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To: Mr. M. Joseph Fontenot, Jr.
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From: Jessica Weimer
Louisiana Department of Justice
Occupational Licensing Review Program

Date: November 13, 2024

Subject: Louisiana State Board of Pharmacy
Proposed Amendment to LAC 46:LIII.1217 and 1509.
Regulatory Project 2024-04 ~ Automated Medication Systems

I. SUMMARY

The Louisiana State Board of Pharmacy (the "***Board***") proposes amending LAC 46:LIII.1217 and 1509 (the "***Proposed Amendments***"), relative to Automated Medication Systems ("***AMS***").[1] The proposed amendment to LAC 46:LIII.1509 removes the reference "human intervention" to prevent confusion regarding different interpretations of the rule due to the ambiguity of the phrase.[2] The proposed amendment to LAC 46:LIII.1217 describes the requirements of stocking and restocking an AMS, differentiating between pharmacies that employ electronic product verification procedures and those that do not, and adds the accountability of the pharmacist in charge for the accuracy of all drug distribution activities.[3]

The Board published a Notice of Intent to promulgate the proposed amendments on July 20, 2024.[4] The Notice invited public comments and testimony on these proposed amendments on August 26, 2024 and received no written or oral public comments.[5]

Regulations placing restrictions on business practices, such as the regulation to stock and restock the AMS, are barriers to market competition, and the proposed amendments to §1217 and §1509 are therefore properly considered occupational regulations with reasonably foreseeable anti-competitive effects.[6]

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[1] 2024-04_1stReport_Pkg_S_2024-0708.pdf at pg. 1.
[2] Id. at pg. 8
[3] Id. at pg. 8
[4] Louisiana Register, Vol. 50, No. 7, at pgs. 1050-1052
[5] Id. at 1052
[6] La. R.S. 49:260 G(4)

Pursuant to La. R.S. 49:260, the Board submitted the proposed amendments to the Louisiana Department of Justice's Occupational Licensing Review Program ("***OLRP***") on October 8, 2024.[7] The OLRP invited public comments on the proposed amendments October 21, 2024 through November 4, 2024 and received no comments. As set forth below, the OLRP has determined the Board's proposed amendments to LAC 46: LIII §1217 and §1509(B) adhere to clearly articulated state policy and therefore approves these amendments for adoption as drafted.

II. ANALYSIS

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] The Uniform Controlled Dangerous Substances Law authorizes the board to promulgate rules and regulations relating to the registration, control, and the licensing of the manufacture, distribution, and dispensing of CDS within this state.[9] Specifically, the Board is responsible for "establishing minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for storage, compounding, and dispensing of drugs or devices."[10]

A. Proposed LAC 46:LIII.1217

The board proposes amending LAC 46:LIII.1217 to (i) describe and differentiate the requirements of stocking and restocking of an AMS between pharmacies that employ electronic product verification and those that do not and (ii) adds accountability of the pharmacist-in-charge for the accuracy of all drug distribution activities.

The LPPA grants the Board the authority to establish minimum specifications for the procedures for the storage, compounding, and dispensing of drugs or devices.[11] This proposed amendment establishes the proper stocking and restocking procedures for the AMS with electronic product verification by proper persons as authorized by the rule and the accuracy of drug distribution activities and establishes accountability for the same in in order to preserve the health, safety and welfare of the state.

The board is responsible for establishing professional standards and rules of conduct of pharmacists engaged in the practice of pharmacy.[12] Further, it is the policy of the state to promote, preserve and protect the health, safety and welfare by regulation of all persons or

[7] LABP at Regulatory Project 2024-04-Automated Medication Systems (AMS)
[8] LA R.S. 37:1163
[9] LA R.S. 40:972-40:975
[10] LA R.S. 37:1182 (A)(13)
[11] Id
[12] LA R.S. 37:1182 (A)(9)

sites that sell drugs or devices to consumers and/or patients within the state.[13]Therefore, the proposed changes are within the Board's aforementioned discretionary powers.

B. Proposed LAC 46:LIII.1509

The Board's proposed amendment to §1509(B)(1) removes the language "and in the absence of any subsequent human intervention in the automated drug selection process." According to the Board, this rule has been amended to remedy ongoing confusion regarding the removed phrase due to differing interpretations and the proposed rule seeks to clarify the intent of the rules. The Board is authorized to promulgate rules and regulations necessary relating to the registration and control of the manufacture, distribution, and dispensing of controlled dangerous substances within the state.[14] As such, this proposed change is within the discretion of the Board's aforementioned discretionary powers.

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."[15] The Board holds the statutory authority to establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy.[16] Furthermore, the Board is responsible for establishing minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for storing, compounding, and dispensing of drugs or devices.[17] Because the proposed rules are within the Board's statutory authority and the proposed amendments to LAC 46:LIII.1217 and 1509 adhere to clearly articulated state policy, these amendments are approved as submitted by the Attorney General and may be adopted by the board.

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[13] LA R.S. 37:1163
[14] LA R.S. 40:972, LA R.S. 40:975
[15] LA R.S. 37:1163, LA R.S. 37:1171
[16] LA R.S. 37:1182 A(9)
[17] LA R.S. 37:1182 A(13)