considered an occupational regulation with reasonably foreseeable anti-competitive effects.⁶

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 October 11,

¹ 2024-06 1stReport Pkg S 2024-0708.pdf

² Id. at pg. 2

³ Louisiana Register, Vol. 50, No. 7, at pgs. 1052-1054

⁴ Id. at 1054

⁵ LAC 46:LIII.2403 (A)

⁶ La. R.S. 49:260 G(4)

2024.⁷ The OLRP invited public comments on the Proposed Amendment October 21, 2024 through November 4, 2024 and received no comments. As set forth below, the OLRP has determined the Board's Proposed Amendment to LAC 46: LIII §2403 adheres to clearly articulated state policy and therefore approves this Amendment for adoption as drafted.

II. <u>ANALYSIS</u>

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.⁸ Specifically, the Board is responsible for issuing and renewing permits deemed necessary to engage in the practice of pharmacy.⁹

A. Proposed LAC 46:LIII.2403

The Board proposes amending LAC 46:LIII.2403 to (i) require a new application be filed and a new permit obtained when a change in identity of the DME permit holder occurs, (ii) require a new application be filed and a new permit obtained when there is a change in the DME permit holder's Federal Employment Identification Number (FEIN), (iii) deem a DME permit non-transferrable, (iv) require a new application be submitted within fifteen (15) days prior to the closing of the transfer of ownership, and (v) clarify that nothing prohibits an entity from applying for a new DME permit in order to separate itself from actions which may have been committed by previous ownership under the existing DME permit.

The LPPA grants the Board the authority to issue and renew permits as deemed necessary to engage in the practice of pharmacy¹⁰ as it is the policy of the state to promote, preserve, and protect the public health, safety, and welfare by and through the permitting and regulation of all persons or sites, in or out of this state that sell drugs or devices to consumers and/or patients.¹¹ The proposed rule outlines in detail the requirements to obtain a DME permit. The existing provisions of LAC 46:LIII.2403 (E)(3) allow for a duplicate or replacement permit to be issued upon written request and 46:LIII.2403(E)(4) requires a new owner to submit a completed application form and permit fee 15 calendar days prior to the transfer of ownership. The current rule indicates a change of ownership is evidence following a (i) sale, (ii) death of proprietor, (iii) addition or deletion of one or more partners in a partnership, (iv) bankruptcy sale; or (v) a 50 percent or more, change in ownership of a corporation, LLC, or association since issuance of the original DME permit¹².

⁷ LABP at Regulatory Project 2024-06~Durable Medical Equipment (DME) Permit Change of Ownership

⁸ LA R.S. 37:1163

⁹ LA R.S. 37:1182 (A)(8)

¹⁰ LA R.S. 37:1182 (A) (8)

¹¹ LA R.S. 37:1163

¹² LAC 46:LIII.2403 (E)(3)

The Proposed Amendment eliminates §2403(E)(3) regarding the duplicate or replacement permit and in regards to the change of ownership procedures, eliminates the list of circumstances constituting when a change of ownership is evidence, and requires a new permit application to be filed when there is a change in the identity of the DME permit holder, or the permit holder's FEIN.¹³ Rather than requiring the existing permit holder to provide advance written notice, the Proposed Amendment requires the new owner to submit a permit application at least 15 days before transfer of ownership is completed.¹⁴ The Proposed Amendment also requires changes in "first indirect level of ownership of 20% or more" to be reported to the Board within thirty (30) days of the change.¹⁵ The Proposed Amendment also clarifies that there is nothing in this section to prohibit an entity from applying for a new DME permit in order to separate itself from actions that may have been committed by the previous ownership under the existing DME permit.¹⁶ The Proposed Amendment is less restrictive than the current rule.

The Louisiana Legislature has granted the Board the authority to issue and renew permits deemed necessary to engage in the practice of pharmacy¹⁷ in order 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, and 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.¹⁸ Therefore, the proposed changes are within the Board's aforementioned discretionary powers.

III. <u>Determination</u>

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 pharmacy²⁰ and holds the statutory authority to issue and renew licenses, permits, certifications and any other designations necessary.²¹ Because the proposed rule is within the Board's statutory authority authority to LAC 46:LIII.2403 adheres to clearly articulated state policy, this Amendment is approved as submitted by the Attorney General and may be adopted by the Board.

¹³ <u>2024-06_1stReport_Pkg_S_2024-0708.pdf</u>, pg. 2-3

¹⁴ Id.

¹⁵ Id. ¹⁶ Id.

¹⁷ LA R.S. 38:1182 (A)(8)

¹⁸ LA R.S. 37:1163

¹⁹ LA R.S. 37:1163, LA R.S. 37:1171

²⁰ LA R.S. 37:1182

²¹ LA R.S. 37:1182 (A)(8)

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