

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

Subchapter A. General Requirements

§1101. Pharmacy

- A. Qualification. Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.
- B. Appearance. The applicants, including the pharmacist-in-charge, may be required to personally appear before the board prior to a board decision on the permit application.
- C. Pharmacy Permit.
 - 1. The initial pharmacy permit application shall be completed and signed by the pharmacist-in-charge and the owner of the pharmacy and submitted to the board for approval. An application for a pharmacy permit shall expire one year after the date of receipt in the board office.
 - 2. Renewal. A pharmacy permit that has not been renewed by December 31 of each year shall expire and be null and void.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007).

§1103. Prescription Department Requirements

- A. A prescription department of a pharmacy shall provide sufficient floor space allocated to ensure that drugs are compounded and dispensed in a well lighted, ventilated, climate controlled, and safely enclosed structure.
- B. Restricted. A prescription department is a restricted area.
- C. Square Footage. A prescription department that is new or remodeled on or after January 1, 2004 shall be not less than ~~three hundred (300)~~ **three hundred (300)** total square feet, and shall be inaccessible to the public.
- D. Prescription Counter. A prescription counter on which to compound or dispense medications shall have a working surface of not less than a minimum of ~~twenty four (24)~~ **twenty four (24)** total square feet. The minimum unobstructed free working surface shall be kept clear at all times for the compounding or dispensing of prescriptions.
- E. Prescription Aisle Space. The aisle space behind the prescription counter shall be not less than ~~thirty (30)~~ **thirty (30)** inches in width.
- F. Prescription Department Plumbing. A sink equipped with hot and cold running water shall be located within the prescription department. A sink located in a pharmacy restroom shall not be sufficient to satisfy this requirement.
- G. Electronic Record Keeping System. An electronic record keeping system shall be utilized in a pharmacy department and shall be a complete, accurate, and readily retrievable prescription record keeping and storage system.
- H. Drug Inventory.
 - 1. Storage. The pharmacy shall provide sufficient space on-site for proper storage of labels, prescription containers, and an adequate prescription inventory in order to compound and dispense prescription orders. Drugs that require special storage shall be properly stored.

Comment [MJB1]: Technical correction, to conform to style rules of State Register.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion. Coding highlighted in **yellow** proposed by LTC Stakeholders; coding highlighted in **blue** proposed by staff.

- 53 2. Missing or Damaged Inventory. When significant drug inventory is missing or damaged for any
- 54 reason, the pharmacy owner or pharmacist-in-charge shall file with the board a signed statement of
- 55 the circumstances of such occurrence and evidence that the appropriate law enforcement authorities
- 56 were notified as required by law.
- 57 3. Equipment. The pharmacy shall provide sufficient fixtures, equipment, and utensils to ensure that
- 58 drugs are properly compounded and dispensed.
- 59 I. Pharmacy Security. The prescription department or the premises housing the prescription department
- 60 shall be adequately secured by the installation of partitions and secured entrances, which shall be
- 61 locked by a pharmacist and made inaccessible when the prescription department is closed. The
- 62 prescription department or any premises housing a prescription department shall be adequately secured
- 63 by an alarm system.
- 64 J. Emergency Access. An additional key to the prescription department may be maintained in a secure
- 65 location outside the prescription department for use during an emergency. A log shall be maintained
- 66 with the key, indicating the name of each non-pharmacist using this key, the date and time of entry,
- 67 and the nature of the emergency.
- 68 K. References. A printed copy of the *Louisiana Board of Pharmacy Laws and Regulations* shall be
- 69 maintained and readily available within the prescription department of a pharmacy. The pharmacy
- 70 shall maintain access to current and appropriate reference materials pertinent to the pharmacy practice,
- 71 including but not limited to, pharmacology, drug interactions, dosing, toxicity, and patient counseling.
- 72

Comment [MJB2]: Suggested simplification.

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

74 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310
75 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, amended LR 39:315 (February
76 2013), amended by Department of Health, Board of Pharmacy, LR.

77
78 **§1105. Pharmacist-in-Charge**

- 79 A. The opportunity to accept an appointment as the pharmacist-in-charge (PIC) of a pharmacy is a
- 80 professional privilege. The following requirements are attached to a PIC privilege.
- 81 1. The acquisition of the PIC privilege shall require:
- 82 a. Possession of an active Louisiana pharmacist license;
- 83 b. Active pharmacy practice for a minimum of two years under the jurisdiction of any board of
- 84 pharmacy in the United States; and
- 85 c. The completion of the Affidavit of Responsibility and Duties described below.
- 86 2. The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no
- 87 less than 20 hours per week during the pharmacy's ordinary course of business. In the event the
- 88 pharmacy's normal hours of business are less than 20 hours per week the PIC shall be present and
- 89 practicing at least 50 percent of the normal business hours.
- 90 B. An initial and renewal pharmacy permit application shall designate and identify the licensed
- 91 pharmacist-in-charge.
- 92 C. Authority and Accountability. The pharmacist-in-charge shall be ultimately responsible for complete
- 93 supervision, management, and compliance with all federal and state pharmacy laws and regulations
- 94 pertaining to the practice of pharmacy of the entire prescription department. This responsibility
- 95 necessarily includes accountability for any violation involving federal or state laws or regulations
- 96 occurring within the prescription department supervised by a pharmacist-in-charge.
- 97 D. Policy and Procedure Manual. The pharmacist-in-charge shall be responsible for the implementation
- 98 of policies and procedures regarding quality pharmacy services including drug control, distribution,
- 99 patient compliance accountability, inspection, and record keeping.
- 100 E. Circumvention. It is a violation of the pharmacy permit for any person to subvert the authority of the
- 101 pharmacist-in-charge by impeding the management of the prescription department in the compliance of
- 102 federal and state pharmacy laws and regulations.
- 103 F. Records. The pharmacist-in-charge shall be responsible for the proper maintenance of all prescription
- 104 records. This necessarily includes electronic prescription records and the system's compliance and
- 105 capacity to produce the required records.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 106 G. Recall. The pharmacist-in-charge shall be responsible for the implementation of a recall procedure that
 107 can be readily activated to assure patient safety.
- 108 H. Discontinued and Outdated Drugs. The pharmacist-in-charge shall be responsible for the
 109 implementation of policies and procedures to ensure that discontinued or outdated drugs, or containers
 110 with worn, illegible, or missing labels are withdrawn from the pharmacy inventory.
- 111 I. Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacist-
 112 in-charge designation for a pharmacy has changed.
- 113 1. The permit holder shall notify the board within ten days of the prior pharmacist-in-charge's
 114 departure date. The permit holder shall designate a new pharmacist-in-charge within ten days of
 115 the departure of the prior pharmacist-in-charge.
- 116 2. The new pharmacist-in-charge shall afford the board written notice of his newly designated
 117 pharmacist-in-charge status within ten days of the departure of the prior pharmacist-in-charge.
- 118 3. A pharmacist-in-charge who voluntarily leaves a pharmacy shall give written notice to the board
 119 and the owner of the permit at least ten days prior to this voluntary departure, unless replaced in a
 120 shorter period of time.
- 121 J. Affidavit of Responsibility and Duties. The designated pharmacist-in-charge shall sign an affidavit on
 122 a form supplied by the board indicating his understanding and acceptance of the duties and
 123 responsibilities of a pharmacist-in-charge. This notarized document shall be submitted to the board for
 124 inclusion in the pharmacy's record in the board office.
- 125 K. A pharmacist shall not hold a pharmacist-in-charge position at more than one pharmacy permit, unless
 126 approved by the board.

Comment [MJB3]: Suggested simplification.

127
 128 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

129 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310
 130 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004, amended LR 38:1239 (May 2012),
 131 amended by Department of Health, Board of Pharmacy, LR.

132 §1107. Pharmacy Operation

- 133 A. A pharmacist shall be on duty at all times during regular open hours of the pharmacy.
- 134 B. A pharmacy shall be open for business a minimum of 10 hours per week, with said business hours
 135 posted at the building entrance in full public view from outside the premises.

136
 137 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

138 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310
 139 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004, amended LR 34:1408 (July 2008).

140 §1109. Pharmacist Temporary Absence

- 141 A. A pharmacist shall be considered to be temporarily absent from the prescription department when not
 142 within the confines of the prescription department but remains on-site.
- 143 B. The pharmacist may be temporarily absent from the prescription department for breaks and meal
 144 periods without closing the prescription department and removing pharmacy personnel providing the
 145 following conditions are met:
- 146 1. at least one certified pharmacy technician or pharmacy intern remains in the prescription
 147 department;
- 148 2. the pharmacist is available for emergencies;
- 149 3. the temporary absence does not exceed thirty minutes at a time and a total of sixty minutes in a
 150 twelve hour period;
- 151 4. the pharmacist reasonably believes that the security of the prescription department will be
 152 maintained in his absence; and
- 153 5. a notice is posted that includes the following information:
- 154 a. the fact that the pharmacist is taking a break; and
- 155 b. the time the pharmacist will return.
- 156
 157

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 158 C. If the pharmacist, in his professional judgment, determines it necessary, all personnel shall be removed
 159 from the pharmacy and the pharmacy shall be secured for the duration of the temporary absence, and
 160 notice shall be posted indicating the pharmacy is closed.
 161 D. During a temporary absence, certified pharmacy technicians or pharmacy interns may continue to
 162 process prescription orders, provided that no orders processed during the pharmacist's temporary
 163 absence be removed from the prescription department prior to the final check by the pharmacist.
 164 E. If the pharmacist is absent less than five minutes from the prescription department, this absence is not
 165 considered a "temporary absence" within the meaning of this chapter and will not require a posted
 166 notice, provided the prescription department's security is not compromised.
 167 F. If at any time the pharmacist deems it necessary to leave the on-site facility, the pharmacy shall be
 168 closed in accordance with § Section 1111 of this Part.
 169

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

171 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311
 172 (October 1997), amended LR 27:2237 (December 2001) effective January 1, 2002, amended LR 29:2088 (October
 173 2003), effective January 1, 2004, amended by Department of Health, Board of Pharmacy, LR.
 174

175 §1111. Pharmacist Absence

- 176 A. A pharmacist is considered absent from the prescription department when he is not in the prescription
 177 department and is off-site.
 178 B. When a pharmacist is absent from the prescription department, the prescription department must be
 179 securely closed and made inaccessible. A sign shall be displayed in a conspicuous position in front of
 180 the prescription department giving notice of closure. The sign shall be at least 8½ x 11 inches with the
 181 following wording in black letters at least one inch high: PRESCRIPTION DEPARTMENT CLOSED.
 182

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

184 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311
 185 (October 1997), amended LR 24:692 (April 1998), amended LR 29:2089 (October 2003), effective January 1, 2004.
 186

187 §1113. Mechanical Drug Dispensing Devices

- 188 A. Dispensing of prescription drugs directly to a patient or caregiver by mechanical devices or machine is
 189 prohibited. This prohibition shall not apply to automated medication systems as defined and provided
 190 for in Chapter 12 of these regulations this Part.
 191

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

193 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311
 194 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, amended by Department of
 195 Health, Board of Pharmacy, LR.
 196

197 §1115. Advertising

- 198 A. False, fraudulent, deceptive, or misleading advertising as prohibited by R.S. 37:1241 of the Pharmacy
 199 Practice Act and this Section shall include, but is not limited to, any public misrepresentation done or
 200 made with the knowledge, whether actual or constructive, that is untrue or illegal, or is said to be done
 201 falsely when the meaning is that the party is in fault for its error. Actual or constructive knowledge as
 202 used in this context shall include intentionally, negligently, mistakenly, or accidentally representing an
 203 untrue fact.
 204 B. No person shall carry on, conduct, or transact business under a name which contains a part thereof of the
 205 words "pharmacist", "pharmacy", "apothecary", "apothecary shop", "chemist's shop", "drug store",
 206 "druggist", "drugs", or any word or words of similar or like import, or in any manner by
 207 advertisement, circular, poster, sign, or otherwise describe or refer to a place of business by the terms
 208 of "pharmacy", "apothecary", "apothecary shop", "chemist's shop", "drug store", "drugs", or any word
 209 or words of similar or like import, unless the place of business is a pharmacy validly permitted by the
 210 board.

