Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov

October 8, 2024

Senator Cameron Henry
President, Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: **Report No. 2 of 3** for Regulatory Project 2024-04 (Summary Report) ~ Automated Medication Systems (AMS)

Dear Senator Henry:

As we indicated in our first report to your office on July 8, 2024, the Board seeks to amend Sections 1217 and 1509 of its rules relative to Automated Medication Systems (AMS).

Subsequent to the publication of our *Notice of Intent* in the July 2024 edition of the *Louisiana Register*, we conducted a public hearing on August 26 to receive comments and testimony on the proposed rule changes. We received no comments or testimony. The Board subsequently determined no revisions were warranted. On October 8th we submitted the project to the Department of Justice's Occupational Licensing Review Program (OLRP) and are awaiting their approval. In connection with this regulatory project, you should find the following documents in this package:

- *Notice of Intent*, as published in the July 2024 edition of the *Louisiana Register*
- Record from the August 26, 2024 Public Hearing
- Full text of proposed rule, as intended for publication in the *Louisiana Register*

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare and approval by the OLRP, the Board proposes to publish the original proposed rule changes without amendment as a *Rule* in the November 20, 2024 edition of the *Louisiana Register* with an immediate effective date. If you have any questions about the enclosed information or our procedures, please contact me directly at jfontenot@pharmacy.la.gov or 225.925.6481.

For the Board:

M. Joseph Fontenot, Jr. Digitally signed by M. Joseph Fontenot, Jr.
Date: 2024.10.08 14:14:41 -05'00'

M. Joseph Fontenot Jr.
Executive Director

cc: Chair, Senate Health & Welfare Committee
Via Email: APA.S-H&W@legis.la.gov
Speaker, House of Representatives
Via Email: APA.HouseSpeaker@legis.la.gov
Chair, House Health & Welfare Committee
Via Email: APA.H-HW@legis.la.gov
Editor, *Louisiana Register*
Via Email: Reg.Submission@la.gov
Reference File

NOTICE: In compliance with Act 256 of the 2019 Louisiana Legislature, the Board gives public notice that any information submitted to the Board may become public record unless specifically exempted by the Public Records Law, R.S. 44:1 *et seq.*

NOTICE OF INTENT

Department of Health
Board of Pharmacy

Automated Medication Systems
(LAC 46:LIII.1217 and 1509)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Board of Pharmacy hereby gives notice of its intent to amend §1217 and §1509 of its rules relative to Automated Medication Systems (AMS). The proposed Rule changes in §1217 and §1509.B. remove references to "human intervention" due to the ambiguity of phrase which has led to different interpretations. The proposed Rule changes in §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.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 12. Automated Medication Systems
§1217. Stocking and Restocking; Electronic Product Verification

A. In the absence of electronic product verification procedures as described within this Section, the stocking and restocking of medications and devices within an automated medication system shall be performed by a pharmacist, or in the alternative, a pharmacy intern, pharmacy technician, or pharmacy technician candidate under the supervision of a pharmacist.

B. When the pharmacy employs electronic product verification procedures as described within this Section, the stocking and restocking of medications and devices within an automated medication system may be performed by a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician candidate.

1. A bar code or other electronic verification shall be utilized to assure the correct selection of drugs to be placed into an automated medication system.

2. The use of a bar code or other electronic verification shall require an initial quality assurance validation followed by ongoing quality assurance reviews at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.

C. The pharmacist-in-charge remains accountable to the board for the accuracy of all drug distribution activities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182(A).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000, amended LR 41:1488 (August 2015), amended by the Department of Health, Board of Pharmacy, LR 47:243 (February 2021), amended LR 50:

Chapter 15. Hospital Pharmacy

§1509. Drug Distribution Control

A. - A.3.e.iii. …

B. Automated Medication Systems. A hospital pharmacy may use one or more automated medication systems in compliance with the provisions of Chapter 12 of this Part.

1. When the pharmacy uses an electronic product verification process as described in Section 1217 of this Part, the pharmacist-in-charge may elect to forego manual checks of drug products selected in that manner, provided however, that such selection by the pharmacist-in-charge shall require an initial quality assurance validation followed by an ongoing quality review at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.

2. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004, amended LR 40:2257 (November 2014), effective January 1, 2015, LR 41:1488 (August 2015), amended by Department of Health, Board of Pharmacy, LR 46:583 (April 2020), amended LR 50:

Family Impact Statement

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the Rule proposed for adoption, repeal, or amendment. The following statements will be published in the *Louisiana Register* with the proposed agency Rule.

1. The Effect on the Stability of the Family. The proposed rule amendment will have no effect on the stability of the family.

2. The Effect on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed rule amendment will have no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The Effect on the Functioning of the Family. The proposed rule amendment will have no effect on the functioning of the family.

4. The Effect on Family Earnings and Family Budget. The proposed rule amendment will have no effect on family earnings and family budget.

5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule amendment will have no effect on the behavior and personal responsibility of children.

6. The Ability of the Family or a Local Government to Perform the Function as Contained in the Proposed Rule. The proposed rule amendment will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed Rule.

Poverty Impact Statement

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the Rule proposed for adoption, repeal, or amendment.

1. The Effect on Household Income, Assets, and Financial Security. The proposed rule amendment will have no effect on household income, assets, or financial security.

2. The Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed rule amendment will have no effect on early childhood development or preschool through postsecondary education development.

3. The Effect on Employment and Workforce Development. The proposed rule amendment will have no effect on employment and workforce development.

4. The Effect on Taxes and Tax Credits. The proposed rule amendment will have no effect on taxes or tax credits.

5. The Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. The proposed rule amendment will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

Small Business Analysis

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses:

1. The Establishment of Less Stringent Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment will have no effect on reporting requirements for small business.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment will have no effect on schedules or deadlines for compliance or reporting requirements for small business.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment will have no effect on consolidation or simplification of compliance or reporting requirements for small business.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed rule amendment will have no effect on establishment of performance standards for small businesses to replace design or operational standards for small business.

5. The Exemption of Small Businesses from All or Any Part of the Requirements Contained in the Proposed Rule. There are no exemptions for small businesses in the proposed rule amendment.

Provider Impact Statement

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

1. The Effect on the Staffing Level Requirements or Qualifications Required to Provide the Same Level of Service. The proposed rule amendment may reduce the staffing level requirements or qualification required to

provide the same level of service by removing the requirement for a pharmacist to be present for the restocking of an AMS in a location other than that of the pharmacy.

2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed rule amendment may decrease the cost to the provider to provide the same level of service by allowing a pharmacy intern, pharmacy technician, or pharmacy technician candidate to restock an AMS at a location other than that of the pharmacy without requiring a pharmacist to be present.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed rule amendment will have no effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to M. Joseph Fontenot Jr., Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding the proposed Rule amendment. The deadline for the receipt of all written comments is 12 p.m. on Monday, August 26, 2024.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule changes is scheduled for 9 a.m. on Monday, August 26, 2024 at the board office. During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

M. Joseph Fontenot, Jr.
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Automated Medication Systems (AMS)

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

Other than the cost of rulemaking, which is approximately $1,000 in FY 25 related to publishing the proposed rule and final rule in the Louisiana Register, the proposed rule changes are not anticipated to result in any additional expenditures or cost savings for the Louisiana Board of Pharmacy (LBP). The cost of rulemaking will be paid from self-generated funds.

To the extent a government-operated pharmacy is utilizing an Automated Medication System (AMS), the proposed rule changes may decrease the costs to the pharmacy to provide the same level of service by allowing a pharmacy intern, pharmacy technician, or pharmacy technician candidate to restock an AMS at a location other than that of the pharmacy without requiring a pharmacist to be present.

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 at a location other than that of the pharmacy, but the proposed rule changes clarify that this is not necessary.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule changes will not affect revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

The proposed rule changes will benefit pharmacies that employ electronic product verification procedures by allowing a pharmacy intern, pharmacy technician, or pharmacy technician candidate to restock an AMS at a location other than that of the pharmacy without requiring a pharmacist to be present.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes may reduce the staffing level requirements or qualification required to provide the same level of service by removing the requirement for a pharmacist to be present for the restocking of an AMS in a location other than that of the pharmacy.

