

**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  
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Patrice Thomas  
Deputy Fiscal Officer  
Legislative Fiscal Office