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

Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 211 C. Pharmacies and pharmacists are prohibited from advertising professional ability, experience, integrity,
- 212 or professional qualifications, or soliciting professional practice by means of providing prescribers of
- 213 prescriptions with prescription forms imprinted with any material referring to a pharmacy or
- 214 pharmacist.
- 215 D. No advertising shall include any reference, direct or indirect, to any controlled dangerous substance as
- 216 provided for in Schedules II, III, IV, or V of R.S. 40:964. The provision of coupons or vouchers for
- 217 controlled substances through authorized prescribers, which accompany legitimate prescriptions for
- 218 such controlled substances issued to patients, shall not be prohibited by this Section.
- 219

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

221 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311
222 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007).

223 **§1117. Centralized Prescription Processing**

224 Repealed.

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

226 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312
227 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, repealed LR 33:1131 (June 2007).

228 **Subchapter B. Pharmacy Records**

229 **§1119. Definitions**

- 230 A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:
- 231 **"Chart order"** means a lawful order entered on the electronic or paper chart or medical record of an
- 232 inpatient or resident of an institutional facility by a practitioner or his licensed healthcare designee for
- 233 a drug or device and shall be considered a prescription drug order provided it contains the following:
- 234 a. Full name of the patient.
- 235 b. Date of issuance.
- 236 c. Name, strength, and dosage form of the drug prescribed.
- 237 d. Directions for use.
- 238 e. Name of the prescribing practitioner.
- 239 f. The prescribing practitioner's written or electronic signature or the written or electronic signature
- 240 of the practitioner's licensed healthcare designee, who shall be a licensed nurse, pharmacist, or
- 241 physician practicing in a long-term care facility. The licensed healthcare designee shall be
- 242 authorized to document a chart order in the patient's medical record on behalf of the prescribing
- 243 practitioner pending the prescribing practitioner's signature, or to communicate a prescription to a
- 244 pharmacy whether telephonically, by facsimile transmission, or electronically.
- 245 **"Department"** means the Louisiana Department of Health and Hospitals or its successor.
- 246 **"Medical order"** means a lawful order of a practitioner that may or may not include a prescription.
- 247 **"Password"** means a private identification that is created by a user to obtain access to an electronic
- 248 pharmacy information system.
- 249 **"Personal identifier"** means a unique user name or number for identifying and tracking a specific
- 250 user's access to a pharmacy information system such as social security number, user identification
- 251 number, or employee number.
- 252 **"Positive identification"** means a method of identifying an individual who prescribes, administers, or
- 253 dispenses a prescription drug.
- 254 a. A method may not rely solely on the use of a private personal identifier such as a password but
- 255 must also include a secure means of identification such as the following:
- 256 i. A manual signature on a hard copy record.
- 257 ii. A magnetic card reader.
- 258 iii. A bar code reader.
- 259 iv. A thumbprint reader or other biometric method.
- 260
- 261
- 262
- 263

Comment [MJB4]: Inserts new term from Act 2018-602.

Comment [MJB5]: Updates name of state agency.

Comment [MJB6]: Inserts existing term from Practice Act.

Comment [MJB7]: LTC suggests replacing these terms with a reference of HIPAA rule [45 CFR 164.5 et seq], or possibly the DEA EPCS standard [21 CFR 1311 et seq].

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 264 v. A proximity badge reader.
- 265 vi. A register in which each individual pharmacist dispensing a prescription shall sign a log each
- 266 day, attesting to the fact that the information entered into the electronic record-keeping system
- 267 has been reviewed that day, and is correct as stated.
- 268 vii. A printout of every transaction that is verified and manually signed within a reasonable period
- 269 of time by the individual who prescribed, administered, or dispensed the prescription drug.
- 270 The printout must be maintained for two years and made available on request to an agent of
- 271 the board.
- 272 b. A method relying on a magnetic card reader, a bar code reader, or a proximity badge reader must
- 273 also include a private personal identifier, such as a password, for entry into a secure mechanical or
- 274 electronic system.

275 **“Prescription” or “prescription drug order” means an order from a practitioner authorized by law to**

276 **prescribe for a drug or device that is patient-specific and is communicated by any means to a**

277 **pharmacist in a permitted pharmacy, and is to be preserved on file as required by law or regulation.**

Comment [MJB8]: Inserts existing term from Practice Act.

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

280 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312

281 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR 40:2252 (November

282 2014), effective January 1, 2015, **amended by the Department of Health, Board of Pharmacy, LR**

283

284 **§1121. General Requirements**

- 285 A. Requirements.
 - 286 1. All records relating to the practice of pharmacy shall be uniformly maintained for a period of
 - 287 two years, be readily available, and promptly produced upon request for inspection by an
 - 288 agent of the board during regular business hours.
 - 289 2. All records required by the laws and regulations of the board shall be provided to the board,
 - 290 or its agents, within **seventy-two (72)** hours of request, unless a shorter period is required, as
 - 291 determined by the board or its agent.
 - 292 3. The failure to produce any pharmacy records requested by the board or its agent within
 - 293 **seventy-two (72)** hours of such request shall substantiate a violation of R.S. 37:1241(A)(22).
- 294 B. Accountability. The holder of the pharmacy permit and the pharmacist-in-charge shall account for all
- 295 prescription drug transactions, consisting of:
 - 296 1. Acquisition records – invoice receipts of drugs acquired;
 - 297 2. Disposition records – drugs dispensed pursuant to prescription **drug orders or chart orders,**
 - 298 administered pursuant to medical orders, or distributed pursuant to purchase orders, and
 - 299 3. Inventory records – drugs in current possession.
- 300 C. Retention. Except as provided in Section 1123 **of this Part,** all records required by this **Chapter Part**
- 301 and by Louisiana law shall be retained for a minimum of two years from the most recent transaction.
- 302 The failure to retain such records for at least two years shall substantiate a violation of R.S. 37:1229.
- 303

Comment [MJB9]: Clarification, to conform to defined term.

Comment [MJB10]: Inserts requirement to maintain records of drugs dispensed pursuant to chart orders.

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

305 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312

306 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR 40:2252 (November

307 2014), effective January 1, 2015, **amended by the Department of Health, Board of Pharmacy, LR**

308

309 **§1123. Records of Prescription Drug Orders and Chart Orders**

- 310 A. There shall be positive identification of the pharmacist, intern, technician, or technician candidate
- 311 responsible for performing all activities related to the practice of pharmacy including, but not limited
- 312 to:
 - 313 1. **Prescription information entered into the pharmacy information system;**
 - 314 2. Prospective drug utilization review;
 - 315 3. Prescription dispensing;
 - 316 4. Administration of immunizations.

Comment [MJB11]: Section 1123 will pertain to records of prescription drug orders and chart orders in all types of pharmacy permits.

Comment [MJB12]: LTC has same suggestion found in definitions in Sec. 1119 on Line 32.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in **yellow** proposed by LTC Stakeholders; coding highlighted in **blue** proposed by staff.

- 317
318
319
320
321
322
323
324
325
326
327
328
329
330
331
332
333
334
335
336
337
338
339
340
341
342
343
344
345
346
347
348
349
350
351
352
353
354
355
356
357
358
359
360
361
362
363
364
365
366
367
368
369
370
- B. A pharmacy may use one of the following types of pharmacy information systems:
 - 1. A system that utilizes the original hard copy prescription or chart order to document the initial dispensing of a prescription, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system shall require the manual signature or initials of a pharmacist on a hard copy record as specified in Paragraph E of this Section.
 - 2. An electronic recordkeeping system that complies with the provisions of 21 CFR 1311 et seq. and documents the positive identification of the pharmacist responsible for the practice of pharmacy. Such systems shall provide for routine backups at least once per day.
 - C. All pharmacy information systems shall be capable of providing immediate retrieval (via display and hard copy printout or other mutually agreeable transfer media) of patient profile information for all prescriptions drug orders and chart orders dispensed within the previous two years. This information shall include the following minimum data:
 - 1. The original prescription number;
 - 2. Date of issuance of the original prescription drug order or chart order by the prescriber;
 - 3. Date of dispensing by the pharmacist;
 - 4. Full name and address of the patient;
 - 5. Full name and address of the prescriber;
 - 6. Directions for use;
 - 7. The name, strength, dosage form, and quantity of the drug prescribed;
 - 8. The quantity dispensed if different from the quantity prescribed;
 - 9. The pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in § Section 515 of these rules this Part. and the pharmacist responsible for dispensing;
 - 10. The total number of refills authorized by the prescriber; and
 - 11. The refill history of the prescription as defined in Paragraph D of this Section.
 - D. The refill history of the prescription record maintained in the pharmacy information system shall include, but is not limited to:
 - 1. The prescription number;
 - 2. The name and strength of the drug dispensed;
 - 3. The date of the refill or partial fill;
 - 4. The quantity dispensed;
 - 5. The pharmacist responsible for prospective drug utilization review as defined in § Section 515 of these rules this Part. and the pharmacist responsible for dispensing each refill;
 - 6. The total number of refills or partial fills dispensed to date for that prescription order
 - E. The hard copy documentation required pursuant to Paragraph (B)(1) of this Section shall be provided by each individual pharmacist who makes use of such system by signing a statement attesting to the fact that the prescription information entered into the computer is correct as displayed.
 - F. Backup Support System
 - 1. The pharmacy information system shall be capable of being reconstructed in the event of an electronic or computer malfunction or unforeseen accident resulting in the destruction of the system or the information contained therein. To prevent the accidental loss of electronic records, an adequate backup system shall be maintained. Backup support systems shall be updated at least once daily.
 - 2. In the event the pharmacy information system experiences down time, a record of all refills dispensed during such time shall be recorded and then entered into the pharmacy information system as soon as it is available for use. During the time the pharmacy information system is not available, prescriptions drug orders and chart orders may only be refilled if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.
 - G. A pharmacy purging a pharmacy information system of prescription records shall develop a method of recordkeeping capable of providing retrieval (via display, hard copy printout, or other mutually agreeable transfer media) of prescription order information for all prescriptions drug orders or chart

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

371 ~~orders~~ filled or refilled within the previous two years. This information shall include, at a minimum,
372 the following data:

- 373 1. Pharmacy name and address;
- 374 2. Original prescription number;
- 375 3. Date of issuance of the original prescription ~~drug~~ order ~~or chart order~~ by the prescriber;
- 376 4. Date of original dispensing by the pharmacist;
- 377 5. Full name and address of the patient;
- 378 6. Full name and address of the prescriber;
- 379 7. Directions for use;
- 380 8. Name, strength, dosage form, and quantity of the drug prescribed;
- 381 9. Quantity dispensed if different from the quantity prescribed;
- 382 10. Total number of refills authorized by the prescriber;
- 383 11. Total number of refills dispensed to date for that prescription ~~drug~~ order ~~or chart order~~;
- 384 12. Date of each refill;
- 385 13. Name or initials of each individual dispensing pharmacist.

386 ~~H. A log shall be maintained of all changes made to a prescription record after the prescription has been~~
387 ~~dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being~~
388 ~~altered in any way. At a minimum, the log shall contain the following information:~~

- 389 1. ~~Date and time of change;~~
- 390 2. ~~Change(s) made;~~
- 391 3. ~~Pharmacist making the change.~~

392 I. Prescriptions ~~drug orders and chart orders~~ entered into a pharmacy information system but not
393 dispensed shall meet all of the following requirements:

- 394 1. The complete prescription information shall be entered in the computer system;
- 395 2. The information shall appear in the patient's profile; and
- 396 3. There is positive identification, in the pharmacy information system or on the hard copy
397 prescription, of the pharmacist who is responsible for entering the prescription information
398 into the system.

399 J. With respect to oral prescriptions received in the pharmacy and then transcribed to written form in the
400 pharmacy, or written prescriptions ~~drug orders or chart orders~~ received by facsimile in the pharmacy,
401 or written prescriptions ~~drug orders or chart orders~~ presented to the pharmacy, a pharmacy may use an
402 electronic imaging system to preserve such prescriptions, but only if:

- 403 1. The system is capable of capturing, storing, and reproducing the exact image of a prescription,
404 ~~including the reverse side of the prescription form and its annotations;~~
- 405 2. Any notes of clarification of and alterations to a prescription shall identify the author and shall
406 be directly associated with the electronic image of the prescription form;
- 407 3. The image of the prescription form and any associated notes of clarification to or alterations
408 to a prescription are retained for a period of not less than two years from the date the
409 prescription is last dispensed;
- 410 4. Policies and procedures for the use of an electronic imaging system are developed,
411 implemented, reviewed, and available for board inspection; and
- 412 5. The prescription is not for a controlled dangerous substance listed in Schedule II.

