NOTICE OF INTENT

Department of Health

Board of Pharmacy

Automated Medication Systems (LAC 46:LIII.Chapter 12)

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 Louisiana Board of Pharmacy hereby gives notice of its intent to amend several sections within Chapter 12 of its rules relative to automated medication systems. The proposed changes in §1201 remove terms already defined in the pharmacy practice act and add two new terms relative to remote dispensing systems.. The proposed changes in §1203 provide clarity in the existing eligibility criteria and add two new locations: detention and correctional facilities for state and local governmental entities as well as unlicensed healthcare settings. Other changes in this section provide clarity to existing credentialing procedures. The proposed changes in §1205 relative to the pharmacist-in-charge's responsibilities include a removal for the 30-day notice requirement when a pharmacy ceases to supply the medications for an automated medication system, a removal of the requirement for the facility to notify prescribers their medication orders are not restricted to the limited number of medications stored in the automated medication system, and an addition for the monitoring of integrity of drug products stored in the device and documentation of drug product integrity. The proposed change in §1207 adds a provision for the retrospective review of medications removed from a non-profile driven system. The proposed change for §1209 is to repeal the itemized list of topics required for the system policies and procedures. The proposed changes for §1211 include a provision for devices to be placed in locations other than licensed healthcare settings as well as a requirement for documentation of security procedures. The proposed changes for recordkeeping requirements in §1213 are technical in nature. The proposed change for §1215 is to repeal the section, the content of which were transferred to the documentation section in §1211. The proposed change in §1217 relative to the stocking and restocking of drugs in devices is to reorganize the content for clarity. The information in §1219 relative to packaging and labeling of drugs placed in devices is found elsewhere in the Board's rules; the proposal is to repeal this redundant section. The information on proof-of-use record in §1221 as well as wasted or discarded drugs in §1223 are already found in the earlier section on documentation in §1211; the proposal is repeal these two redundant sections. Since the Board already has statutory authority to conduct inspections, the proposed change for §1225 is to repeal this unnecessary section. The Board's rules for nonresident pharmacies already require such pharmacies to possess a permit to conduct business in the state; the proposal is to repeal this redundant §1227. The Board's authority relative to the assessment of penalties for violations of pharmacy law is found in the pharmacy practice act; the proposal is to repeal this unnecessary §1229. The requirement to read the chapter of rules jointly with the pharmacy law and board's rules is redundant; the proposal is to repeal the unnecessary §1231.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 12. Automated Medication Systems

§1201. Definitions

Healthcare Setting—a place where healthcare services are rendered on a routine basis by credentialed healthcare professionals.

Remote Dispensing System—a profile-driven automated medication dispensing system employing bidirectional audio-visual technology to facilitate pharmacist communication with a patient or caregiver.

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 by the Department of Health, Board of Pharmacy, LR 46:

§1203. Automated Medication System Registration

A. Requirement for Registration

1. A pharmacy intending to supply medications for use within an automated medication system, as defined at R.S. 37:1164, shall obtain an automated medication system (AMS) registration prior to engaging in such activity.

2. The placement of medications within an automated medication system in the absence of an AMS registration shall substantiate a violation of R.S. 37:1241(A)(12) and shall subject the pharmacy to disciplinary action by the board.

3. A pharmacy intending to supply controlled substances for use within an automated medication system shall obtain a controlled dangerous substance (CDS) license in addition to the AMS registration. The pharmacy shall also obtain a federal registration from the U.S. Drug Enforcement Administration (DEA) prior to placing controlled substances within the automated medication system.

4. The placement of controlled substances within an automated medication system in the absence of an AMS registration, CDS license, and DEA registration shall substantiate a violation of R.S. 37:1241(A)(12) and R.S. 40:973 and shall subject the pharmacy to disciplinary action by the board.

5. The operation of a remote dispensing system without an AMS registration shall substantiate a violation of R.S. 37:1241(A)(12) and shall subject the pharmacy to disciplinary action by the board.

B. Eligibility for Registration

1. A pharmacy intending to supply medications for use within an automated medication system may do so when the AMS is placed at any of the following locations:

a. within a facility in possession of a controlled dangerous substance license issued by the board;

b. within a hospital or other institutional facility in possession of an operating license issued by the state department of health;

c. within a detention or correctional facility operated by or under contract with the state department of public safety and corrections or other local governmental entity.

2. A pharmacy may operate a remote dispensing system when the system is placed within a healthcare setting where the pharmacist-in-charge can ensure the security and environmental integrity of the medications and devices placed within the system as well as the security and confidentiality of the protected health information used therein.

C. Application for Initial Issuance of Registration

1. The board shall develop an application form suitable for the AMS registration. The board may revise that application on its own initiative in order to collect the information it deems necessary to properly evaluate an applicant.

