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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:

February 14, 2023

Subject:

OLRP File No. 22-11-OR-0011

Proposed LAC 46:LIII.Chapter 23 - Nonresident Pharmacy

I. <u>Summary</u>

The Louisiana Board of Pharmacy (the "Board") proposes amending the regulations governing nonresident pharmacies located in Chapter 23 of LAC 46:LIII, specifically LAC 46:LIII §§ 2301, 2303, 2305, 2307, 2309, 2317, and 2319. The Board published a Notice of Intent to promulgate the proposed amendments on July 20, 2022, invited comments on the proposed amendments, and held a public hearing on August 26, 2022. The Board received one written comment suggesting additional changes to LAC 46:LIII.2307 on July 28, 2022, to which a response was provided on December 12, 2022, in accordance with La. R.S. 49:961(B)(3).

While the proposed regulations are likely to have minimal, if any, effect on market competition, permitting requirements create barriers to market entry for individuals desiring to engage in a profession or occupation, and the proposed amendments to Chapter 23 of LAC 46:LIII are therefore properly considered occupational regulations with reasonably foreseeable anti-competitive effects.¹ Pursuant to La. R.S. 49:260, the Board submitted the proposed amendments to the Louisiana Attorney General and a review was initiated on December 14, 2022. The Attorney General invited public comments on the proposed amendments for a 20-day period ending on January 25, 2022 and received no comments. As set forth below, the Attorney General has determined the Board's proposed amendments to LAC 46:LIII §§ 2301, 2303, 2305, 2307, 2309, 2317, and 2319 adhere to clearly articulated state policy and therefore approves these amendments for adoption as drafted.

II. Analysis

¹ La. R.S. 49:260(G)(4).

The Louisiana Pharmacy Practice Act, La. R.S. 37:1161 *et seq.*, subjects all "persons or sites" that sell drugs or devices to individuals located within Louisiana, or that otherwise assist in the practice of pharmacy within the state, to regulation by the Board for the purpose of promoting, preserving, and protecting the public health, safety and welfare.² All pharmacies, whether located in Louisiana or another state, must receive a permit from the Board prior to providing pharmacy services to Louisiana residents.³ Pharmacies located outside of Louisiana are statutorily designated as "nonresident pharmacies" and the Board may issue "nonresident pharmacy permits" authorizing such pharmacies to provide pharmacy services to Louisiana residents.⁴

A. Proposed LAC 46:LIII.2301, 2305, 2309, 2311, 2317, and 2319

The Board proposes changing the language of §§ 2301, 2305, 2309, 2311, 2317, and 2319 to reference "nonresident" pharmacies instead of "out-of-state" pharmacies, as the regulations currently provide. The proposed changes incorporate modifications to the language of La. R.S. 37:1232 made in Act No. 282 of the 2013 Louisiana Legislative Regular Session and do not affect the substance of the regulations.

B. Proposed LAC 46:LIII.2303

The proposed amendments to § 2303 involve several changes to the language of the existing regulation. First, the Board proposes amending § 2303.A to remove language indicating that nonresident pharmacies must possess permits in each state in which the pharmacy practices, clarifying that nonresident pharmacies need only be licensed in the state where they reside.⁵ The Board also proposes changing the language of § 2303.B to eliminate a reference to multiple "state(s)" in which pharmacists affiliated with nonresident pharmacies practice to clarify that pharmacists affiliated with a nonresident pharmacy must be licensed in the state where the nonresident pharmacy is located.⁶ Finally, the Board proposes eliminating entirely the provisions of § 2303.C, which currently require nonresident pharmacies to designate a registered agent and a registered office in Louisiana for service of process.⁷

The proposed changes to § 2303.A are in accord with the express language of La. R.S. 37:1232(C), which requires non-resident pharmacies to "maintain at all times authorization to conduct the pharmacy in compliance with the laws of the state in which it is a resident." In addition to being consistent with La. R.S. 37:1232(C), elimination of the reference to multiple states in the proposed revision to § 2303.B provides clarity and conforms to the provisions of La. R.S. 37:1182(A)(1) and (9) (authorizing promulgation of rules and regulations pertaining to issuance of credentials to engage in the practice of

² La. R.S. 37:1163; La. R.S. 37:1171.

³ La. R.S. 37:1221.

⁴ La. R.S. 37:1232.

⁵ July 20, 2020 Notice of Intent.

⁶ Id.

⁷ *Id.*

^{8 (}emphasis supplied).

pharmacy), La. R.S. 37:1201(A) (requiring all individuals engaging or assisting in the practice of pharmacy to be licensed or registered with the Board), La. R.S. 37:1203(A) (authorizing licensure by reciprocity for pharmacists licensed in another jurisdiction), and La. R.S. 37:1222(A) (authorizing the imposition of requirements on pharmacy license applicants as the Board deems necessary).