413 K. Filing and Retention of Prescription Forms

- 414 1. Written prescription ~~drug order or chart order~~ forms (including transcriptions of verbal
415 prescriptions received in the pharmacy, prescriptions ~~drug orders or chart orders~~ received by
416 facsimile in the pharmacy, as well as written prescription ~~drug order or chart order~~ forms
417 presented to the pharmacy ~~not stored in an electronic imaging system as described in~~
418 ~~Paragraph J of this Section~~) shall be assembled and stored in prescription number sequence.
419 Prescriptions for controlled dangerous substances listed in Schedule II shall be filed
420 separately from all other prescriptions. Where multiple medications are ordered on a single
421 prescription form and includes one or more controlled dangerous substances listed in
422 Schedule II, then such forms shall be filed with other Schedule II prescriptions. These
423 original hard copy prescription ~~drug order and chart order~~ forms shall be retained in the
424 prescription department for a minimum of two years following the most recent transaction.

Comment [MJB13]: LTC has same suggestion as Note on Line 32.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 425
426
427
428
429
430
431
432
433
434
435
436
437
438
439
440
441
2. For those pharmacies utilizing an electronic imaging system as described in Paragraph J of this Section, written prescription drug order forms may be assembled and stored in prescription number sequence, or in the alternative, a date-scanned sequence. Further, these original hard-copy prescriptions drug orders shall be retained in the prescription department for a minimum of one year following the most recent transaction.
 3. Prescription drug order and chart order forms received stored as in an electronic image imaging or electronic facsimile directly within the pharmacy information system shall be retained within the information system and in a readily retrievable manner for a minimum of two years following the most recent transaction. Further, the pharmacy may produce a hard copy of the prescription drug order form but shall not be required to do so merely for recordkeeping purposes.
 4. Electronic prescriptions drug orders and chart orders – those generated electronically by the prescriber, transmitted electronically to the pharmacy, and then received electronically directly into the pharmacy information system – shall be retained within the information system for a minimum of two years following the most recent transaction. The pharmacy may produce a hard copy of the prescription drug order or chart order, but shall not be required to do so merely for recordkeeping purposes.

442 L. Patient Profiles

443 All pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of
444 information regarding those patients who have received prescriptions from that pharmacy.

- 445 1. The dispensing pharmacist shall be responsible for ensuring that a reasonable effort has been made
446 to obtain, document, and maintain at least the following records:
- a. The patient's data record, which should consist of, but is not limited to, the following information:
 - i. Full name of the patient for whom the drug is intended;
 - ii. Residential address and telephone number of the patient;
 - iii. Patient's date of birth;
 - iv. Patient's gender;
 - v. A list of the patient specific data consisting of at least the following:
 - (a) Known drug related allergies;
 - (b) Previous drug reactions;
 - (c) History of or active chronic conditions or disease states;
 - (d) Other drugs and nutritional supplements, including nonprescription drugs used on a routine basis, or devices.
 - vi. The pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug.
 - b. The patient's drug therapy record, which shall contain at least the following information for all the prescriptions drug orders and chart orders that were filled at the pharmacy:
 - i. Name and strength of the drug or device;
 - ii. Prescription number;
 - iii. Quantity dispensed;
 - iv. Date dispensed;
 - v. Name of the prescriber;
 - vi. Directions for use.
 - c. Any information that is given to the pharmacist by the patient or caregiver to complete the patient data record shall be presumed to be accurate, unless there is reasonable cause to believe the information is inaccurate.

472 M. Exceptions

473 The provisions of this Section shall not apply to the following:

- 474 1. Pharmacies permitted as hospital pharmacies by the board shall comply with the provisions
475 of Chapter 15 of these rules.
- 476 2. Other pharmacies providing medications and services to patients within facilities other than
477 hospitals licensed by the department shall comply with the provisions of Section 1124 of these
478 rules for those activities.

Comment [MJB14]: With inclusion of chart orders in this Section and removal of these exceptions, result is a single section of dispensing record requirements applicable to all types of pharmacy permits.

479
480
481
482
483
484
485
486
487
488
489
490
491
492
493
494
495
496
497
498
499
500
501
502
503
504
505
506
507
508
509
510
511
512
513
514
515
516
517
518
519
520
521
522
523
524
525
526
527
528
529

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR 36:755 (April 2010), amended LR 40:2253 (November 2014), effective January 1, 2015, **amended by the Department of Health, Board of Pharmacy, LR**

§1124. Records of Pharmacy Services for Patients in Licensed Healthcare Facilities Other than Hospitals

A. Definitions

~~Dispensing of a drug pursuant to an inpatient prescription~~—the professional review by a pharmacist required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a prescriber. In the case of an automated medication system meeting the requirements of Chapter 12 of these rules ~~this Part~~, the final association with the name of a particular inpatient will be deemed to have occurred when the pharmacist has given the final approval to the patient specific order in the system.

Comment [MJB15]: Term no longer needed now that we have Chart Order.

Electronic drug record keeping system – a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.

Inpatient – a person receiving health care services within a healthcare facility other than a hospital licensed by the department.

Inpatient Prescription – a written, electronic or oral order for a drug for use in treating a patient within a healthcare facility other than a hospital licensed by the department.

Comment [MJB16]: Term no longer needed now that we have Chart Order.

Password – a private identification that is created by a user to obtain access to an electronic drug record keeping system.

Comment [MJB17]: LTC has same suggestion as found on Line 32.

Personal identifier – a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as social security number, user identification number, or employee number

Positive identification –

a. has the same meaning as defined in Section 1119 of these rules ~~this Part~~, except that a specific facility having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for the prescribing and administration of a drug, provided the pharmacist in charge has determined:

- i. adequate audit controls are in place to detect and deter drug diversion;
- ii. adequate access controls are in place to assure the identity of the user and to assign accountability of the user for any drug transaction;
- iii. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;
- iv. an ongoing quality assurance program is in place to ensure that (a) through (c) of this term are being fulfilled and reviewed; and
- v. appropriate policies and procedures are in place to address items (a) through (d) of this term.

b. All of the above notwithstanding, however, positive identification as defined in Section 1119 of these rules ~~this Part~~ shall always be used to document the:

- i. Dispensing, compounding, or prepackaging of a drug;
- ii. Removal and possession of a controlled substance to administer to a patient; and
- iii. Waste of a controlled substance.

B. Drug Distribution and Control

The pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs.

- 530
531
532
533
534
535
536
537
538
539
540
541
542
543
544
545
546
547
548
549
550
551
552
553
554
555
556
557
558
559
560
561
562
563
564
565
566
567
568
569
570
571
572
573
574
575
576
577
578
579
580
581
582
583
1. Procedure Manual. The pharmacist-in-charge shall maintain defined procedures for the safe and efficient distribution of medications and pharmacy care. A current copy of the manual shall be available for board inspection upon request.
 2. Inventories. The pharmacist-in-charge shall be responsible for the performance of an annual inventory of all controlled dangerous substances within his span of control, in compliance with the provisions of Section 2733 of ~~these rules this Part.~~
 3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:
 - a. A record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured.
 - b. All drug orders and records relating to the practice of pharmacy.
 - i. Records of drugs dispensed shall include, but are not limited to:
 - (a) The name, strength, and quantity of drugs dispensed;
 - (b) The date of dispensing;
 - (c) The name of the inpatient to whom, or for whose use, the drug was dispensed; and
 - (d) Positive identification of all pharmacists involved in the dispensing.
 - ~~ii. All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:~~
 - ~~(a) The name of the inpatient to whom, or for whose benefit, the activity was performed;~~
 - ~~(b) The nature of the pharmacy practice activity performed;~~
 - ~~(c) The results of the activity, if applicable; and~~
 - ~~(d) Positive identification of all pharmacists involved in the activity; identifying the function performed by each pharmacist.~~
 - iii. Records of drugs dispensed to patients for use outside the facility shall be maintained in compliance with Section 1123 of ~~these rules this Part.~~
 - a. A record of all drugs compounded or prepackaged for use only within that facility, which shall include at least the following:
 - i. Name of drug, strength, quantity, and dosage form;
 - ii. Manufacturer's or distributor's ~~control lot~~ number (except for patient-specific sterile compounded preparations);
 - iii. Manufacturer's or distributor's name, if a generic drug is used;
 - iv. Pharmacy ~~control batch/lot~~ number;
 - v. Manufacturer's or distributor's expiration date (except for patient-specific sterile compounded preparations);
 - vi. ~~Pharmacy's Drug's~~ expiration date or beyond-use date;
 - vii. Identification of the licensed person responsible for the compounding or prepackaging of the drug.
 - b. ~~A record of the distribution of drugs to patient care areas and other areas of the facility held for administration, which shall include at least the following:~~
 - ~~i. The name, strength, dosage form, and amount of the drug distributed;~~
 - ~~ii. The area receiving the drug;~~
 - ~~iii. The date distributed;~~
 - ~~iv. Identification of the individual receiving the drug if it is a controlled dangerous substance;~~
 - ~~v. The area of the facility receiving the controlled dangerous substance shall make a record of all such drugs administered to patients. Such records shall include at least the following:~~
 - ~~(a) Name of the patient;~~
 - ~~(b) Name, dosage form, and strength when applicable of the drug;~~
 - ~~(c) Date and time the drug was administered;~~
 - ~~(d) Quantity administered;~~
 - ~~(e) Positive identification of the personnel administering the drug.~~
 - c. A log that shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:

Comment [MJB18]: LTC proposes to delete since does not appear to be applicable to LTC.

Comment [MJB19]: LTC proposes to delete since does not appear to be applicable to LTC.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 584 i. Date and time of change;
- 585 ii. Changes made;
- 586 iii. Person making the change.
- 587

588 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
 589 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 40:2255
 590 (November 2014), effective January 1, 2015, amended by Department of Health, Board of Pharmacy, LR
 591

592 **§1125. Security and Confidentiality**

- 593 A. The holder of the pharmacy permit shall provide adequate safeguards against improper, illegal, or
- 594 unauthorized manipulation or alteration of any records in the pharmacy information system.
- 595 B. A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to
- 596 confidential information. If confidential health information is not transmitted directly between a
- 597 pharmacist and a practitioner, but is transmitted through a data communications device, the
- 598 confidential health information may not be accessed, maintained, or altered by the operator of the data
- 599 communications device. Confidential information is privileged and may be released only subject to
- 600 federal privacy laws and regulations, and subject to applicable Louisiana statutes.
- 601

602 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
 603 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312,
 604 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, amended LR 40:2256 (November
 605 2014), effective January 1, 2015.
 606

607 **§1127. Register**

608 Repealed.

609 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
 610 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312
 611 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, repealed LR 40:2256 (November
 612 2014), effective January 1, 2015.
 613
 614

615 **§1129. Louisiana Uniform Prescription Drug Prior Authorization Form; Requirements; Referral for Enforcement**

- 616 A. A prescriber or pharmacy required to obtain prior authorization from a third party payor shall complete
- 617 the Louisiana Uniform Prescription Drug Prior Authorization Form referenced below in Section 1130,
- 618 either in written form or its electronic equivalent.
- 619 B. In the event a third party payor demands the completion of an alternative authorization process, the
- 620 prescriber or pharmacy shall refer the demand to the appropriate enforcement agency.
- 621 1. If the demand is made by a Medicaid managed care organization, the prescriber or pharmacy shall
- 622 refer the demand to the Dept. of Health.
- 623 2. In the demand is made by any other third party payor, the prescriber or pharmacy shall refer the
- 624 demand to the Dept. of Insurance.
- 625
 626

627 AUTHORITY NOTE: Promulgated in accordance with R.S. 22:1006.1(C) and 46:460.33(B).
 628 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 44:2157 (December
 629 2018), effective January 1, 2019.
 630

631 **§1130. Louisiana Uniform Prescription Drug Prior Authorization Form**

632 * * *

633 AUTHORITY NOTE: Promulgated in accordance with R.S. 22:1006.1(C) and 46:460.33(B).
 634 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 44:2157 (December
 635 2018), effective January 1, 2019.
 636

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

637 **Subchapter C. Pharmacy Opening, Closing, Change of Ownership, and Change of**
 638 **Location Procedures**
 639

640 **§1131. Pharmacy Opening Procedures**

- 641 A. The board has established the following procedures as a prerequisite to the opening of any
 642 pharmacy:
- 643 1. Application Form. The applicant shall obtain a Pharmacy Permit Application and Louisiana
 644 Controlled Dangerous Substance License Application from the board. The completed form(s)
 645 shall be signed by the pharmacist-in-charge and returned to the board office, with appropriate
 646 fees, not less than thirty days prior to the anticipated opening of the pharmacy.
 - 647 2. Inspection. After the board has reviewed and approved the application, a board compliance officer
 648 shall conduct an on-site inspection of the premises.
 - 649 3. Compliance. Upon receipt of satisfactory evidence that the applicant is in complete compliance,
 650 the board shall issue a pharmacy permit and, if requested, a Louisiana Controlled Dangerous
 651 Substance License.
 - 652 4. DEA Registration. If applicable, the applicant shall obtain the appropriate application from the
 653 DEA, and then return said form, with appropriate fees, to the DEA.

