Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 12. Automated Medication Systems

§1201. Definitions

Automated Medication System – includes, but is not limited to, a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, or delivery of medications, and which collects, controls, and maintains all transaction information. An automated medication system may be profile-driven, non-profile driven, or a combination of both.

Final Checks of Work – the requirement that only a pharmacist supervises and releases the completed product prepared by a pharmacy technician.

Floor Stock/First Dose Cabinet – a medication storage device, which shall be used by personnel, authorized by a protocol established by the pharmacist-in-charge, to gain access to doses as needed and first doses in patient care areas. In addition, a floor stock/first dose cabinet may be used to store medications in such specialty areas including, but not limited to, emergency room, surgery suite, and endoscopy suites.

Non-Profile Driven – system does not require prior or concomitant pharmacist review of medication order/prescriptions in order to gain access to the system for medication administration. A non-profile driven system may include, but is not limited to, a night drug cabinet, emergency drug kits, or floor stock/first dose cabinet.

Off-Site Facility – the location of a building that houses a licensee of the Department of Health and Hospitals, but which does not house a board permitted pharmacy.

On-Site Facility – the location of a building that houses a board permitted pharmacy.

Profile Driven – system requires that medication orders/prescriptions be reviewed by the pharmacist for appropriateness, dosage, and contraindications prior to, or concomitantly with, being entered into the system, and before access is allowed into the system for 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.

§1203. System(s) Registration

A. The entire system shall be registered with the board and facilities shall meet the following conditions:
   1. Facility shall possess a:
      a. license from the Health Standards Section of the Department of Health and Hospitals, or
      b. Controlled Dangerous Substance License from the Health Standards Section of the Department of Health and Hospitals, or
      c. permit from the board.
   2. Registration fee for a facility not permitted by the board is as identified in R.S. 37:1184.C.xii.
   3. No registration fee will be assessed a board permitted pharmacy.
   4. Registration expires annually on June 30.
   5. Initial application shall be completed and signed by the registrant of the facility and the pharmacist-in-charge of the system(s). The completed, signed application and required fee shall be submitted to the board office no later than 30 days prior to installation of the system.
   6. Annual Renewal. The board shall make available an application for renewal to each registrant on or before May 1 each year. Said application shall be completed, signed, and, with annual fee, returned to the board office to be received on or before June 1 each year.
   7. Expired Registration. A registration that is not renewed shall be null and void. A renewal application for an expired registration shall be requested by the registrant and the completed, signed application may be referred to the board's reinstatement committee for disposition in accordance with R.S. 37:1230.
   8. Reinstatement. The holder of a registration that has expired may be reinstated only upon written application to the board and upon payment of all lapsed fees and a penalty to be fixed

by the board. Other conditions of reinstatement may be required at the discretion of 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 LR 38:1235 (May 2012).

§1205. Pharmacist-in-Charge Responsibilities

A. The pharmacist-in-charge shall be a Louisiana licensed pharmacist and has 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 written policies and procedures developed by the pharmacist-in-charge.
   3. provide 30 days written notice to the board of removal of the system.
   4. define access to the system in policy and procedures of the pharmacy, in compliance with state and federal regulations.
   5. assign, discontinue, or change access to the system.
   6. ensure that access to the medications complies with state and federal regulations as applicable.
   7. ensure that the system is stocked/restocked accurately and in accordance with established written pharmacy policies and procedures.
   8. maintain or have access to all records of documentation specified in this Section for two years or as otherwise required by law.
   9. notify each licensed prescriber that his medication orders/prescriptions are not restricted to the limited number of medications which are stocked within a facility's automated medication system by placing a prominent notice to that effect on the cover of or near the beginning of such patient's medical chart or medical record.

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.

§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 protocol shall be adopted to retrospectively review medications which cannot be reviewed prior to administration, as provided in LAC 46:LIII.1209.2.

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.

§1209. Policies and Procedures

A. The development of an automated medication system policy and procedures is the responsibility of the pharmacist-in-charge, who shall submit the complete automated medication system policy and procedures to the board for approval, on request. These policies and procedures shall be reviewed by the pharmacist-in-charge, at least annually and modified if needed, and such review documented. They shall include, but are not limited to, the following:
   1. criteria for selection of medications to be stored in each system, provided that in facilities licensed by the Department of Health and Hospitals, but not by the board, the selection criteria shall not include the substitution by the pharmacist of a product that is not an equivalent drug product to the product originally prescribed by the physician or practitioner without the explicit consent of the physician or practitioner;

