



Louisiana Board of Pharmacy

3388 Brentwood Drive
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July 8, 2024

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

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2024-04 ~ Automated Medication Systems (AMS)

Dear Senator Henry:

The Board seeks to amend Sections 1217 and 1509 of its rules relative to Automated Medication Systems (AMS). The proposed rule changes in Section 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 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.

In connection with this regulatory project, the following items are appended:

- Notice of Intent
- Fiscal & Economic Impact Statement

As indicated in the solicitation, we will convene a public hearing at 9:00 a.m. on Monday, August 26, 2024 to receive public comments and testimony on these proposed rule changes. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information about this project, please contact me directly at jfontenot@pharmacy.la.gov or 225.925.6481.

For the Board:

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 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~~ 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 ~~other licensed personnel approved by the pharmacist in charge~~ a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician candidate without the necessity of direct pharmacist supervision.

1. A bar code ~~or other electronic verification, electronic verification, or similar verification process which prohibits any human intervention following pharmacist verification of the product may~~ 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, electronic verification, or similar verification process~~ 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, ~~and in the absence of any subsequent human intervention in the automated drug product selection process,~~ 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 GOVERNMENTAL 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 NON-GOVERNMENTAL 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.

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

Person Preparing Statement: <u>M. Joseph Fontenot Jr. Executive Director</u>	Dept.: <u>Dept. of Health</u>
Phone: <u>225.925.6481</u>	Office: <u>Board of Pharmacy</u>
Return Address: <u>3388 Brentwood Drive Baton Rouge, LA 70809</u>	Rule Title: <u>Automated Medication Systems</u>
	Date Rule Takes Effect: <u>Upon promulgation November 20, 2024 (est.)</u>

**SUMMARY
(Use complete sentences)**

In accordance with Section 961 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL 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 NON-GOVERNMENTAL 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. J. Fontenot, Jr.

Signature of Head or Designee

M. Joseph Fontenot Jr., Executive Director

Typed Name & Title of Agency Head or Designee

July 03, 2024

Date of Signature

Alvin Thomas Deputy Fiscal Officer

Legislative Fiscal Officer or Designee

7/68/2024

Date of Signature

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The proposed rule changes in Section 1217 and Section 1509.8 remove references to "human intervention" due to the ambiguity of phrase 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.

- B. Summarize the circumstances, which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

LBP was aware of much confusion concerning the phrases "which prohibits any human intervention following pharmacy verification of the product" and "any subsequent human intervention." In order to clarify the intent of the rules, LBP deemed it necessary to amend Section 1217 and Subsection 1509.8 of its rules relative to automated medication systems.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session

- (1) Will the proposed Rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

LBP has allocated \$1,000 for printing the Notice of Intent and the Rule. LBP operates on self-generated funds.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) _____ YES. If yes, attach documentation.

(b) _____ NO. If no, provide justification as to why this rule change should be published at this time

LBP operates on self-generated funds, and they have determined the proposed rule changes are in the public's best interest.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 25	FY 26	FY 27
PERSONAL SERVICES	\$0	\$0	\$0
OPERATING EXPENSES	\$1,000	\$0	\$0
PROFESSIONAL SERVICES	\$0	\$0	\$0
OTHER CHARGES	\$0	\$0	\$0
EQUIPMENT	\$0	\$0	\$0
MAJOR REPAIR & CONSTR.	\$0	\$0	\$0
TOTAL	\$1,000	\$0	\$0
POSITIONS (#)	0	0	0

2. Provide a narrative explanation of the costs or savings shown in "A. 1.," including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

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 cost 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 amount of such a decrease is indeterminable.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 25	FY 26	FY 27
STATE GENERAL FUND	\$0	\$0	\$0
AGENCY SELF-GENERATED	\$1,000	\$0	\$0
DEDICATED	\$0	\$0	\$0
FEDERAL FUNDS	\$0	\$0	\$0
OTHER (Specify)	\$0	\$0	\$0
TOTAL	\$1,000	\$0	\$0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

LBP has sufficient self-generated funds available to implement the proposed rule changes.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

To the extent a government-operated pharmacy is utilizing an Automated Medication System (AMS), the proposed rule changes may decrease the cost 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 amount of such a decrease is indeterminable.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

The proposed rule changes will not impact sources of funding of local governmental units.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

REVENUE INCREASE/DECREASE	FY 25	FY 26	FY 27
STATE GENERAL FUND	\$0	\$0	\$0
AGENCY SELF-GENERATED	\$0	\$0	\$0
DEDICATED	\$0	\$0	\$0
FEDERAL FUNDS	\$0	\$0	\$0
LOCAL FUNDS	\$0	\$0	\$0
TOTAL	\$0	\$0	\$0

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

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

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

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

- A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule changes will benefit pharmacies that employ electronic product verification procedures by removing the requirement for a pharmacist to be present during the stocking and restocking of an AMS at a location other than that of the pharmacy.

- B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

The proposed rule changes will not impact a licensee's receipts or revenue.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

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.