654
 655 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

656 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091
 657 (October 2003), effective January 1, 2004.
 658

659 **§1133. Pharmacy Closing Procedures**

- 660 A. A pharmacy permit holder shall notify the public and the board prior to discontinuing a prescription
 661 department operation, or upon petitioning for bankruptcy.
- 662 1. Public Notice. The holder of a pharmacy permit shall post a closing notice in a conspicuous place
 663 in the front of the prescription department, and at all public entrance doors to the pharmacy. The
 664 closing notice to the public shall be posted not less than ten days prior to the anticipated date of
 665 closure, and the notice shall contain the following minimum information:
 666 a. the anticipated date of closure of the prescription department;
 667 b. the anticipated date of transfer or relocation of prescription files, if different than closure date;
 668 c. the name and address of the pharmacy to which the prescription files will be transferred; and
 669 d. a statement that if a patient objects to the transfer of their prescription files to the intended
 670 recipient pharmacy, the patient shall make alternative arrangements for the transfer of their
 671 prescription files to another pharmacy prior to the anticipated file transfer date.
 - 672 2. Board Notice. The holder of a pharmacy permit shall send written notice to the board not less than
 673 ten days prior to the anticipate date of closure, and the notice shall include the following minimum
 674 information:
 675 a. the anticipated date of closure of the prescription department;
 676 b. the name and address of the permitted pharmacy operating within a reasonably close
 677 proximity of the closing pharmacy that shall be the custodian of the transferred prescription
 678 files; and
 679 c. any prescription drug sale or transfer, with a complete drug inventory including recipient's
 680 name and address and/or seizure action, sequestration, executory process, public auction,
 681 liquidation, creditor assignment, and bankruptcy.
 - 682 3. Disposition of Inventory
 683 a. Drugs Listed in Schedule II. These drugs shall be either returned to the supplier or transferred
 684 to an authorized registrant, accompanied by an executed DEA Form 222, or its successor.
 685 Alternatively, these drugs shall be inventoried on the DEA Form 41 (Registrants Inventory of
 686 Drugs Surrendered), or its successor, and then either returned to the regional DEA office, or
 687 destroyed pursuant to permission from the DEA or agent of the board. The permit holder shall
 688 retain triplicate copies of returns, transfers, and/or destructions.
 689 b. Drugs Listed in Schedules III, IV, or V. These drugs shall be either returned to the supplier or

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 690 transferred to an authorized registrant, accompanied by appropriate inventory records.
 691 Alternatively, these drugs shall be inventoried on the DEA Form 41, or its successor, and then
 692 either returned to the regional DEA office, or destroyed pursuant to permission from the DEA
 693 or agent of the board.
 694 c. All Other Prescription Drugs. These drugs shall be returned to the supplier, transferred to an
 695 authorized registrant, or destroyed.
 696 4. Surrender of Pharmacy Permit and Louisiana Controlled Dangerous Substance License. The
 697 holder of the permit and license shall surrender same to the board upon closing, accompanied by
 698 written confirmation of the:
 699 a. surrender of unused DEA order forms and the DEA registration certificate to the regional
 700 DEA office with a memorandum indicating the closing date of the prescription department;
 701 b. location of applicable records of controlled dangerous substance and other prescription drugs,
 702 order forms, inventories, acquisitions, and purchase records, with commitment to store such
 703 records for not less than two years, and to make such records available for inspection by an
 704 agent of the board; and
 705 c. removal of all pharmacy signage from the property.
 706

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

708 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091
 709 (October 2003), effective January 1, 2004.
 710

711 §1135. Pharmacy Change of Ownership Procedures

- 712 A. The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership,
 713 in order for the board to complete an inspection of the pharmacy premises.
 714 1. A change of ownership of a pharmacy is evident under the following conditions:
 715 a. sale of a pharmacy;
 716 b. death of a sole proprietor;
 717 c. the addition or deletion of one or more partners in a partnership;
 718 d. bankruptcy sale, or
 719 e. a 50 percent, or more, change in ownership of a corporation, limited liability company, or
 720 association since the issuance of the original permit or the last renewal application.
 721 2. The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit
 722 application, with appropriate fee, to the board.
 723 3. Upon receipt of the new permit, the seller shall:
 724 a. notify the board of the transaction, including the identity of the new owner(s); and
 725 b. surrender the voided pharmacy permit and voided Louisiana Controlled Dangerous Substance
 726 License to the board.
 727 4. Pharmacy permits are not transferable from the original holder(s) of the permit to the new
 728 owner(s).
 729

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

731 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2092
 732 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007).
 733

734 §1137. Pharmacy Change of Location Procedures

- 735 A. The board has established the following procedures for changing the location of any pharmacy that
 736 does not involve a change of ownership or divestiture of that pharmacy:
 737 1. The permit holder shall notify the board in writing prior to relocating a prescription department
 738 operation.
 739 2. The proper notice procedures for the relocation shall include the notice requirements applicable to
 740 pharmacy closing procedures noted in this Subpart. However, a permit cancellation is not required
 741 for a permit holder that is moving to a location in reasonably close proximity to the original
 742 location and planning to continue pharmacy operations without a transfer of ownership. The

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 743 permit holder shall notify the board for the proper re-designation of permit address and re-issuance
 744 of that same permit.
 745 3. Inspection. A board compliance officer shall conduct an on-site inspection of the premises
 746 following receipt of written notice in the board office and prior to the opening of a prescription
 747 department in a new location.
 748

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

750 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2092
 751 (October 2003), effective January 1, 2004.

752

753

754

755 **Subchapter D. Off-Site Services**

756

757 **§1139. Definitions**

758

- 759 A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this
 760 Section, unless the context clearly indicates otherwise.

761

762 *Centralized Prescription Dispensing* – the fulfillment by one permitted pharmacy of a request from
 763 another permitted pharmacy to fill or refill a prescription drug order.

764

765 *On-Site Pharmacy* – a permitted pharmacy which utilizes centralized prescription dispensing services
 766 from a remote dispenser or remote processing services from a remote processor.

767

768 *Remote Dispenser* – a Louisiana permitted pharmacy which provides centralized prescription
 769 dispensing services for another permitted pharmacy in Louisiana.

770

771 *Remote Processing Services* – the processing of a medical order or prescription drug order by one
 772 permitted pharmacy on behalf of another permitted pharmacy, including:

773

- 774 a. receipt, interpretation, or clarification of an order;

775

- 776 b. data entry and information transfer;

777

- 778 c. interpretation of clinical data;

779

- 780 d. performance of drug utilization review; and

781

- 782 e. provision of drug information concerning a patient's drug therapy; provided, however, that remote
 783 processing does not include the physical preparation or physical transfer of drugs.

784

785 *Remote Processor* – a Louisiana permitted pharmacy which provides remote processing services for
 786 another permitted pharmacy in Louisiana.

787

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

789

790 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131
 791 (June 2007), amended LR 39:313 (February 2013).

792

793

794 **§1141. Centralized Prescription Dispensing**

795

796 **A. General Requirements**

797

- 798 1. An on-site pharmacy may obtain centralized prescription dispensing services from a remote
 799 dispenser provided the pharmacies:

800

- 801 a. have the same owner or have entered into a written contract or agreement that outlines the
 802 services to be provided and the responsibilities and accountabilities of each pharmacy in
 803 compliance with federal and state laws, rules, and regulations; and

804

- 805 b. share a common electronic file or have appropriate technology to allow access to sufficient
 806 information necessary or required to provide the requested services.

807

- 808 2. All drugs dispensed to a patient that have been dispensed by a remote dispenser shall bear a label
 809 containing an identifiable code that provides a complete audit trail of the dispensing of the drug
 810 and pharmacy primary care activities.

811

812 **B. Policies and Procedures**

813

- 814 1. On-site pharmacies and remote dispensers engaging in the acquisition or provision of centralized
 815 dispensing services shall maintain a policy and procedure manual for reference by all personnel; it
 816 shall be made available for inspection and copying by the board.

817

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

Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

796
797
798
799
800
801
802
803
804
805
806
807
808
809
810
811
812
813
814
815
816
817
818
819
820
821
822
823
824
825
826
827
828
829
830
831
832
833
834
835
836
837
838
839
840
841
842
843
844
845
846
847
848

- 2. At a minimum, the manual shall include policies for:
 - a. a description of how the parties will comply with federal and state laws and regulations;
 - b. the maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling process;
 - c. the maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;
 - d. the maintenance of a mechanism to identify on the prescription label all pharmacies involved in the dispensing of the prescription drug order; and
 - e. the provision of adequate security to protect the confidentiality and integrity of patient information and to prevent its illegal use or disclosure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007).

§1143. Remote Processing of Medical Orders or Prescription Drug Orders

- A. General Requirements
 - 1. An on-site pharmacy may obtain remote processing services from a remote processor provided the pharmacies:
 - a. have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
 - b. share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.
 - 2. A contract or agreement for remote processing services shall not relieve the on-site pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services. The activities authorized by this Section are intended to supplement pharmacy services and are not intended to eliminate the need for an on-site pharmacy or pharmacist.
 - a. In the event the pharmacy soliciting remote processing services is located within a hospital with more than 100 occupied beds, there shall be at least one pharmacist on duty at that hospital at all times, and any remote processing services provided to that pharmacy shall be supplemental in nature.
 - b. (Repealed).
- B. Access to Patient Information
 - 1. The pharmacist at the remote processor shall have secure electronic access to the on-site pharmacy's patient information system and to all other electronic systems directly involved with the preparation of prescriptions that the on-site pharmacist has access to when the on-site pharmacy is operating. The pharmacist at the remote processor shall receive training in the use of the on-site pharmacy's electronic systems.
 - 2. If an on-site pharmacy is not able to provide remote electronic access to the remote processor, both pharmacies shall have appropriate technology to allow access to the required patient information.
- C. Policies and Procedures
 - 1. On-site pharmacies and remote processors engaging in the acquisition or provision of remote processing services shall maintain a policy and procedure manual for reference by all personnel; it shall be available for inspection and copying by the board.
 - 2. At a minimum, the manual shall include policies and procedures for:
 - a. identification of the responsibilities of each of the pharmacies;
 - b. protection of the integrity and confidentiality of patient information; and
 - c. maintenance of appropriate records to identify the name, initials, or unique identification code of each pharmacist performing processing functions, the specific services performed, and the date of such services.

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

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

849 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1132
 850 (June 2007), amended LR 38:1240 (May 2012), amended LR 39:313 (February 2013), amended LR 41:2148
 851 (October 2015).

852
 853 *LTC has requested the ability for an on-call pharmacist to have access to a pharmacy information system after*
 854 *hours to process prescription drug orders or chart orders, similar to the current provision now found in the hospital*
 855 *pharmacy chapter. Their recommendation suggests alteration of remote processing language in §1143; however,*
 856 *staff suggests simply moving the existing language from Chapter 15 to Chapter 11 so that it applies to all types of*
 857 *pharmacy permits.*

858 **§1145. Remote Access to Prescription Drug Orders, Medical Orders, and Chart Orders**

- 859 A. Notwithstanding any provision of rules to the contrary, nothing shall prohibit a Louisiana-licensed
 860 pharmacist who is an employee of or under contract with a hospital pharmacy in Louisiana from
 861 accessing that pharmacy's dispensing information system from a location other than the pharmacy in
 862 order to process prescription drug orders, or medical orders, or chart orders, but only when all of the
 863 following conditions are satisfied:
 864
- 865 1. The pharmacy establishes controls to protect the privacy and security of confidential records;
 - 866 2. The pharmacist does not engage in the receiving of written prescription drug orders or
 867 medical orders or chart orders or the maintenance of prescription drug orders or medical such
 868 orders; and
 - 869 3. No part of the pharmacy's dispensing information system is duplicated, downloaded, or
 870 removed from the pharmacy's dispensing information system.

