

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; or a correctional facility operated by or under contract with the Louisiana Department of Public Safety & Corrections or parish or municipality with patient administration conducted by a licensed healthcare provider.

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

§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.
d. a correctional facility operated by or under contract with the Louisiana Department of Public Safety & Corrections or parish or municipality with patient administration conducted by a licensed healthcare provider.
2. Registration fee for a facility not permitted by the board is as identified in R.S. 37:1184.C.xii.(3)(i).
3. No registration fee will be assessed a board permitted pharmacy.
4. Registration expires annually on June 30.

Comment [MJB1]: Consider reconstruction to address eligibility, initial issuance, renewal, and reinstatement.

Comment [MJB2]: Initial thought to address the reason for the referral of the rule to the committee is to authorize placement of AMS in any healthcare or other residential care facility licensed by LDH as well as any detention or correctional facility operated by or under contract with the LDPSC or parish or municipality.

Comment [MJB3]: There are other reasonable placement options for AMS devices, including physician offices, general office buildings, and other locations which offer reasonable security and environmental integrity for the inventory. An option to raise the comfort level at these locations would be to require bidirectional A/V interface with pharmacist at supplying pharmacy.

CODING: Underscored text proposed for addition, and stricken text proposed for deletion. Changes recommended by staff in yellow; changes requested by committee in blue.

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- 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), amended by the Department of Health, Board of Pharmacy, LR

§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.
 - 10. Continuous monitoring and documentation of temperature in the drug storage areas including a mechanism to alert the pharmacist when 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 may constitute a sufficient basis for the suspension or revocation of the registration.

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

Comment [MJB4]: The reason AMS devices were originally limited to pharmacies and facilities licensed by LDH was because such devices were probably inspected by pharmacy or other personnel. With the expansion of devices to other locations, there should be some mechanism to ensure the integrity of the drug products stored within the device.

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106 **§1207. Pharmacist Review**

107 A. System shall be used in settings that ensure medication orders are reviewed by a pharmacist prior to
 108 administration and in accordance with established policies and procedures and good pharmacy
 109 practice. A policy and procedure protocol shall be adopted to retrospectively review medications
 110 which cannot be reviewed prior to administration, as provided in LAC 46:LI.1209.A.2.
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112 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

113 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
 114 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR
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116 **§1209. Policies and Procedures**

117 A. The development of an automated medication system policy and procedures is the responsibility of the
 118 pharmacist-in-charge, who shall submit the complete automated medication system policy and
 119 procedures to the board for approval, on request. These policies and procedures shall be reviewed by
 120 the pharmacist-in-charge, at least annually and modified if needed, and such review documented.

121 They shall include, but are not limited to, the following:

- 122 1. criteria for selection of medications to be stored in each system, provided that in facilities
 123 licensed by the Department of Health and Hospitals, but not by the board, the selection
 124 criteria shall not include the substitution by the pharmacist of a product that is not an
 125 equivalent drug product to the product originally prescribed by the physician or practitioner
 126 without the explicit consent of the physician or practitioner;
- 127 2. criteria for medications qualifying for use with a non-profile driven system and the locations
 128 and situations that this type of system can be used in; and
- 129 3. information on the system as outlined below:
 - 130 a. access.
 - 131 i. system entry.
 - 132 ii. access codes.
 - 133 iii. system access privileges.
 - 134 iv. changing access privileges.
 - 135 v. termination of user.
 - 136 vi. temporary access codes.
 - 137 vii. password assignment.
 - 138 b. controlled substances.
 - 139 i. chain of custody.
 - 140 ii. discrepancy resolution.
 - 141 c. data.
 - 142 i. archiving.
 - 143 ii. stored/uploading to database.
 - 144 iii. backup.
 - 145 d. definitions.
 - 146 e. downtime procedures (see malfunction).
 - 147 f. emergency procedures.
 - 148 g. information security/confidentiality.
 - 149 i. patient information.
 - 150 ii. medication information.
 - 151 iii. transaction files.
 - 152 iv. information update plan.
 - 153 v. patient update plan.
 - 154 vi. information access.
 - 155 h. inspection.
 - 156 i. installation requirements.
 - 157 j. maintenance, e.g., service and repair protocols.
 - 158 k. medication administration.

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- 159 i. medication and patient validation.
- 160 ii. administration verification.
- 161 l. medication security.
- 162 i. acquisition and disposition records.
- 163 ii. proof of delivery.
- 164 iii. chain of custody of controlled substances (institutions).
- 165 iv. security management and control.
- 166 v. medication loading and storage, including wasted, discarded, or unused
- 167 doses.
- 168 vi. medication loading records.
- 169 vii. medication containers.
- 170 viii. cross contamination.
- 171 ix. lot number control.
- 172 x. inventory.
- 173 xi. utilization review.
- 174 xii. research.
- 175 m. malfunction.
- 176 i. troubleshooting.
- 177 ii. power failure.
- 178 n. quality assurance/quality improvement
- 179 i. documentation and verification of proper loading and refilling of
- 180 device.
- 181 ii. removal of drugs for administration, return, or waste.
- 182 iii. recording, resolving, and reporting of discrepancies.
- 183 iv. periodic audits to assure compliance with policies and procedures.
- 184 o. reports.
- 185 i. system maintenance.
- 186 ii. administrative functions.
- 187 iii. inventory.
- 188 iv. error.
- 189 v. discrepancies.
- 190 vi. activity.
- 191 vii. problem.
- 192 p. medication inventory management.
- 193 q. staff education and training.
- 194 r. system set-up.
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Comment [MJB5]: Could probably transfer the packaging and labeling provisions of §1219 to this entry.