2. The application shall be accompanied by payment of the registration fee authorized by R.S. 37:1184.

3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.

4. The submission of a false or fraudulent application shall substantiate a violation of R.S. 37:1241(A)(2) and shall subject the applicant to disciplinary action by the board.

5. When determined appropriate by the board, the applicant may be required to meet with a committee or agent of the board prior to the issuance of the registration.

D. Maintenance of Registration

1. A registration shall be valid only for the pharmacy to which it was issued and the physical location of the AMS identified on the application. The registration shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the registration be valid for any premises other than the physical location for which it was issued.

2. A duplicate or replacement registration shall be issued upon the written request of the owner of the registration and payment of the fee authorized by R.S. 37:1184. A duplicate or replacement registration shall be marked as such, and it shall not serve or be used as an additional or second registration.

3. In the event a pharmacy intends to relocate an automated medication system to a different address, the pharmacy shall notify the board of its intent to do so, providing both current and new addresses. A change in business address may require an inspection by the board or its designee.

E. Application for Renewal of Registration

1. The pharmacy shall complete an application for the renewal of the registration and submit it to the board prior to the expiration date of the registration. The application shall be accompanied by the fee authorized by R.S. 37:1184.

2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.

3. An AMS registration not renewed by the expiration date shall be classified as expired. The operation of an automated medication system with an expired registration shall substantiate a violation of R.S. 37:1241(A)(12) and shall subject the pharmacy to disciplinary action by the board.

F. Relinquishment of Registration

1. In the event a pharmacy intends to cease supplying medications or devices to an automated medication system, it shall relinquish the registration to the board no later than 10 days following the effective date of such decision.

2. A pharmacy may not transfer a registration to another pharmacy.

G. Application for Reinstatement of Suspended or Revoked Registration

1. An application for the reinstatement of an AMS registration previously suspended or revoked by the board may only be approved in compliance with R.S. 37:1249.

2. The applicant shall complete an application form for this specific purpose supplied by the board and shall attach any documentation requested by the board and fees identified in R.S. 37:1184.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1184.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 38:1235 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:

§1205. Pharmacist-in-Charge Responsibilities

A. The pharmacist-in-charge shall be a Louisiana-licensed pharmacist with the following responsibilities:

1. assuring that the system is in good working order and accurately provides the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards.

2. establishment of a quality assurance program prior to implementation of a system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of a system, which is evidenced by policies and procedures developed by the pharmacist-in-charge.

3. define access to the system in policy and procedures of the pharmacy, in compliance with state and federal regulations.

4. assign, discontinue, or change access to the system.

5. ensure that access to the medications complies with state and federal regulations as applicable.

6. ensure that the system is stocked and restocked accurately and in accordance with established pharmacy policies and procedures.

7. maintain or have access to all records of documentation specified in this Chapter for two years or as otherwise required by law.

8. continuous monitoring and documentation of temperature in the drug storage areas including a mechanism to alert the pharmacist when defined parameters are out of range as well as an action plan to address such excursions. A pharmacy's failure to document the integrity of the drug supply or remediate for excursions as appropriate shall substantiate a violation of R.S. 37:1241(A)(18) and shall subject the pharmacy to disciplinary action by the board.

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 by the Department of Health, Board of Pharmacy, LR 46:

§1207. Pharmacist Review

A. System shall be used in settings that ensure medication orders are reviewed by a pharmacist prior to administration and in accordance with established policies and procedures and good pharmacy practice. A policy and procedure shall be adopted for non-profile driven systems to retrospectively review medications orders which cannot be reviewed prior to medication administration.

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 by the Department of Health, Board of Pharmacy, LR

§1209. Policies and Procedures

Repealed.

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, repealed by the Department of Health, Board of Pharmacy, LR 46:

§1211. Documentation

A. Documentation as to type of equipment, serial number, content, policies and procedures and location shall be maintained in the pharmacy for review by the board. Such documentation shall include, but is not limited to:

1. name, address, and permit number of the pharmacy and the location where the system is operational;

2. manufacturer's name and model;

3. quality assurance policies and procedures to determine continued appropriate use and performance of the system;

4. policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, controlled substances, data retention, definitions, downtime procedures, emergency or first dose procedures, inspection, installation requirements, maintenance security, quality assurance, medication inventory, staff education and training, system set-up, and malfunction procedures; and

5. security procedures sufficient to prevent unauthorized access or use, prevent the illegal use or disclosure of protected health information, and comply with any applicable federal or state regulations.

6. a current copy of all pharmacy policies and procedures related to the use of the system shall be maintained at all locations where the system is being used.