871
 872 **AUTHORITY NOTE:** Promulgated in accordance with R.S. 37:1182.

873 **HISTORICAL NOTE:** Promulgated by the Department of Health, Board of Pharmacy, LR.

874
 875 *LTC has requested the ability to obtain a 'starter dose' from another pharmacy when the primary pharmacy*
 876 *servicing the facility is either closed or does not have the drug needed. To authorize the starter dose pharmacy to*
 877 *dispense the needed drug, LTC proposes to allow the primary pharmacy to 'share' a valid chart order with the*
 878 *starter dose pharmacy without the necessity to transfer the chart order. This concept is recognized in the NABP*
 879 *Model Act and Rules. LTC proposed this language be placed within the Transfer of Prescription Information*
 880 *currently located in Chapter 25. Staff proposes a different location, within the Off-Site Services subchapter in*
 881 *Chapter 11.*

882 **§1147. Starter Doses for Patients in Licensed Healthcare Facilities**

- 883 A. **Definitions**
- 884 "Starter dose order" means a prescription drug order or chart order transmitted by a vendor pharmacy
 885 to a starter dose pharmacy for the purpose of obtaining medication for a patient in a licensed health
 886 care facility.
 887 "Starter dose pharmacy" means a Louisiana-licensed pharmacy that dispenses a starter dose of
 888 medication to a patient in a licensed health care facility pursuant to a starter dose order.
 889 "Vendor pharmacy" means a Louisiana-licensed pharmacy which has a contract with a licensed health
 890 facility to dispense medications to patients within that facility.
- 891 B. A vendor pharmacy may share a chart order with a starter dose pharmacy without the necessity of
 892 transferring such order, for the purpose of authorizing the starter dose pharmacy to dispense starter
 893 doses of medication to a patient in a licensed health care facility under the following circumstances:
 894
- 895 1. The vendor pharmacy has secured authorization from the facility to utilize a starter dose
 896 pharmacy;
 - 897 2. The vendor pharmacy is in possession of a valid chart order and is unable to furnish the
 898 medication ordered in a timely manner; and
 - 899 3. The vendor pharmacy and starter dose pharmacy maintain records of all chart orders and starter
 900 dose orders for a period of not less than two years following date of transmission of such orders.

901

902 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
 903 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR.
 904
 905

906 Chapter 12. Automated Medication Systems

907 §1201. Definitions

908 *Automated Medication System* – includes, but is not limited to, a mechanical system that performs
 909 operations or activities, other than compounding or administration, relative to the storage, packaging, or
 910 delivery of medications, and which collects, controls, and maintains all transaction information. An
 911 automated medication system may be profile-driven, non-profile driven, or a combination of both.
 912 *Final Checks of Work* – the requirement that only a pharmacist supervises and releases the completed
 913 product prepared by a pharmacy technician.
 914 *Floor Stock/First Dose Cabinet* – a medication storage device, which shall be used by personnel,
 915 authorized by a protocol established by the pharmacist-in-charge, to gain access to doses as needed and first
 916 doses in patient care areas. In addition, a floor stock/first dose cabinet may be used to store medications in
 917 such specialty areas including, but not limited to, emergency room, surgery suite, and endoscopy suites.
 918 *Non-Profile Driven* – system does not require prior or concomitant pharmacist review of medication
 919 order/prescriptions in order to gain access to the system for medication administration. A non-profile
 920 driven system may include, but is not limited to, a night drug cabinet, emergency drug kits, or floor
 921 stock/first dose cabinet.
 922 *Off-Site Facility* – the location of a building that houses a licensee of the Department of Health and
 923 Hospitals, but which does not house a board permitted pharmacy.
 924 *On-Site Facility* – the location of a building that houses a board permitted pharmacy.
 925 *Profile Driven* – system requires that medication orders/prescriptions be reviewed by the pharmacist for
 926 appropriateness, dosage, and contraindications prior to, or concomitantly with, being entered into the
 927 system, and before access is allowed into the system for medication administration.
 928
 929

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

931 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
 932 (June 2000) effective July 1, 2000, amended by Department of Health, Board of Pharmacy, LR.
 933

934 §1203. System(s) Registration

- 935 A. The entire system shall be registered with the board and facilities shall meet the following conditions:
 936 1. Facility shall possess a:
 937 a. license from the Health Standards Section of the Department of Health and
 938 Hospitals, or
 939 b. Controlled Dangerous Substance License from the Health Standards Section of the
 940 Department of Health and Hospitals, or
 941 c. permit from the board.
 942 2. Registration fee for a facility not permitted by the board is as identified in R.S. 37:1184.C.xii.
 943 3. No registration fee will be assessed a board permitted pharmacy.
 944 4. Registration expires annually on June 30.
 945 5. Initial application shall be completed and signed by the registrant of the facility and the
 946 pharmacist-in-charge of the system(s). The completed, signed application and required fee
 947 shall be submitted to the board office no later than 30 days prior to installation of the system.
 948 6. Annual Renewal. The board shall make available an application for renewal to each registrant
 949 on or before May 1 each year. Said application shall be completed, signed, and, with annual
 950 fee, returned to the board office to be received on or before June 1 each year.
 951 7. Expired Registration. A registration that is not renewed shall be null and void. A renewal
 952 application for an expired registration shall be requested by the registrant and the completed,
 953 signed application may be referred to the board's reinstatement committee for disposition in
 954 accordance with R.S. 37:1230.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

955
956
957
958
959
960
961
962
963
964
965
966
967
968
969
970
971
972
973
974
975
976
977
978
979
980
981
982
983
984
985
986
987
988
989
990
991
992
993
994
995
996
997
998
999
1000
1001
1002
1003
1004
1005
1006
1007

- 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 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.

Comment [MJB20]: LTC suggests this requirement is problematic when facility closes and surrender permit.

Comment [MJB21]: LTC suggests this is overburdensome and not practical.

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 Department of Health, Board of Pharmacy, LR.

§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 46:111.1209.2 Section 1209 of this Chapter.

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 Department of Health, Board of Pharmacy, LR.

§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

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1008 procedures to the board for approval, on request. These policies and procedures shall be reviewed by
 1009 the pharmacist-in-charge, at least annually and modified if needed, and such review documented.
 1010 They shall include, but are not limited to, the following:
- 1011 1. criteria for selection of medications to be stored in each system, provided that in facilities
 1012 licensed by the Department of Health ~~and Hospitals~~, but not by the board, the selection
 1013 criteria shall not include the substitution by the pharmacist of a product that is not an
 1014 equivalent drug product to the product originally prescribed by the physician or practitioner
 1015 without the explicit consent of the physician or practitioner;
 - 1016 2. criteria for medications qualifying for use with a non-profile driven system and the locations
 1017 and situations that this type of system can be used in; and
 - 1018 3. information on the system as outlined below:
 - 1019 a. access.
 - 1020 i. system entry.
 - 1021 ii. access codes.
 - 1022 iii. system access privileges.
 - 1023 iv. changing access privileges.
 - 1024 v. termination of user.
 - 1025 vi. temporary access codes.
 - 1026 vii. password assignment.
 - 1027 b. controlled substances.
 - 1028 i. chain of custody.
 - 1029 ii. discrepancy resolution.
 - 1030 c. data.
 - 1031 i. archiving.
 - 1032 ii. stored/uploading to database.
 - 1033 iii. backup.
 - 1034 d. definitions.
 - 1035 e. downtime procedures (see malfunction).
 - 1036 f. emergency procedures.
 - 1037 g. information security/confidentiality.
 - 1038 i. patient information.
 - 1039 ii. medication information.
 - 1040 iii. transaction files.
 - 1041 iv. information update plan.
 - 1042 v. patient update plan.
 - 1043 vi. information access.
 - 1044 h. inspection.
 - 1045 i. installation requirements.
 - 1046 j. maintenance, e.g., service and repair protocols.
 - 1047 k. medication administration.
 - 1048 i. medication and patient validation.
 - 1049 ii. administration verification.
 - 1050 l. medication security.
 - 1051 i. acquisition and disposition records.
 - 1052 ii. proof of delivery.
 - 1053 iii. chain of custody of controlled substances (institutions).
 - 1054 iv. security management and control.
 - 1055 v. medication loading and storage.
 - 1056 vi. medication loading records.
 - 1057 vii. medication containers.
 - 1058 viii. cross contamination.
 - 1059 ix. lot number control.
 - 1060 x. inventory.
 - 1061 xi. utilization review.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1062 xii. research.
- 1063 m. malfunction.
- 1064 i. troubleshooting.
- 1065 ii. power failure.
- 1066 n. quality assurance/quality improvement
- 1067 i. documentation and verification of proper loading and refilling of
- 1068 device.
- 1069 ii. removal of drugs for administration, return, or waste.
- 1070 iii. recording, resolving, and reporting of discrepancies.
- 1071 iv. periodic audits to assure compliance with policies and procedures.
- 1072 o. reports.
- 1073 i. system maintenance.
- 1074 ii. administrative functions.
- 1075 iii. inventory.
- 1076 iv. error.
- 1077 v. discrepancies.
- 1078 vi. activity.
- 1079 vii. problem.
- 1080 p. medication inventory management.
- 1081 q. staff education and training.
- 1082 r. system set-up.

1083
1084 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

1085 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
1086 (June 2000) effective July 1, 2000. amended by Department of Health, Board of Pharmacy, LR

1087
1088 **§1211. Documentation**

- 1089 A. Documentation as to type of equipment, serial number, content, policies and procedures and location
- 1090 shall be maintained on-site in the pharmacy for review by the board. Such documentation shall
- 1091 include, but is not limited to:
- 1092 1. name, address, and permit number of the pharmacy or licensed health care facility where the
- 1093 system is operational;
- 1094 2. manufacturer's name and model;
- 1095 3. quality assurance policies and procedures to determine continued appropriate use and
- 1096 performance of the system;
- 1097 4. policies and procedures for system operation, safety, security, accuracy, patient
- 1098 confidentiality, access, controlled substances, data retention, definitions, downtime
- 1099 procedures, emergency or first dose procedures, inspection, installation requirements,
- 1100 maintenance security, quality assurance, medication inventory, staff education and training,
- 1101 system set-up, and malfunction procedures; and
- 1102 5. a current copy of all pharmacy policies and procedures related to the use of the system shall
- 1103 be maintained at all off-site facility locations where the system is being used, as well as the
- 1104 pharmacy of the pharmacist-in-charge.
- 1105

1106 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

1107 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
1108 (June 2000) effective July 1, 2000.

