



Louisiana Board of Pharmacy

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October 8, 2024

To: Attorney General Liz Murrill
Attn: Department of Justice, Occupational Licensing Review Program

From: Joe Fontenot, Executive Director
Louisiana Board of Pharmacy

Subject: **Regulatory Project 2024-04 ~ Automated Medication Systems (AMS)**

The Board of Pharmacy seeks to amend Section 1217 and Section 1509 of its rules relative to Automated Medication Systems (AMS). The proposed rule changes in Section 1217 and Section 1509.B. remove references to "human intervention" which has led to different interpretations. The proposed rule changes in Section 1217 also describe the requirements of stocking and restocking of 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.

To facilitate the Department of Justice's review of the proposed rule, the Louisiana Board of Pharmacy provides answers to the following questions.

1. Describe any relevant factual background to the occupational regulation and the purpose of the occupational regulation?

The Board of Pharmacy became aware of confusion concerning the phrases "which prohibits any human intervention following pharmacy verification of the product" and "any subsequent human intervention" and deemed it necessary to amend the rules.

The proposed rule changes describe the requirements of stocking and restocking of 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. Current rules have been interpreted as requiring the pharmacist to be present when stocking an AMS using electronic product verification, but the proposed rule changes clarify that this is not necessary.

2. Is the occupational regulation within the scope of the occupational licensing board's general authority to regulate in a given occupation or industry? If so, identify the law that provides the authority for the rule and describe how the occupational regulation is within the scope.

Yes. LA R.S. 37:1182 contains the powers and duties of the Board which includes: to establish minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, compounding, and dispensing of drugs or devices.

3. Check all of the following that apply as reasons the occupational regulation is subject to review
- Creates a barrier to market competition
 - Fixes prices, limits price competition, or results in high prices for a product or service provided by or to a license holder.
 - Reduces competition or excludes present or potential competitors from the occupation regulated by the board
 - Limits output or supply in this state of any good or service provided by the members of the regulated occupation.
 - Reduces the number of providers that can serve a particular set of customers
 - Other activity (please describe)

The regulation places restrictions on who may stock and restock automated medication systems (AMS).

4. Identify the clearly articulated state policy (e.g., health, safety, welfare, or consumer protection) in state statute, or any supporting evidence of the harm the action/proposed action is intended to protect against?

The purpose of the Louisiana Pharmacy Practice Act, as stated in LA R.S 37:1163, is 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.

5. Do any less restrictive alternatives to the occupational regulation exist for addressing the same harm? If so, include a comparison of the occupational regulation to the alternatives and a justification for not pursuing a less restrictive alternative. If no less restrictive alternatives exist, explain why.

No, less restrictive alternatives do not exist in regard to our core mission of licensing.

6. Describe the process that the occupational licensing board followed in developing the proposed rule, including any public hearings held, studies conducted, and data collected or analyzed.

07-18-2023 – The Board’s Regulation Revision Committee held a public meeting and the committee reviewed and considered a draft proposal with public participation.
04-25-2024 – The Regulation Revision Committee held a public meeting and the committee approved Draft #6 with public participation.
05-08-2024 – During a public meeting of the Board, the Board approved this regulatory proposal for promulgation.
06-10-2024 – Fiscal & Economic Impact Statement (FEIS) submitted to the Legislative Fiscal Office (LFO) for approval.
07-08-2024 – LFO approved fiscal and economic impact statement.
07-08-2024 – First report submitted to the Joint Legislative Oversight Committee on Health & Welfare.
07-08-2024 – Notice of Intent (NOI) submitted to the Louisiana Register for publication on July 20, 2024.
07-20-2024 – NOI published in the 2024 Louisiana Register, Volume 50, July Edition. NOI, as published, can be found here.
07-20-2024 – Public Hearing scheduled for August 26, 2024.
07-22-2024 – Notice of Rulemaking Activity & Public Hearing distributed.
08-26-2024 – Public Hearing held at the Board office.

7. Does the occupational regulation relate to a matter on which there is pending litigation or a final court order? *No*

8. Please identify the board members voting in favor of this rule, and state whether the member is an active market participant.

On May 8, 2024, 16 members were present and one member (Robert C. LeBas) was absent. The vote in favor of the proposed rule was unanimous (15-0, with President McKay not voting as Chair). Members present: Robert Cloud, David Darce, Jennifer Dupree, Jacqueline Hall, Richard Indovina, Jr., Charles Jones, Kevin LaGrange, Richard Mannino, Marty McKay, Chris Melancon, Troy Menard, Anthony Mercante, Blake Pitre, Don Resweber, Raymond Strong, and Rhonny Valentine. All members voting are active market participants except for Mr. Resweber, the public member.

9. Is there anything else that the occupational licensing board would like the Department to know about the proposed rule? *No*