2. criteria for medications qualifying for use with a non-profile driven system and the locations and situations that this type of system can be used in; and
3. information on the system as outlined below:
    a. access.
        i. system entry.
        ii. access codes.
        iii. system access privileges.
        iv. changing access privileges.
        v. termination of user.
        vi. temporary access codes.
        vii. password assignment.
    b. controlled substances.
        i. chain of custody.
        ii. discrepancy resolution.
    c. data.
        i. archiving.
        ii. stored/uploading to database.
        iii. backup.
    d. definitions.
    e. downtime procedures (see malfunction).
    f. emergency procedures.
    g. information security/confidentiality.
        i. patient information.
        ii. medication information.
        iii. transaction files.
        iv. information update plan.
        v. patient update plan.
        vi. information access.
    h. inspection.
    i. installation requirements.
    j. maintenance, e.g., service and repair protocols.
    k. medication administration.
        i. medication and patient validation.
        ii. administration verification.
    l. medication security.
        i. acquisition and disposition records.
        ii. proof of delivery.
        iii. chain of custody of controlled substances (institutions).
        iv. security management and control.
        v. medication loading and storage.
        vi. medication loading records.
        vii. medication containers.
        viii. cross contamination.
        ix. lot number control.
        x. inventory.
        xi. utilization review.
        xii. research.
    m. malfunction.
        i. troubleshooting.
        ii. power failure.
    n. quality assurance/quality improvement
        i. documentation and verification of proper loading and refilling of device.
        ii. removal of drugs for administration, return, or waste.
        iii. recording, resolving, and reporting of discrepancies.
        iv. periodic audits to assure compliance with policies and procedures.
    o. reports.
        i. system maintenance.
        ii. administrative functions.

iii. inventory.
iv. error.
v. discrepancies.
vi. activity.
vii. problem.

p. medication inventory management.
q. staff education and training.
r. system set-up.

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.

§1211. Documentation

A. Documentation as to type of equipment, serial number, content, policies and procedures and location shall be maintained on-site 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 or licensed health care facility 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. a current copy of all pharmacy policies and procedures related to the use of the system shall be maintained at all off-site facility locations where the system is being used, as well as the pharmacy of the pharmacist-in-charge.

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.

§1213. Records

A. Records and/or 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. 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 of the patient, or identification numbers 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.

§1215. Security System(s)

A. System shall have adequate security system and procedures, evidenced by written pharmacy policies and procedures, to:
   1. prevent unauthorized access or use;
   2. comply with any applicable federal and state regulations; and

3. maintain patient confidentiality.

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.

§1217. Stocking and Restocking

A. *On-Site Facility System(s).* The stocking and restocking of all medications in the on-site system shall be accomplished by Louisiana licensed pharmacists and/or Louisiana certified pharmacy technicians under the supervision of Louisiana licensed pharmacists. A pharmacist must conduct final checks of work performed by a pharmacy technician. The pharmacy shall have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the pharmacist checking the accuracy of the medications to be stocked or restocked in the automated medication systems.

B. *Off-Site Facility System(s).* The stocking and restocking of all medications in the off-site system shall be accomplished by Louisiana licensed pharmacists; however, the certified pharmacy technician may stock or restock an off-site facility system provided a pharmacist is physically present at the off-site facility and supervises and verifies the stocking and/or restocking prior to use. The pharmacy shall have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the pharmacist checking the accuracy of the medications to be stocked or restocked in the system.

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.

§1219. Packaging and Labeling

A. All containers of medications stored in the system shall be packaged and labeled in accordance with federal and state laws and regulations and contain an established satisfactory beyond use date based on U.S.P. standards.

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.

§1221. Proof of Use

A. For medication removed from the system for patient administration, the system shall document, at a minimum, the following:
   1. name of the patient or resident;
   2. patient's or resident's medical record number or identification number, or room and bed number;
   3. date and time medication was removed from the system;
   4. name, initials, or other unique identifier of the person removing the drug; and
   5. name, strength, and dosage form of the medication or description of the medical device removed.

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.

§1223. Wasted, Discarded, or Unused Medications

A. The system shall provide a mechanism for securing and accounting for wasted, discarded, or unused medications removed from the system according to policies and procedures, and existing state and federal law.

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.

§1225. Inspection

A. System records shall be available and readily retrievable for board inspection and review during regular working hours of operation. The system itself is also subject to inspection at that time.

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.

§1227. Out-of-State Pharmacies

A. Out-of-state pharmacies must have applied for and been issued an out-of-state pharmacy permit by the board as identified in regulations. Out-of-state pharmacies must have the proper pharmacy permit issued by the state in which they reside in order to utilize a system in Louisiana.

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.

§1229. Violations; Penalties

A. The board may refuse to issue or renew, or may revoke, summarily suspend, suspend, place on probation, censure, reprimand, issue a warning against, or issue a cease and desist order against, the licenses or the registration of, or assess a fine/civil penalty or costs/administrative costs against any person pursuant to the procedures set forth in R.S. 37:1245, for any violation of the provisions of this Section.

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.

§1231. Revised Statutes and Louisiana Administrative Code

A. These regulations shall be read and interpreted jointly with Chapter 14 of Title 37 of the Revised Statutes and Part LIII of Title 46 of the Louisiana Administrative Code.

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.