1109
1110 **§1213. Records**

- 1111 A. Records and/or electronic data kept by the system shall meet the following requirements:
- 1112 1. All events involving access to the contents of the system shall be recorded electronically.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1113 2. In the event controlled substances are stored in the system, the records shall include the
 1114 positive identification (as defined in Section 1119 of ~~the Board's rules this Part~~) of the
 1115 personnel retrieving and administering the controlled substances to the patient.
 1116 3. These internal records shall be maintained for one year by the pharmacist-in-charge and shall
 1117 be readily available to the board. Such records shall include:
 1118 a. identity of system accessed;
 1119 b. identification of the individual accessing the system;
 1120 c. type of transaction;
 1121 d. name, strength, dosage form, and quantity of the drug accessed;
 1122 e. name of the patient, or identification numbers for whom the drug was ordered;
 1123 f. identification of the certified pharmacy technician or pharmacist stocking or
 1124 restocking the medications in the system; and
 1125 g. such additional information as the pharmacist-in-charge may deem necessary.
 1126

1127 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

1128 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
 1129 (June 2000) effective July 1, 2000, amended LR 40:2256 (November 2014), effective January 1, 2015, ~~amended by~~
 1130 ~~Department of Health, Board of Pharmacy, LR.~~
 1131

1132 §1215. Security System(s)

- 1133 A. System shall have adequate security system and procedures, evidenced by written pharmacy policies
 1134 and procedures, to:
 1135 1. prevent unauthorized access or use;
 1136 2. comply with any applicable federal and state regulations; and
 1137 3. maintain patient confidentiality.
 1138

1139 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

1140 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
 1141 (June 2000) effective July 1, 2000.
 1142

1143 §1217. Stocking and Restocking

- 1144 A. *On-Site Facility System(s)*. The stocking and restocking of all medications in the on-site system shall
 1145 be accomplished by Louisiana licensed pharmacists and/or Louisiana certified pharmacy technicians
 1146 under the supervision of Louisiana licensed pharmacists. A pharmacist must conduct final checks of
 1147 work performed by a pharmacy technician. The pharmacy shall have a mechanism in place to identify
 1148 the certified pharmacy technician stocking or restocking and the pharmacist checking the accuracy of
 1149 the medications to be stocked or restocked in the automated medication systems.
 1150 B. *Off-Site Facility System(s)*. The stocking and restocking of all medications in the off-site system shall
 1151 be accomplished by Louisiana licensed pharmacists; however, the certified pharmacy technician may
 1152 stock or restock an off-site facility system provided a pharmacist is physically present at the off-site
 1153 facility and supervises and verifies the stocking and/or restocking prior to use. The pharmacy shall
 1154 have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the
 1155 pharmacist checking the accuracy of the medications to be stocked or restocked in the system.
 1156 C. Electronic Product Verification
 1157 1. A bar code verification, electronic verification, or similar verification process may be utilized
 1158 to assure the correct selection of drugs to be placed into an automated medication system.
 1159 2. The use of a bar code, electronic, or similar verification process shall require an initial quality
 1160 assurance validation followed by ongoing quality assurance reviews at intervals no greater
 1161 than 90 days since the previous review, all conducted by a pharmacist.
 1162 3. When a bar code verification, electronic verification, or similar verification process is utilized
 1163 as specified in the Paragraph, ~~and in the absence of any human intervention in the product~~
 1164 ~~selection process~~, the stocking and restocking functions in systems located either on-site or

Comment [MJB22]: LTC suggests if the preceding part of the sentence is true, then the second clause is not necessary.

1165 off-site may be performed by a pharmacy technician or licensed facility personnel approved
1166 by the Pharmacist-in-Charge without the necessity of direct pharmacist supervision.
1167

1168 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
1169 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
1170 (June 2000) effective July 1, 2000, amended LR 41:1488 (August 2015), amended by Department of Health, Board
1171 of Pharmacy, LR.
1172

1173 **§1219. Packaging and Labeling**

1174 A. All containers of medications stored in the system shall be packaged and labeled in accordance with
1175 federal and state laws and regulations and contain an established satisfactory beyond use date based on
1176 U.S.P. standards.
1177

1178 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
1179 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
1180 (June 2000) effective July 1, 2000.
1181

1182 **§1221. Proof of Use**

1183 A. For medication removed from the system for patient administration, the system shall document, at a
1184 minimum, the following:
1185 1. name of the patient or resident;
1186 2. patient's or resident's medical record number or identification number, or room and bed
1187 number;
1188 3. date and time medication was removed from the system;
1189 4. name, initials, or other unique identifier of the person removing the drug; and
1190 5. name, strength, and dosage form of the medication or description of the medical device
1191 removed.
1192

1193 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
1194 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
1195 (June 2000) effective July 1, 2000.
1196

1197 **§1223. Wasted, Discarded, or Unused Medications**

1198 A. The system shall provide a mechanism for securing and accounting for wasted, discarded, or unused
1199 medications removed from the system according to policies and procedures, and existing state and
1200 federal law.
1201

1202 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
1203 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
1204 (June 2000) effective July 1, 2000.
1205

1206 **§1225. Inspection**

1207 A. System records shall be available and readily retrievable for board inspection and review during
1208 regular working hours of operation. The system itself is also subject to inspection at that time.
1209

1210 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
1211 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271
1212 (June 2000) effective July 1, 2000.
1213

1214 **§1227. Out-of-State Pharmacies**

1215 A. Out-of-state pharmacies must have applied for and been issued an out-of-state pharmacy permit by the
1216 board as identified in regulations. Out-of-state pharmacies must have the proper pharmacy permit
1217 issued by the state in which they reside in order to utilize a system in Louisiana.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

1218
1219
1220
1221
1222
1223
1224
1225
1226
1227
1228
1229
1230
1231
1232
1233
1234
1235
1236
1237
1238
1239
1240
1241
1242
1243
1244
1245
1246
1247
1248
1249
1250
1251
1252
1253
1254
1255
1256
1257
1258
1259
1260
1261
1262
1263
1264
1265
1266
1267
1268

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~~ ~~Chapter~~.

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 Department of Health, Board of Pharmacy, LR~~.

§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.

Chapter 15. Hospital Pharmacy

§1501. Cross References

- A. For all regulations that apply to permitted hospital pharmacies concerning pharmacy practices ~~and records~~ not specifically stated in this ~~Chapter~~, refer to Chapters 11 and 25 ~~of this Part~~.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:808 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, amended LR 38:1235 (May 2012), ~~amended by Department of Health, Board of Pharmacy, LR~~.

§1503. Definitions

- A. As used in this chapter, the following terms shall have the meanings ascribed to them in this Section:
~~Dispensing of a drug pursuant to a hospital prescription – the professional review by a pharmacist required to place a specific drug in final association with the name of a particular hospital patient pursuant to the lawful order of a prescriber. In the case of an automated medication system meeting the requirements of Chapter 12 of these rules, the final association with the name of a particular hospital patient will be deemed to have occurred when the pharmacist has given the final approval to the patient specific order in the system.~~
Electronic drug record keeping system – a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.
Hospital Off-Site Satellite Pharmacy – a pharmacy located within a hospital licensed by the Louisiana Department of Health ~~and Hospitals~~, or its successor, the location of which is physically separate from the location of the provider pharmacy.
Hospital Patient – a person receiving health care services within a hospital facility.

Comment [MJB23]: With Chart Order term in place, this term no longer necessary.

1269 *Hospital Pharmacy* – a pharmacy department permitted by the board and located in a hospital licensed
 1270 pursuant to R.S. 40:2100 *et seq.* For the purposes of this Chapter, a hospital pharmacy is one example
 1271 of a primary care treatment modality pharmacy.

1272 ~~*Hospital Prescription* – a written, electronic or oral order for a drug for use in treating a hospital~~
 1273 ~~*patient.*~~

Comment [MJB24]: With Chart Order in place,
 this term no longer necessary.

1274 *Password* – a private identification that is created by a user to obtain access to an electronic drug
 1275 record keeping system.

1276 *Personal identifier* – a unique user name or number for identifying and tracking a specific user's
 1277 access to an electronic drug record keeping system such as social security number, user identification
 1278 number, or employee number

1279 *Positive identification* –

- 1280 1. has the same meaning as defined in Section 1119 of ~~these rules this Part~~, except that a specific
 1281 hospital having a closed electronic drug record keeping system may be permitted to use identifiers
 1282 utilizing both a password combined with a personal identifier to document the positive
 1283 identification of each user for the prescribing and administration of a drug, provided the
 1284 pharmacist-in-charge has determined:
- 1285 a. adequate audit controls are in place to detect and deter drug diversion;
 - 1286 b. adequate access controls are in place to assure the identity of the user and to assign
 1287 accountability of the user for any drug transaction;
 - 1288 c. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's
 1289 password and personal identifier;
 - 1290 d. an ongoing quality assurance program is in place to ensure that all three provisions cited above
 1291 in this definition are being fulfilled and reviewed; and
 - 1292 e. appropriate policies and procedures are in place to address all four provisions cited above in
 1293 this definition.
- 1294 2. All of the above notwithstanding, however, positive identification as defined in Section 1119 of
 1295 ~~these rules this Part~~ shall always be used to document the:
- 1296 a. Dispensing, compounding, or prepackaging of a drug;
 - 1297 b. Removal and possession of a controlled substance to administer to a patient; and
 - 1298 c. Waste of a controlled substance.

1299 *Provider Pharmacy* – a hospital pharmacy which provides administrative control, staffing as well as
 1300 products and services to a hospital off-site satellite pharmacy.

1301 *Registered Patient* – A person receiving health care services within a hospital facility.

1302 *Unit Dose* – the packaging of individual prescription doses in a suitable container that have been
 1303 properly labeled as to the identity of the generic, chemical, or trade name of the drug; strength; lot
 1304 number; and expiration date. All unit doses qualify as "prepackaging" as used in this chapter.
 1305 However, all prepackaging is not necessarily in "unit dose" packaging.

1306

1307 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1308 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
 1309 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004,
 1310 amended LR 33:1132 (June 2007), amended LR 39:1282 (May 2013), amended LR 40:2256 (November 2014),
 1311 effective January 1, 2015, amended LR 41:2147 (October 2015), ~~amended by Department of Health, Board of~~
 1312 ~~Pharmacy, LR.~~

1313

1314 §1505. Hospital Pharmacy Permit

- 1315 A. A hospital pharmacy permit shall be required to operate a pharmacy department located within a
 1316 hospital for registered patients in a hospital. The permit shall be applied for, and renewed, in the
 1317 manner prescribed by the board in Chapter 11 of ~~these regulations this Part~~.

1318

1319 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1320 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
 1321 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004,
 1322 amended LR 33:1132 (June 2007), ~~amended by Department of Health, Board of Pharmacy, LR.~~

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

1323
1324
1325
1326
1327
1328
1329
1330
1331
1332
1333
1334
1335
1336
1337
1338
1339
1340
1341
1342
1343
1344
1345
1346
1347
1348
1349
1350
1351
1352
1353
1354
1355
1356
1357
1358
1359
1360
1361
1362
1363
1364
1365
1366
1367
1368
1369
1370
1371
1372
1373
1374
1375

§1507. Pharmacist in Charge

A. The pharmacist in charge of a hospital pharmacy permit shall have had at least two years of experience as a licensed and practicing pharmacist prior to accepting the appointment.

Comment [MJB25]: Since this requirement was expanded to all PICs in 2012, staff recommends repealing this Section.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1509. Drug Distribution Control

- A. The hospital pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs. The staff of the hospital facility shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering, administering, and accounting for pharmaceuticals.
 - 1. Procedure Manual. The pharmacist-in-charge shall maintain written procedures for the safe and efficient distribution of pharmaceutical products and delivery of pharmacy care. An updated copy shall be available for board inspection upon request.
 - 2. Inventories. The pharmacist-in-charge shall:
 - a. perform an annual inventory on all controlled dangerous substances; and
 - b. maintain a perpetual inventory of Schedule I and II controlled dangerous substances.
 - 3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:
 - a. A record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured.
 - b. All drug orders and records relating to the practice of pharmacy.
 - i. Records of drugs dispensed shall include, but are not limited to:
 - (a) The name, strength, and quantity of drugs dispensed;
 - (b) The date of dispensing;
 - (c) The name of the hospital patient to whom, or for whose use, the drug was dispensed; and
 - (d) Positive identification of all pharmacists involved in the dispensing.
 - ii. All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:
 - (a) The name of the hospital patient to whom, or for whose benefit, the activity was performed;
 - (b) The nature of the pharmacy practice activity performed;
 - (c) The results of the activity, if applicable; and
 - (d) Positive identification of all pharmacists involved in the activity; identifying the function performed by each pharmacist.
 - iii. Records of drugs dispensed to patients for use outside the hospital shall be maintained in compliance with Section 1123 of ~~these rules~~ this Part.
 - c. A record of all drugs compounded or prepackaged for use only within that hospital, which shall include at least the following:
 - i. Name of drug, strength, quantity, and dosage form;
 - ii. Manufacturer's or distributor's control number (except for patient-specific sterile compounded preparations);
 - iii. Manufacturer's or distributor's name, if a generic drug is used;
 - iv. Pharmacy control number;
 - v. Manufacturer's or distributor's expiration date (except for patient-specific sterile compounded preparations);
 - vi. Pharmacy's expiration date or beyond-use date;
 - vii. Identification of the licensed person responsible for the compounding or prepackaging of the drug.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion. Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1376
1377
1378
1379
1380
1381
1382
1383
1384
1385
1386
1387
1388
1389
1390
1391
1392
1393
1394
1395
1396
1397
1398
1399
1400
1401
1402
1403
1404
1405
1406
1407
1408
1409
- d. A record of the distribution of drugs to patient care areas and other areas of the hospital held for administration, which shall include at least the following:
 - i. The name, strength, dosage form, and amount of the drug distributed;
 - ii. The area receiving the drug;
 - iii. The date distributed;
 - iv. Identification of the individual receiving the drug if it is a controlled dangerous substance;
 - v. The area of the hospital receiving the controlled dangerous substance shall make a record of all such drugs administered to patients. Such records shall include at least the following:
 - (a) Name of the patient;
 - (b) Name, dosage form, and strength when applicable of the drug;
 - (c) Date and time the drug was administered;
 - (d) Quantity administered;
 - (e) Positive identification of the personnel administering the drug.
 - e. A log that shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:
 - i. Date and time of the change;
 - ii. Changes made;
 - iii. Person making the change.
- B. Automated Medication Systems. A hospital pharmacy may use one or more automated medication systems in compliance with the provisions of *Chapter 12. Automated Medication Systems of the Board's rules this Part*.
- 1. When the pharmacy uses an electronic product verification process as described in *§ Section 1217 of the Board's rules this Part*, and in the absence of any subsequent human intervention in the automated drug product selection process, the pharmacist-in-charge may elect to forego manual checks of drug products selected in that manner, provided however, that such selection by the pharmacist-in-charge shall require an initial quality assurance validation followed by an ongoing quality review at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.
 - 2. The pharmacist-in-charge remains accountable to the Board for the accuracy of all drug distribution activities.

