

## Louisiana Administrative Code

### Title 46 – Professional and Occupational Standards

#### Part LIII: Pharmacists

#### Chapter 12. Automated Medication Systems

##### §1201. Definitions

*Automated Medication System (AMS)* – 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 the board, or~~

e. ~~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.

a. Registration fee for a facility not permitted by the board is as identified in R.S. 37:1184.C.xii.(3)(i).

b. ~~No registration fee will be assessed a board permitted pharmacy.~~

e. ~~Registration expires annually on June 30.~~

- 53 ~~d. Initial application shall be completed and signed by the registrant of the~~  
 54 ~~facility and the pharmacist in charge of the system(s). The completed,~~  
 55 ~~signed application and required fee shall be submitted to the board office~~  
 56 ~~no later than 30 days prior to installation of the system.~~  
 57 ~~e. Annual Renewal. The board shall make available an application for~~  
 58 ~~renewal to each registrant on or before May 1 each year. Said application~~  
 59 ~~shall be completed, signed, and, with annual fee, returned to the board~~  
 60 ~~office to be received on or before June 1 each year.~~  
 61 ~~f. Expired Registration. A registration that is not renewed shall be null and~~  
 62 ~~void. A renewal application for an expired registration shall be requested~~  
 63 ~~by the registrant and the completed, signed application may be referred to~~  
 64 ~~the board's reinstatement committee for disposition in accordance with~~  
 65 ~~R.S. 37:1230.~~  
 66 ~~g. Reinstatement. The holder of a registration that has expired may be~~  
 67 ~~reinstated only upon written application to the board and upon payment of~~  
 68 ~~all lapsed fees and a penalty to be fixed by the board. Other conditions of~~  
 69 ~~reinstatement may be required at the discretion of the board.~~  
 70

71 **§1203. System(s) Registration Licensing Procedures** *{A suggested replacement section}*

72 A. Eligibility for Registration

- 73 1. A pharmacy intending to supply medications for use within an automated medication system shall  
 74 apply for an AMS registration. The AMS may be placed at any of the following locations:  
 75 a. within a pharmacy in possession of a pharmacy permit issued by the board;  
 76 b. within a facility in possession of a controlled dangerous substance license issued by the board;  
 77 c. within a facility in possession of an operating license issued by the state department of health;  
 78 d. within a detention or correctional facility operated by or under contract with the state  
 79 department of public safety and corrections;  
 80 e. within a detention or correctional facility operated by or under contract with a parish or  
 81 municipality; or  
 82 f. within a facility in compliance with the provisions of Section \_\_\_\_\_ of this Chapter.

83 B. Application for Initial Issuance of Registration

- 84 1. The board shall develop an application form suitable for the AMS registration. The board may  
 85 revise that application form on its own initiative in order to collect the information it deems  
 86 necessary to properly evaluate an applicant.  
 87 2. The application shall be accompanied by payment of the registration fee authorized by R.S.  
 88 37:1184. The board may waive the fee for applicants placing an AMS within a pharmacy in  
 89 possession of a permit issued by the board.  
 90 3. The board shall not process applications received by facsimile, or that are incomplete, or  
 91 submitted with the incorrect fee.  
 92 4. An applicant submitting a false or fraudulent application shall be deemed to have violated R.S.  
 93 37:1241(A)(2) and shall be subject to disciplinary action by the board.  
 94 5. If determined appropriate by the board, the applicant may be required to meet with a committee of  
 95 the board or an agent of the board prior to the issuance of the registration.  
 96 6. Regardless of the date issued, the registration shall expire on June 30 of every year.

97 C. Maintenance of Registration

- 98 1. An AMS registration shall be valid only for the pharmacy to which it was issued and at the  
 99 location of the facility identified on the application. The registration shall not be subject to sale,  
 100 assignment or other transfer, voluntary or involuntary, nor shall the registration be valid for any  
 101 other premises other than the physical location for which it was issued.  
 102 2. A duplicate or replacement permit shall be issued upon the written request of the owner of the  
 103 registration and payment of the fee authorized by R.S. 37:1184. A duplicate or replacement  
 104 registration shall be marked as such, and it shall not serve or be used as an additional or second  
 105 permit.

106 D. Application for Renewal of Registration

- 107 E. Relinquishment of Registration  
108 F. Application for Reinstatement of Suspended or Revoked Registration  
109

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

111 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271  
112 (June 2000) effective July 1, 2000, amended LR 38:1235 (May 2012), amended by the Department of Health, Board  
113 of Pharmacy, LR  
114