196 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
 197 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
 198 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR
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200 **§1211. Documentation**

- 201 A. Documentation as to type of equipment, serial number, content, policies and procedures and location
- 202 shall be maintained on-site in the pharmacy for review by the board. Such documentation shall
- 203 include, but is not limited to:
- 204 1. name, address, and permit number of the pharmacy or licensed health care facility where the
- 205 system is operational;
- 206 2. manufacturer's name and model;
- 207 3. quality assurance policies and procedures to determine continued appropriate use and
- 208 performance of the system;
- 209 4. policies and procedures for system operation, safety, security, accuracy, patient
- 210 confidentiality, access, controlled substances, data retention, definitions, downtime
- 211 procedures, emergency or first dose procedures, inspection, installation requirements,

Comment [MJB6]: Consider consolidation of records (at §1213) with this section on documentation.

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- 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. In the event controlled substances are stored in the system, the records shall include the positive identification (as defined in Section 1119 of the Board's rules) 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 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.

Comment [MJB7]: Consider relocating the proof-of-use provisions in §1221 to 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, amended LR 40:2256 (November 2014), effective January 1, 2015.

§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.

Comment [MJB8]: Consider incorporation of these requirements into policies and procedures 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.

§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

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265 have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the
 266 pharmacist checking the accuracy of the medications to be stocked or restocked in the system.

267 C. Electronic Product Verification

- 268 1. A bar code verification, electronic verification, or similar verification process may be utilized
- 269 to assure the correct selection of drugs to be placed into an automated medication system.
- 270 2. The use of a bar code, electronic, or similar verification process shall require an initial quality
- 271 assurance validation followed by ongoing quality assurance reviews at intervals no greater
- 272 than 90 days since the previous review, all conducted by a pharmacist.
- 273 3. When a bar code verification, electronic verification, or similar verification process is utilized
- 274 as specified in the Paragraph, and in the absence of any human intervention in the product
- 275 selection process, the stocking and restocking functions in systems located either on-site or
- 276 off-site may be performed by a pharmacy technician without the necessity of direct
- 277 pharmacist supervision.

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 279 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

280 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
 281 (June 2000) effective July 1, 2000, amended LR 41:1488 (August 2015).

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 283 **§1219. Packaging and Labeling**

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

Comment [MJB9]: Consider transfer of these provisions to policies and procedures, specifically at §1209.A.3.1.vii.

288 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

289 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
 290 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR

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 292 **§1221. Proof of Use**

- 293 A. For medication removed from the system for patient administration, the system shall document, at a
 294 minimum, the following:
- 295 1. name of the patient or resident;
 - 296 2. patient's or resident's medical record number or identification number, or room and bed
 297 number, or in the case of a patient in a detention or correctional facility, the location of such
 298 patient;
 - 299 3. date and time medication was removed from the system;
 - 300 4. name, initials, or other unique identifier of the person removing the drug; and
 - 301 5. name, strength, and dosage form of the medication or description of the medical device
 302 removed.

Comment [MJB10]: Assuming placement is authorized for detention and correctional facilities.

304 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

305 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
 306 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR

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 308 **~~§1223. Wasted, Discarded, or Unused Medications~~**

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

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 313 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

314 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
 315 (June 2000) effective July 1, 2000, amended/repealed by the Department of Health, Board of Pharmacy, LR

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 317 **§1225. Inspection**

CODING: Underscored text proposed for addition, and stricken text proposed for deletion.

Changes recommended by staff in yellow; changes requested by committee in blue.

318 A. System records shall be available and readily retrievable for board inspection and review during
319 regular working hours of operation. The system itself is also subject to inspection at that time.
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321 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

322 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
323 (June 2000) effective July 1, 2000.
324

325 **§1227. Out-of-State Pharmacies**

326 A. ~~Out-of-state pharmacies must have applied for and been issued an out-of-state pharmacy permit by the~~
327 ~~board as identified in regulations. Out-of-state pharmacies must have the proper pharmacy permit~~
328 ~~issued by the state in which they reside in order to utilize a system in Louisiana.~~
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330 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

331 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
332 (June 2000) effective July 1, 2000, ~~amended/repealed by the Department of Health, Board of Pharmacy, LR~~
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334 **§1229. Violations; Penalties**

335 A. ~~The board may refuse to issue or renew, or may revoke, summarily suspend, suspend, place on~~
336 ~~probation, censure, reprimand, issue a warning against, or issue a cease and desist order against, the~~
337 ~~licenses or the registration of, or assess a fine/civil penalty or costs/administrative costs against any~~
338 ~~person pursuant to the procedures set forth in R.S. 37:1245, for any violation of the provisions of this~~
339 ~~Section.~~
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341 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

342 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
343 (June 2000) effective July 1, 2000, ~~amended/repealed by the Department of Health, Board of Pharmacy, LR~~
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345 **§1231. Revised Statutes and Louisiana Administrative Code**

346 A. ~~These regulations shall be read and interpreted jointly with Chapter 14 of Title 37 of the Revised~~
347 ~~Statutes and Part LHH of Title 46 of the Louisiana Administrative Code.~~
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349 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

350 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
351 (June 2000) effective July 1, 2000, ~~amended/repealed by the Department of Health, Board of Pharmacy, LR~~