1410 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1411 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093
1412 (October 2003), effective January 1, 2004, amended LR 40:2257 (November 2014), effective January 1, 2015,
1413 amended LR 41:1488 (August 2015), amended by Department of Health, Board of Pharmacy, LR
1414

1415 §1511. Prescription Drug Orders

- 1416 A. The pharmacist shall review the practitioner's medical order prior to dispensing the initial dose of
1417 medication, except in cases of emergency.
1418

1419 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1420 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
1421 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.
1422

1423 §1512. Hospital Pharmacy Prepackaging

- 1424 A. Prepackaging is the preparation of medication in a unit-of-use container by credentialed pharmacy
1425 personnel in a pharmacy prior to the receipt of a prescription or medical order for ultimate issuance by
1426 a pharmacist in Louisiana.
1427 B. Labeling. The label on the prepackaged container shall contain the following minimum information:
1428 1. Drug name;

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1429 2. Dosage form;
 1430 3. Strength;
 1431 4. Quantity dispensed when appropriate;
 1432 5. Special storage requirements;
 1433 6. A unique pharmacy prepackage lot number which shall correspond to the following:
 1434 a. Name of manufacturer and/or distributor;
 1435 b. Manufacturer's lot or batch number;
 1436 c. Date of preparation; and
 1437 d. Verifying pharmacist's initials;
 1438 7. Expiration date, according to United States Pharmacopeia (USP) guidelines.
 1439

1440 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1441 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1235
 1442 (May 2012).
 1443

1444 §1513. Labeling

- 1445 A. All drugs dispensed or compounded by a hospital pharmacy, intended for use within the facility, shall
 1446 be dispensed in appropriate containers and adequately labeled as to identify patient name and location,
 1447 drug name(s) and strength, and medication dose(s). Additionally, compounded preparations and sterile
 1448 preparations shall be labeled with the expiration date or beyond-use date, initials of the preparer, and
 1449 the pharmacist performing the final check.
 1450

1451 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1452 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
 1453 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004,
 1454 amended LR 38:1235 (May 2012).
 1455

1456 §1515. Ambulance Service Drugs

- 1457 A. Hospital pharmacies that supply prescription drugs, including any controlled dangerous substances, to
 1458 any authorized ambulance service or emergency medical service shall maintain proper records to
 1459 ensure control, proper utilization, inventory, and accountability.
 1460

1461 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1462 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093
 1463 (October 2003), effective January 1, 2004.
 1464

1465 §1517. Pharmacist Absence/Drug Cabinet

- 1466 A. Pharmacist Absence. In the absence of a licensed pharmacist, admittance to the pharmacy by
 1467 unauthorized persons is prohibited. When the pharmacy is closed, a pharmacist shall be on emergency
 1468 call.
 1469 B. Drug Cabinets. In the absence of a licensed pharmacist, arrangements shall have been formulated in
 1470 advance by the pharmacist-in-charge to provide drugs for the patients by the use of drug cabinets.
 1471 1. Emergency Use. A drug cabinet is solely intended for the proper and safe storage of needed
 1472 drugs when the pharmacy is closed and shall be available for emergency use by authorized
 1473 hospital personnel only.
 1474 2. Security. The drug cabinet shall be a securely constructed and locked enclosure located
 1475 outside the permitted pharmacy ensuring access to authorized personnel only.
 1476 3. Inventory. The pharmacist-in-charge shall be responsible for the selection and quantity of the
 1477 drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any
 1478 controlled dangerous substances stored in the drug cabinet.
 1479 4. Labeling. Medications stored in a drug cabinet shall be properly labeled.
 1480 5. Quantities. Prepackaged drugs shall be available in amounts sufficient for immediate
 1481 therapeutic or emergency requirements.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1482 6. Accessibility. Written medical practitioner’s orders and proof of use, if applicable, shall be
- 1483 provided when a drug cabinet inventory is utilized.
- 1484 7. Inspection. Medications stored in a drug cabinet shall be inspected every thirty days.
- 1485 8. Policy Manual. A policy and procedure manual shall be maintained to implement the drug
- 1486 cabinet requirements and is to be made available to the board upon request for inspection and
- 1487 approval.
- 1488

1489 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1490 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093
1491 (October 2003), effective January 1, 2004.

1492
1493 **§1519. Drug Returns**

- 1494 A. In a hospital with a permitted hospital pharmacy on site, drugs may be returned to the pharmacy in
- 1495 accordance with good professional practice standards.

1496
1497 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1498 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094
1499 (October 2003), effective January 1, 2004.

1500
1501 **§1521. Off-Site Pharmacy Services**

- 1502 A. Availability. Pharmacy services may be procured contractually from outside the hospital for inpatient
- 1503 administration.
- 1504 B. Contractual agreements shall provide for:
 - 1505 1. emergency – the pharmacy provider shall be available for on-call for emergency pharmacy
 - 1506 services.
 - 1507 2. storage – adequate drug storage facilities shall be provided to the pharmacy provider.
 - 1508 3. labeling – prescription drugs supplied to hospital inpatients shall be properly labeled to ensure
 - 1509 that adequate control, supervision, and recall of medication are monitored.
 - 1510 4. contractual pharmacy service – off-site contractual pharmacy services rendered to the hospital
 - 1511 shall be in accordance with federal and state laws, rules, and regulations.
- 1512 C. A pharmacy providing off-site contractual pharmacy services to a hospital shall not be considered a
- 1513 hospital pharmacy.
- 1514 D. Medications. Prescription medications independently supplied to registered patients shall comply with
- 1515 all appropriate board regulations and statutes and/or hospital rules, regulations, and policies.

1516
1517 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1518 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094
1519 (October 2003), effective January 1, 2004.

1520
1521 **§1523. Outpatient Pharmacy Dispensing**

- 1522 A. Hospital outpatient dispensing shall require a separate pharmacy permit for the specialty
- 1523 classification(s) under these regulations. All records including the annual inventory of controlled
- 1524 dangerous substances for the outpatient pharmacy shall be maintained and kept separate and apart from
- 1525 that of the inpatient pharmacy, as the outpatient pharmacy may not acquire drugs through the hospital
- 1526 pharmacy permit under the provisions of the Robinson-Patman Act, 15 U.S.C. §13(c).
- 1527 B. Nothing in this section shall prohibit the dispensing of certain prescriptions from the hospital
- 1528 pharmacy, as allowed under the Robinson-Patman Act, 15 U.S.C. §13, including:
 - 1529 1. dispensing to the hospital inpatient for use in his treatment at the hospital;
 - 1530 2. dispensing to the patient admitted to the hospital’s emergency facility for use in the patient’s
 - 1531 treatment at that location;
 - 1532 3. dispensing to the hospital outpatient for personal use on the hospital premises;
 - 1533 4. dispensing in the context of a genuine take-home prescription, intended for a limited and
 - 1534 reasonable time as a continuation of, or supplement to, the treatment that was administered at

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1535 the hospital to the recipient while an inpatient, an outpatient, or an emergency facility patient
- 1536 if the patient needs that treatment; or
- 1537 5. dispensing to the hospital’s physicians, employees, or its students for their personal use or for
- 1538 the personal use of their dependents.
- 1539

1540 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1541 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094
1542 (October 2003), effective January 1, 2004.

1543 **§1525. Hospital Off-Site Satellite Pharmacy**

1544 A. Issuance and Maintenance of Permit

- 1545 1. A hospital pharmacy may establish a hospital off-site satellite pharmacy within a facility
- 1546 bearing the same hospital license number as the facility housing the provider pharmacy.
- 1547 2. The provider pharmacy, acting through its pharmacist-in-charge, shall make application for
- 1548 the satellite pharmacy permit using a form and process specified by the board.
- 1549 3. The applicant shall pay the fee for the initial issuance and renewal as specified in R.S.
- 1550 37:1184.
- 1551 4. Once issued, the satellite pharmacy permit shall expire at midnight on December 31 of each
- 1552 year, unless suspended or revoked earlier by the board.
- 1553 5. The satellite pharmacy shall renew its permit using the form and process specified by the
- 1554 board.
- 1555 6. The operation of a hospital off-site satellite pharmacy without a pharmacy permit, or with an
- 1556 expired permit, shall constitute a violation of R.S. 37:1241(A)12.
- 1557 7. In the event a provider pharmacy sustains a change of ownership sufficient to require a new
- 1558 pharmacy permit, the hospital off-site satellite pharmacy shall also obtain a new pharmacy
- 1559 permit.
- 1560 8. In the event a provider pharmacy closes permanently and surrenders its permit, the hospital
- 1561 off-site satellite pharmacy shall also close and surrender its permit.

1562 B. General Requirements

- 1563 1. The hospital off-site satellite pharmacy shall be of sufficient size and shall contain sufficient
- 1564 fixtures, equipment and supplies commensurate with the scope of practice for that pharmacy,
- 1565 provided:
- 1566 a. The pharmacy shall be of sufficient size to allow for the safe and proper storage of
- 1567 prescription drugs and/or controlled substances;
- 1568 b. All areas where drugs and devices are stored shall be dry, well-lighted, well
- 1569 ventilated, and maintained in a clean and orderly condition, and more specifically,
- 1570 storage areas shall be maintained at temperatures which will ensure the integrity of
- 1571 drugs prior to their dispensing as stipulated by the United States Pharmacopeia
- 1572 (USP) and/or the manufacturer’s or distributor’s product labeling unless otherwise
- 1573 indicated by the board;
- 1574 c. The pharmacy shall be secured by either a physical barrier with suitable locks and/or
- 1575 an electronic barrier to detect entry at a time when the pharmacist is not present; and
- 1576 d. Prescription and other patient healthcare information shall be maintained in a manner
- 1577 that protects the integrity and confidentiality of such information.
- 1578 2. The pharmacist-in-charge of the provider pharmacy shall be responsible for all pharmacy
- 1579 operations involving the hospital off-site satellite pharmacy including supervision of
- 1580 pharmacy personnel.
- 1581 3. The hospital off-site satellite pharmacy shall have at least one licensed pharmacist on duty
- 1582 and physically present in the pharmacy at all times the hospital off-site satellite pharmacy is
- 1583 open for the transaction of business.
- 1584 4. The hospital off-site satellite pharmacy shall have a sufficient number of pharmacists on duty
- 1585 to operate the pharmacy competently, safely, and adequately to meet the needs of the patients
- 1586 of the pharmacy.
- 1587

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1588 5. When the hospital off-site satellite pharmacy is closed or there is no pharmacist on duty, other
- 1589 individuals shall not have access to the hospital off-site satellite pharmacy except for
- 1590 temporary absences as provided for in Chapter 11 of ~~these rules this Part.~~
- 1591 6. The provider pharmacy and the hospital off-site satellite pharmacy shall have:
- 1592 a. The same owner; and
- 1593 b. Share a common electronic file or have the appropriate technology to allow access to
- 1594 sufficient information necessary or required to process a prescription or medical
- 1595 order.
- 1596 7. The hospital off-site satellite pharmacy shall comply with the recordkeeping provisions
- 1597 identified in Chapter 11 of ~~these rules this Part.~~
- 1598 8. The compounding of preparations in a hospital off-site satellite pharmacy shall be
- 1599 accomplished in compliance with the current federal standards applicable to such practices:
- 1600 USP Chapter 797, or its successor, for the compounding of sterile preparations, and USP
- 1601 Chapter 795, or its successor, for the compounding of non-sterile preparations.
- 1602

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:1283 (May 2013), ~~amended by Department of Health, Board of Pharmacy, LR.~~

~~§1527. Remote Access to Medical Orders~~

- 1608 ~~B. Notwithstanding any provision of rules to the contrary, nothing shall prohibit a Louisiana-licensed~~
- 1609 ~~pharmacist who is an employee of or under contract with a hospital pharmacy in Louisiana from~~
- 1610 ~~accessing that pharmacy's dispensing information system from a location other than the pharmacy in~~
- 1611 ~~order to process prescription drug orders or medical orders, but only when all of the following~~
- 1612 ~~conditions are satisfied:~~
- 1613 ~~4. The pharmacy establishes controls to protect the privacy and security of confidential records;~~
- 1614 ~~5. The pharmacist does not engage in the receiving of written prescription drug orders or~~
- 1615 ~~medical orders or the maintenance of prescription drug orders or medical orders; and~~
- 1616 ~~6. No part of the pharmacy's dispensing information system is duplicated, downloaded, or~~
- 1617 ~~removed from the pharmacy's dispensing information system.~~

Comment [MJB26]: If this authority is extended to all permit types in Chapter 11, recommend deleting this Section.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2147 (October 2015).

