Louisiana Administrative Code

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 47:241 (February 2021).

§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; Exemption
   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.
   3. A pharmacy intending to supply medications for use within an AMS which is placed within the building housing that pharmacy shall not be required to obtain an AMS registration; however, the pharmacist-in-charge of the pharmacy shall be responsible for compliance with the operational standards in this Chapter.

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 form 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 and fees identified in R.S. 37:1184.

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 38:1235 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 47:241 (February 2021).

§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 record-keeping 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 written 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 47:241 (February 2021).

§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 medication 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 47:242 (February 2021).

§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 47:242 (February 2021).

§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.

B. 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 47:242 (February 2021).

§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 Section 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 person 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 47:242 (February 2021).

§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 47:243 (February 2021).

§1217. Stocking and Restocking; Electronic Product Verification

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 licensed personnel approved by the pharmacist-in-charge without the necessity of direct pharmacist supervision.

    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, 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 47:243 (February 2021).

§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 47:243 (February 2021).

§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 47:243 (February 2021).

§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 47:243 (February 2021).

§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 47:243 (February 2021).

§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 47:243 (February 2021).

§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 47:243 (February 2021).

§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 47:243 (February 2021).