M. Joseph Fontenot, Jr.
Executive Director
2407#032

Patrice Thomas
Deputy Fiscal Officer
Legislative Fiscal Office

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov

NOTICE IS HEREBY GIVEN that a Public Hearing has been ordered and called for **9:00 a.m. on Monday, August 26, 2024** at the Board office, for the purpose to wit:

AGENDA

Revised 07-20-2024

1. Call to Order 9:04 a.m.
2. Appearances
3. Solicitation of Comments & Testimony on Proposed Rule Changes
   - A. Regulatory Project 2024-04 ~ Automated Medication Systems (AMS)
   - B. Regulatory Project 2024-05 ~ Pharmacy Technicians
   - C. Regulatory Project 2024-06 ~ Durable Medical Equipment Change of Ownership
   - D. Regulatory Project 2024-07 ~ Prescription Transfers
4. Opportunity for Public Comment
5. Adjourn 12:00 p.m.

Public Comments
Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to M. Joseph Fontenot Jr., Executive Director, at the Board office. He is responsible for responding to inquiries regarding the proposed Rule amendments. The deadline for the receipt of all written comments is 12 p.m. on Monday, August 26, 2024.

Public Hearing
During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request a disability accommodation, please contact Joe Fontenot, Executive Director, at 225.925.6496 or email at jfontenot@pharmacy.la.gov .

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Louisiana Board of Pharmacy

Public Hearing Attendance Record ~ August 26, 2024

Regulatory Project 2024-04 ~ Automated Medication Systems (AMS)
Regulatory Project 2024-05 ~ Pharmacy Technicians
Regulatory Project 2024-06 ~ Durable Medical Equipment Change of Ownership
Regulatory Project 2024-07 ~ Prescription Transfers

Name	Address	E-mail	Group or Agency Represented
1. Shelly Dupré	804 Main St. BR 70802	shelly@impactmanagement.com	LARP
2. Sarah Perkins	301 Main St.	sarah.perkins@bswllp.com	
3.			
4.			
5.			

Louisiana Board of Pharmacy

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Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov

August 26, 2024

Public Hearing

Opportunity for Public Comment

1. Name _____ representing _____

   Comments:

2. Name _____ representing _____

   Comments: None

3. Name _____ representing _____

   Comments:

4. Name _____ representing _____

   Comments:

Louisiana Board of Pharmacy

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Summary of Testimony & Public Comments

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

at

August 26, 2024 Public Hearing

No Letters or Comments Received.

RULE

Department of Health

Board of Pharmacy

Automated Medication Systems (LAC 46:LIII.1217 and 1509)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Board of Pharmacy amended §1217 and §1509 of its rules relative to Automated Medication Systems (AMS). The Rule changes in §1217 and §1509.B. remove references to "human intervention" due to the ambiguity of phrase which has led to different interpretations. The Rule change in §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. This Rule is hereby adopted on the day of publication.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 12. Automated Medication Systems

§1217. Stocking and Restocking: Electronic Product Verification

A. In the absence of electronic product verification procedures as described within this Section, the stocking and restocking of medications and devices within an automated medication system shall be performed by a pharmacist, or in the alternative, a pharmacy intern, pharmacy technician, or pharmacy technician candidate under the supervision of a pharmacist.

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1. A bar code or other electronic verification shall be utilized to assure the correct selection of drugs to be placed into an automated medication system.

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C. The pharmacist-in-charge remains accountable to the board for the accuracy of all drug distribution activities.

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Chapter 15. Hospital Pharmacy

§1509. Drug Distribution Control

A.- A.3.e.iii. …

B. Automated Medication Systems. A hospital pharmacy may use one or more automated medication systems in compliance with the provisions of Chapter 12 of this Part.

1. When the pharmacy uses an electronic product verification process as described in Section 1217 of this Part, the pharmacist-in-charge may elect to forego manual checks of drug products selected in that manner, provided however, that such selection by the pharmacist-in-charge shall require an initial quality assurance validation followed by an ongoing quality review at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.

2. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004, amended LR 40:2257 (November 2014), effective January 1, 2015, LR 41:1488 (August 2015), amended by Department of Health, Board of Pharmacy, LR 46:583 (April 2020), amended LR 50:

M. Joseph Fontenot Jr.
Executive Director