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 by the Department of Health, Board of Pharmacy, LR 46:

§1213. Records

A. Records and electronic data kept by the system shall meet the following requirements:

1. all events involving access to the contents of the system shall be recorded electronically;

2. in the event controlled substances are stored in the system, the records shall include the positive identification (as defined in §1119 of this Part) of the personnel retrieving and administering the controlled substances to the patient;

3. these internal records shall be maintained for one year by the pharmacist-in-charge and shall be readily available to the board. Such records shall include:

a. identity of system accessed;

b. identification of the individual accessing the system;

c. type of transaction;

d. name, strength, dosage form, and quantity of the drug accessed;

e. name or identification number of the patient for whom the drug was ordered;

f. identification of the certified pharmacy technician or pharmacist stocking or restocking the medications in the system; and

g. such additional information as the pharmacist-in-charge may deem necessary.

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 40:2256 (November 2014), effective January 1, 2015, amended by the Department of Health, Board of Pharmacy, LR

§1215. Security System(s)

Repealed.

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, repealed by the Department of Health, Board of Pharmacy, LR

§1217. Stocking and Restocking

A. 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 personnel approved by the pharmacist-in-charge.

1. A bar code verification, electronic verification, or similar verification process which prohibits any human intervention following pharmacist verification of the product may be utilized to assure the correct selection of drugs to be placed into an automated medication system.

2. The use of a bar code, 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.

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 46:

§1219. Packaging and Labeling

Repealed.

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, repealed by the Department of Health, Board of Pharmacy, LR 46:

§1221. Proof of Use

Repealed.

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, repealed by the Department of Health, Board of Pharmacy, LR 46:

§1223. Wasted, Discarded, or Unused Medications

Repealed.

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, repealed by the Department of Health, Board of Pharmacy, LR 46:

§1225. Inspection

Repealed.

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, repealed by the Department of Health, Board of Pharmacy, LR 46:

§1227. Out-of-State Pharmacies

Repealed.

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, repealed by the Department of Health, Board of Pharmacy, LR 46:

§1229. Violations; Penalties

Repealed.

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, repealed by the Department of Health, Board of Pharmacy, LR 46:

§1231. Revised Statutes and *Louisiana Administrative Code*

Repealed.

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, repealed by the Department of Health, Board of Pharmacy, LR 46:

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 or 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 or 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 amendment does not change the current compliance or reporting requirements for small businesses.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The proposed amendment does not change the current schedule or deadline for compliance or reporting requirements.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed amendment does not change the current compliance or reporting requirements for small businesses.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed amendment adds one additional operational standard relative to the monitoring of temperature of the drug storage areas; there are economical options available to small businesses.

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.

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 will have no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.

2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed Rule amendment will have no effect on the cost to the provider to provide the same level of service.

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 Malcolm J Broussard, 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.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule amendment is scheduled for 9 a.m. on Friday, May 29, 2020. During the hearing, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12 p.m. noon that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

Malcolm J Broussard
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Automated Medication Systems

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

The proposed rule change will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in one-time costs of $2,000 in FY 20 and $2,000 in FY 21. There will be no additional expenditures or cost savings for LBP.

The proposed rule change expands the eligibility criteria for the automated medication system (AMS) registration which is a credential issued by LBP to pharmacies placing medications in such devices housed in locations other than the pharmacy itself. The proposed rule change would authorize a pharmacy to place an AMS at a correctional facility operated by or under contract with the Dept. of Public Safety & Corrections or a local governmental entity. To the extent a correctional facility operated by a state or local governmental entity elects to house an AMS provided by their pharmacy, it is possible the facility may realize a savings in the total cost of medications needed for offenders served by that facility. The amount of the savings would depend on the number of offenders, the number, type, and cost of medications stored in the device, and the duration of each offender's drug therapy regimen.

To the extent a state or local governmental entity operates a pharmacy which elects to utilize an AMS, the proposed rule change will require the pharmacist-in-charge to implement a continuous monitoring and documentation of temperature in the drug storage areas including a mechanism to alert the pharmacist when defined parameters are out of range as well as an action plan to address such circumstances. Some AMS devices include such monitoring and documentation features and some do not. To the extent the pharmacy elects to use a system which does not include such features, the pharmacy will need to purchase additional monitoring equipment.

The proposed rule change makes a number of technical changes and repeals a number of redundant and unnecessary provisions.

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

The proposed rule change will not affect revenue collections for state or local governmental units.

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

To the extent a pharmacy elects to place an AMS in a healthcare setting and supply the medications for use in the system, the proposed rule change will expand the types of locations where such devices can be placed. The proposed rule changes allow for AMS devices to be placed in state and local correctional facilities and unlicensed healthcare settings. Systems are available in a variety of configurations and the prices vary considerably. The requirement for temperature monitoring of the drug storage areas may or may not increase the total cost of operating a system. The use of such devices could reduce the amount of drug wastage in the location housing the system, which could lower the total cost of drugs used by the facility housing the system.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will not affect competition or employment.