### 115 §1205. Pharmacist-in-Charge Responsibilities

- 116 A. The pharmacist-in-charge shall be a Louisiana licensed pharmacist and has the following  
117 responsibilities:
- 118 1. assuring that the system is in good working order and accurately provides the correct strength,  
119 dosage form, and quantity of the drug prescribed while maintaining appropriate record-  
120 keeping and security safeguards.
  - 121 2. establishment of a quality assurance program prior to implementation of a system and the  
122 supervision of an ongoing quality assurance program that monitors appropriate use and  
123 performance of a system, which is evidenced by written policies and procedures developed by  
124 the pharmacist-in-charge.
  - 125 ~~3. provide 30 days written notice to the board of removal of the system.~~
  - 126 3. define access to the system in policy and procedures of the pharmacy, in compliance with  
127 state and federal regulations.
  - 128 4. assign, discontinue, or change access to the system.
  - 129 5. ensure that access to the medications complies with state and federal regulations as  
130 applicable.
  - 131 6. ensure that the system is stocked/restocked accurately and in accordance with established  
132 written pharmacy policies and procedures.
  - 133 7. maintain or have access to all records of documentation specified in this Section for two years  
134 or as otherwise required by law.
  - 135 ~~9. notify each licensed prescriber that his medication orders/prescriptions are not restricted to the  
136 limited number of medications which are stocked within a facility's automated medication  
137 system by placing a prominent notice to that effect on the cover of or near the beginning of  
138 such patient's medical chart or medical record.~~
  - 139 8. Continuous monitoring and documentation of temperature in the drug storage areas including  
140 a mechanism to alert the pharmacist when parameters are out of range as well as an action  
141 plan to address such excursions. A pharmacy's failure to document the integrity of the drug  
142 supply or remediate for excursions as appropriate may constitute a sufficient basis for the  
143 suspension or revocation of the registration.  
144

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

146 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271  
147 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR  
148

### 149 §1207. Pharmacist Review

- 150 A. System shall be used in settings that ensure medication orders are reviewed by a pharmacist prior to  
151 administration and in accordance with established policies and procedures and good pharmacy  
152 practice. A policy and procedure protocol shall be adopted to retrospectively review medications  
153 which cannot be reviewed prior to administration, as provided in ~~LAC 46:LIII.1209.A.2~~ Section 1209  
154 of this Chapter.  
155

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

157 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271  
158 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR  
159

160 **§1209. Policies and Procedures**

- 161 A. The development of an automated medication system policy and procedures is the responsibility of the
- 162 pharmacist-in-charge, who shall submit the complete automated medication system policy and
- 163 procedures to the board for approval, on request. These policies and procedures shall be reviewed by
- 164 the pharmacist-in-charge, at least annually and modified if needed, and such review documented.
- 165 They shall include, but are not limited to, the following:
- 166 1. ~~criteria for selection of medications to be stored in each system, provided that in facilities~~
- 167 ~~licensed by the Department of Health and Hospitals, but not by the board, the selection criteria~~
- 168 ~~shall not include the substitution by the pharmacist of a product that is not an equivalent drug~~
- 169 ~~product to the product originally prescribed by the physician or practitioner without the~~
- 170 ~~explicit consent of the physician or practitioner;~~
- 171 1. criteria for medications qualifying for use with a non-profile driven system and the locations
- 172 and situations that this type of system can be used in; and
- 173 2. information on the system as outlined below:
- 174 a. access.
- 175 i. system entry.
- 176 ii. access codes.
- 177 iii. system access privileges.
- 178 iv. changing access privileges.
- 179 v. termination of user.
- 180 vi. temporary access codes.
- 181 vii. password assignment.
- 182 b. controlled substances.
- 183 i. chain of custody.
- 184 ii. discrepancy resolution.
- 185 c. data.
- 186 i. archiving.
- 187 ii. stored/uploading to database.
- 188 iii. backup.
- 189 d. definitions.
- 190 e. downtime procedures (see malfunction).
- 191 f. emergency procedures.
- 192 g. information security/confidentiality.
- 193 i. patient information.
- 194 ii. medication information.
- 195 iii. transaction files.
- 196 iv. information update plan.
- 197 v. patient update plan.
- 198 vi. information access.
- 199 h. inspection.
- 200 i. installation requirements.
- 201 j. maintenance, e.g., service and repair protocols.
- 202 k. medication administration.
- 203 i. medication and patient validation.
- 204 ii. administration verification.
- 205 l. medication security.
- 206 i. acquisition and disposition records.
- 207 ii. proof of delivery.
- 208 iii. chain of custody of controlled substances (institutions).
- 209 iv. security management and control.
- 210 v. medication loading and storage, including wasted, discarded, or unused
- 211 doses.
- 212 vi. medication loading records.
- 213 vii. medication containers.