The proposed elimination of § 2303.C would also align the content of the regulation with the provisions of La. R.S. 37:1222(C), which provides that Board-permitted pharmacies "may" designate a registered agent in Louisiana for service of process. Furthermore, while businesses located in other jurisdictions are generally required to designate a registered agent and registered office in Louisiana prior to transacting business in the state,⁹ requiring these designations may not be appropriate in all circumstances.¹⁰ Where no registered agent or registered office has been designated, Louisiana law provides other avenues for obtaining service of process.¹¹

C. Proposed LAC 46:LIII.2305

In addition to substituting "nonresident" for "out-of-state" as described above, the Board also proposes amending the text of § 2305 to eliminate the existing reference to La. R.S. 37:1184 and provide instead that the annual fee for a nonresident pharmacy permit will be defined by the Board in accordance with State law. Consistent with this proposed change, La. R.S. 37:1182(A)(11) directs the Board to establish by regulation the fees and costs to be imposed in implementing and enforcing the Louisiana Pharmacy Practice Act.

While the Board has indicated its intent to establish the amount of these costs and fees by regulation, such a regulation was not included in the Board's submission and is not addressed in the current review.¹² When promulgating regulations to fix the amount of costs and fees associated with permits and other credentials issued by the Board, the provisions of La. R.S. 37:1184 should be given proper consideration.¹³

D. Proposed LAC 46:LIII.2307

The proposed amendments to § 2307 involve multiple changes to the language of the existing regulation. The Board first proposes modifying the language of § 2307.D to state that a nonresident pharmacy's designated pharmacist-in-charge shall be responsible for the "implementation" of certain "policies and procedures" instead of the "development and maintenance" of specified "policies." In addition, the proposed amendments revise § 2307.I to increase the amount of time in which a nonresident pharmacy is required to notify the Board of a change to its pharmacist-in-charge designation, from within 10 days of the prior designee's departure date to within 30 days of the triggering event. Lastly,

⁹ See La. R.S. 12:301; 12:308 (corporations); 12:1350 (limited liability companies)

¹⁰ See La. R.S. 12:302 (identifying activities not considered to be "transacting business in this state").

¹¹ See La. R.S. 37:1222(D); La. Code Civ. Proc. arts 1261 and 1262.

¹² July 20, 2020 Notice of Intent.

¹³ See e.g. Mid-City Auto., L.L.C. v. Dep't of Pub. Safety & Corr., 2018-0056 (La.App. 1 Cir. 11/7/18), 267 So.3d 165.

the proposed amendments also modify the text of § 2307.J to remove reference to the notarization of the "Affidavit of Responsibility and Duties" submitted by a designated pharmacist-in-charge, and to provide that such affidavits are maintained in the Board's record for the pharmacist instead of the nonresident pharmacy.

The proposed revisions to § 2307.D do not involve substantive changes and eliminate existing discrepancies in the regulatory language applicable to domestic pharmacies and nonresident pharmacies. The modifications to § 2307.I made in the proposed amendment also achieve parity in the regulations governing domestic and nonresident pharmacies, providing that *all* pharmacies shall provide notice of a change in the pharmacist-in-charge designation within 30 days of the departure of a pharmacist holding the designation. These changes do not run afoul of the authorizing statutes.

As with the other Subsections of § 2307, removal of the reference to notarization of the Affidavit of Responsibility and Duties in §2307.J will cause the regulatory provisions governing nonresident pharmacies to mirror existing regulations applicable to domestic pharmacies.¹⁷ It is noted, however, that continued use of the term "affidavit" in the regulation implies that notarization is still required.¹⁸ The referenced affidavit is not referenced in the Louisiana Pharmacy Practice Act, though the Board is clearly authorized to require such documentation from an applicant for a pharmacy permit, and to impose formal requirements as it deems necessary.¹⁹ If the Board believes no formality in execution is necessary for the Affidavit of Responsibilities and Duties, then it may wish to consider discontinuing use of the term "affidavit" in both §§ 1105.J and 2307.J. If the Board instead wishes to preserve some level of formality, albeit in a less onerous manner, it may be guided by provisions of federal law that serve to achieve this result.²⁰

III. Determination

As discussed above, the proposed amendments to the regulations governing nonresident pharmacies will increase consistency with authorizing legislation and reduce the regulatory burdens imposed upon nonresident pharmacies in a manner that creates parity with domestic pharmacies and adheres to the clearly articulated state policies embodied in the Louisiana Pharmacy Practice Act. As the Attorney General has determined the provisions of proposed LAC 46:LIII §§ 2301, 2303, 2305, 2307, 2309, 2317, and 2319 adhere to clearly articulated state policy, these regulations are approved and may be formally adopted by the Board.

¹⁴ Compare LAC 46:LIII.1105.D and LAC 46:LIII.2307.D.

¹⁵ Compare LAC 46:LIII.1105.I and LAC 46:LIII.2307.I.

¹⁶ See La. R.S. 37:1222(A) and La. R.S. 1231(B)(2).

¹⁷ Compare LAC 46:LIII.1105.J and LAC 46:LIII.2307.J.

¹⁸ See Septs v. Control Valve Specialist, Inc., 2011-1383 (La. App. 1 Cir. 3/23/12), 2012 WL 994620, writ denied, 2012-1241 (La. 9/21/12), 98 So. 3d 344, citing State v. Duhon, 95-2724, 95-2726 (La. 5/21/96), 674 So.2d 944, 946 ("[c]learly, however, an affidavit's definitive characteristic is the fact that the writing is made under oath") (emphasis in original).

¹⁹ La. R.S. 37:1222(A).

²⁰ See 28 U.S.C. § 1746.

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