267 **§1213. Records**

- 268 A. Records and/or electronic data kept by the system shall meet the following requirements:
- 269 1. All events involving access to the contents of the system shall be recorded electronically.
- 270 2. In the event controlled substances are stored in the system, the records shall include the
- 271 positive identification (as defined in Section 1119 of ~~the Board's rules~~ this Part) of the
- 272 personnel retrieving and administering the controlled substances to the patient.
- 273 3. These internal records shall be maintained for one year by the pharmacist-in-charge and shall
- 274 be readily available to the board. Such records shall include:
- 275 a. identity of system accessed;
- 276 b. identification of the individual accessing the system;
- 277 c. type of transaction;
- 278 d. name, strength, dosage form, and quantity of the drug accessed;
- 279 e. name of the patient, or identification numbers for whom the drug was ordered;
- 280 f. identification of the certified pharmacy technician or pharmacist stocking or
- 281 restocking the medications in the system; and
- 282 g. such additional information as the pharmacist-in-charge may deem necessary.
- 283

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

285 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271

286 (June 2000) effective July 1, 2000, amended LR 40:2256 (November 2014), effective January 1, 2015.

287

288 **§1215. Security System(s)**

- 289 A. System shall have adequate security system and procedures, evidenced by written pharmacy policies
- 290 and procedures, to:
- 291 1. prevent unauthorized access or use;
- 292 2. comply with any applicable federal and state regulations; and
- 293 3. maintain patient confidentiality.
- 294

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

296 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271

297 (June 2000) effective July 1, 2000.

298

299 **§1217. Stocking and Restocking**

- 300 A. *On-Site Facility System(s)*. The stocking and restocking of all medications in the on-site system shall
- 301 be accomplished by Louisiana licensed pharmacists and/or Louisiana certified pharmacy technicians
- 302 under the supervision of Louisiana licensed pharmacists. A pharmacist must conduct final checks of
- 303 work performed by a pharmacy technician. The pharmacy shall have a mechanism in place to identify
- 304 the certified pharmacy technician stocking or restocking and the pharmacist checking the accuracy of
- 305 the medications to be stocked or restocked in the automated medication systems.
- 306 B. *Off-Site Facility System(s)*. The stocking and restocking of all medications in the off-site system shall
- 307 be accomplished by Louisiana licensed pharmacists; however, the certified pharmacy technician may
- 308 stock or restock an off-site facility system provided a pharmacist is physically present at the off-site
- 309 facility and supervises and verifies the stocking and/or restocking prior to use. The pharmacy shall
- 310 have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the
- 311 pharmacist checking the accuracy of the medications to be stocked or restocked in the system.
- 312 C. Electronic Product Verification
- 313 1. A bar code verification, electronic verification, or similar verification process may be utilized
- 314 to assure the correct selection of drugs to be placed into an automated medication system.
- 315 2. The use of a bar code, electronic, or similar verification process shall require an initial quality
- 316 assurance validation followed by ongoing quality assurance reviews at intervals no greater
- 317 than 90 days since the previous review, all conducted by a pharmacist.
- 318 3. When a bar code verification, electronic verification, or similar verification process is utilized
- 319 as specified in ~~the this Paragraph Subsection~~, and in the absence of any human intervention in

320 the ~~product selection process~~ following pharmacist verification, the stocking and restocking  
321 functions in systems located either on-site or off-site may be performed by a pharmacy  
322 technician without the necessity of direct pharmacist supervision.  
323

324 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.  
325 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271  
326 (June 2000) effective July 1, 2000, amended LR 41:1488 (August 2015).  
327

328 **§1219. Packaging and Labeling**

329 A. All containers of medications stored in the system shall be packaged and labeled in accordance with  
330 federal and state laws and regulations and contain an established satisfactory beyond use date based on  
331 ~~U.S.P.~~ standards established by the United States Pharmacopeia.  
332

333 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.  
334 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271  
335 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR  
336

337 **§1221. Proof of Use**

338 A. For medication removed from the system for patient administration, the system shall document, at a  
339 minimum, the following:  
340 1. name of the patient or resident;  
341 2. patient's or resident's medical record number or identification number, or room and bed  
342 number, or in the case of a patient in a detention or correctional facility, the location of such  
343 patient;  
344 3. date and time medication was removed from the system;  
345 4. name, initials, or other unique identifier of the person removing the drug; and  
346 5. name, strength, and dosage form of the medication or description of the medical device  
347 removed.  
348

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 by the Department of Health, Board of Pharmacy, LR  
352

353 ~~**§1223. Wasted, Discarded, or Unused Medications**~~

354 A. ~~The system shall provide a mechanism for securing and accounting for wasted, discarded, or unused~~  
355 ~~medications removed from the system according to policies and procedures, and existing state and~~  
356 ~~federal law.~~  
357

358 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.  
359 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271  
360 (June 2000) effective July 1, 2000, amended/repealed by the Department of Health, Board of Pharmacy, LR  
361

362 **§1225. Inspection**

363 A. System records shall be available and readily retrievable for board inspection and review during  
364 regular working hours of operation. The system itself is also subject to inspection at that time.  
365

366 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.  
367 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271  
368 (June 2000) effective July 1, 2000.  
369

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371

372 **~~§1227. Out of State Pharmacies~~**

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

376  
377 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

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

380  
381 **~~§1229. Violations; Penalties~~**

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

387  
388 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

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

391  
392 **~~§1231. Revised Statutes and Louisiana Administrative Code~~**

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

395  
396 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

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