Chapter 17. Institutional Pharmacy

Subchapter A. General Requirements

§1701. Cross References

- 1629 A. For all regulations that apply to permitted institutional pharmacies concerning pharmacy
- 1630 practices ~~and records~~ not specifically stated in this chapter, refer to Chapter 11.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2094 (October 2003), effective January 1, 2004, ~~amended by Department of Health, Board of Pharmacy, LR.~~

§1703. Definitions

- 1637 A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this
- 1638 section:

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion. Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1640 *Institutional Facility* – any organization whose primary purpose is to provide a physical environment
 1641 for a patient to obtain health care services, including but not limited to a(n):
 1642 a. convalescent home;
 1643 b. nursing home;
 1644 c. extended care facility;
 1645 d. mental health facility;
 1646 e. rehabilitation center;
 1647 f. psychiatric center;
 1648 g. developmental disability center;
 1649 h. drug abuse treatment center;
 1650 i. family planning clinic;
 1651 j. penal institution;
 1652 k. hospice;
 1653 l. public health facility;
 1654 m. athletic facility.

1655 *Institutional Pharmacy* – that physical portion of an institutional facility where drugs, devices, and
 1656 other materials used in the diagnosis and treatment of an injury, illness, and disease are dispensed,
 1657 compounded, and distributed and pharmacy primary care is provided, and is permitted by the board
 1658 and is devoted exclusively to providing professional services to a patient in that institutional setting,
 1659 other than a hospital.

1660 *Long Term Care Facility* – a nursing home, retirement center, mental care, or other facility or
 1661 institution that provides extended health care to a residential patient, including but not limited to health
 1662 care facilities licensed by the Department of Health ~~and Hospitals~~.

1664 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1665 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
 1666 (October 1988), effective January 1, 1989, amended LR 29:2094 (October 2003), effective January 1, 2004,
 1667 ~~amended by Department of Health, Board of Pharmacy, LR~~.

1668 §1705. Institutional Pharmacy Permit

- 1670 A. An institutional pharmacy permit shall be required to operate a pharmacy department located within an
 1671 institutional facility, other than a hospital or penal institution, for residents or patients of that
 1672 institutional facility. The permit shall be applied for, and renewed, in the manner prescribed by the
 1673 board in Chapter 11 of ~~these regulations this Part~~.
 1674 B. Pharmacies operated within a hospital shall be operated in accordance with Chapter 15 of ~~these~~
 1675 ~~regulations this Part~~.
 1676 C. Pharmacies operated within a ~~penal institution correctional center~~ shall be operated in accordance with
 1677 Chapter 18 of ~~these regulations this Part~~.

1678 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1679 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
 1680 (October 1988), effective January 1, 1989, amended LR 29:2095 (October 2003), effective January 1, 2004,
 1681 amended LR 39:313 (February 2013), ~~amended by Department of Health, Board of Pharmacy, LR~~.

1682 §1707. Drug Cabinet

- 1684 A. In the absence of a licensed pharmacist, arrangements shall have been formulated in advance by the
 1685 pharmacist-in-charge to provide drugs for the residents/patients by the use of drug cabinets. When the
 1686 pharmacy is closed, a pharmacist shall be on emergency call.
 1687 1. Emergency Use. A drug cabinet is solely intended for the proper and safe storage of needed
 1688 drugs when the pharmacy is closed and shall be available for emergency use by authorized
 1689 facility personnel only.
 1690 2. Security. The drug cabinet shall be a securely constructed and locked enclosure located
 1691 outside the permitted pharmacy area ensuring access by authorized personnel only.
 1692

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1693
1694
1695
1696
1697
1698
1699
1700
1701
1702
1703
1704
1705
1706
1707
1708
1709
1710
3. Inventory. The pharmacist-in-charge shall be responsible for the selection and quantity of drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances. Medications shall be available in quantities sufficient only for immediate therapeutic needs.
 4. Labeling. Medications stored in a drug cabinet shall bear a label with the following minimum information:
 - a. drug name;
 - b. dosage form;
 - c. strength;
 - d. name of manufacturer and/or distributor;
 - e. manufacturer's lot or batch number;
 - f. pharmacist's initials; and
 - g. expiration date, according to United States Pharmacopeia guidelines.
 5. Accountability. Documented medical practitioner's orders and proof of use shall be provided when any of the drug cabinet inventory is utilized.
 6. Inspection. The pharmacy shall inspect medications stored in a drug cabinet every 30 days, plus or minus five days.

1711 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1712 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095
1713 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

1714
1715

1716 Subchapter B. Emergency Drug Kits

1717

1718 §1709. Definitions

- 1719 A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this
1720 section:

1721 *Emergency Drug Kit (EDK)* – for long-term care facilities or other board-approved sites, other than a
1722 hospital, means a drug kit containing designated emergency drugs which may be required to meet the
1723 immediate therapeutic needs of a resident or patient.

1724 *Emergency Drugs* – those drugs which may be required to meet the immediate therapeutic needs of
1725 patients and which are not available from any other authorized source in sufficient time to prevent risk
1726 of harm to patients or residents because of delay resulting from obtaining such medications from such
1727 other source.

1728

1729 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1730 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095
1731 (October 2003), effective January 1, 2004.

1732

1733 §1711. Emergency Drug Kit Permit

- 1734 A. A long-term care facility, institutional facility without an institutional pharmacy, or other board-
1735 approved site, other than a hospital, that desires to maintain an Emergency Drug Kit shall obtain an
1736 EDK permit from the board.
- 1737 B. Permit Application and Requirements. Application for an EDK permit shall be made on a form
1738 provided by the board.
- 1739 1. The provider pharmacy shall apply to the board for an EDK permit. The administrator of the
1740 applicant facility shall also sign the application for said permit. Upon compliance with the
1741 required provisions, the provider pharmacy shall be issued a permit by the board for the
1742 provider pharmacy to establish and maintain an EDK in the facility.
 - 1743 2. The provider pharmacy shall be a Louisiana-licensed pharmacy.
 - 1744 3. Only one provider pharmacy shall be assigned to and be responsible for each EDK.
 - 1745 4. EDK permits are institutional facility-specific and not transferable.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 1746 5. A separate permit is required for each EDK.
 1747 6. The original EDK permit shall be **conspicuously displayed readily retrievable** at the provider
 1748 pharmacy. A copy of the EDK permit shall be maintained in the room where the EDK is
 1749 located.
 1750 C. Pharmacist-in-Charge. The pharmacist-in-charge of the provider pharmacy shall be the pharmacist-in-
 1751 charge of the EDK. The maintenance of the EDK shall at all times remain the responsibility of the
 1752 pharmacist-in-charge.
 1753 D. Renewal. Each EDK permit issued by the board shall be renewed annually by the provider pharmacy,
 1754 at the time designated by the board. If an EDK permit is not renewed by July 1 of each year, the
 1755 existing permit shall expire and become null and void.
 1756

1757 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1758 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095
 1759 (October 2003), effective January 1, 2004, amended by the Department of Health Board of Pharmacy, LR.
 1760

1761 §1713. Emergency Drug Kit Requirements

- 1762 A. Emergency Use. An EDK is solely intended for the immediate therapeutic emergency needs of a
 1763 resident or patient.
 1764 B. Security. The EDK shall be tamper-evident and shall be maintained in a secure enclosure located
 1765 within the institutional facility and shall be available for emergency use by authorized personnel only.
 1766 C. Exterior Identification and Labeling. The EDK shall be clearly labeled to indicate that it is an
 1767 emergency drug kit. In addition, the attached exterior label shall have an inventory of contents and
 1768 contact information of the provider pharmacy.
 1769 D. Labeling. Medications stored in an EDK shall bear a label with the following minimum information:
 1770 1. drug name;
 1771 2. dosage form;
 1772 3. strength;
 1773 4. name of manufacturer and/or distributor;
 1774 5. manufacturer's lot or batch number; and
 1775 6. expiration date, according to United States Pharmacopeia guidelines.
 1776 E. Storage. All drugs in an EDK shall be stored to ensure a proper environment for the preservation of
 1777 the drugs. If federal or state laws or regulations require adequate storage outside the EDK,
 1778 documentation shall be kept with the EDK properly identifying this special storage requirement and
 1779 drug(s) involved.
 1780 F. Policies and Procedures. Policies and procedures shall be maintained by the provider pharmacy and
 1781 the applicant facility to implement the EDK requirements.
 1782 G. Accountability. Documented medical practitioner's orders and proof of use shall be provided when an
 1783 EDK inventory is utilized. Medication administered to patients from the EDK shall be documented
 1784 with the following information, in accordance with the institutional facility policy manual, that shall be
 1785 immediately reduced to writing and a copy delivered to the provider pharmacy:
 1786 1. name of the resident patient;
 1787 2. drug name, strength, and quantity;
 1788 3. nature of the emergency;
 1789 4. time and date of administration;
 1790 5. name of person administering the medication; and
 1791 6. name of prescriber authorizing the medication.
 1792 H. Records. Records shall be readily retrievable and comply with applicable federal and state laws and
 1793 regulations.
 1794 I. Inspection.
 1795 1. The provider pharmacy shall inspect the EDK every **thirty (30)** days, plus or minus five ~~(5)~~
 1796 days. Proper documentation of these inspections, EDK inventory, and all records of use shall
 1797 be maintained and made available to the board upon request.
 1798 2. The EDK shall be available for inspection by the board.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in **yellow** proposed by LTC Stakeholders; coding highlighted in **blue** proposed by staff.

1799
1800
1801
1802
1803
1804
1805
1806
1807
1808
1809
1810
1811
1812
1813
1814
1815
1816
1817
1818
1819
1820
1821
1822
1823
1824
1825
1826
1827
1828
1829
1830
1831
1832
1833
1834
1835
1836
1837
1838
1839
1840
1841
1842
1843
1844
1845
1846
1847
1848
1849
1850
1851

- J. The placement of controlled dangerous substances in an EDK in non-federally registered long-term care facilities shall be deemed in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:
1. Controlled dangerous substances shall be stored in the EDK as deemed necessary and jointly approved by the pharmacist, medical director and the director of nursing services;
 2. The source from which the controlled dangerous substances for EDKs are obtained shall be a pharmacy licensed by the board in possession of a valid DEA registration and Louisiana CDS license;
 3. The number of different controlled dangerous substances in a single EDK shall be limited to a maximum of eight separate drug entities with not more than eight single-use containers of each drug entity;
 4. The EDK containing controlled dangerous substances shall be closed with a tamper proof seal and kept in a located medication room, cart or closet;
 5. Access to controlled dangerous substances stored in an EDK shall be limited to the pharmacist, a practitioner, the director of nursing services, or the registered nurse or licensed practical nurse on duty;
 6. Controlled dangerous substances stored in an EDK shall be administered to a patient only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.21 or their successors;
 7. A usage record shall be retained in the EDK for each separate drug included which shall be completed by the nursing staff when retrieving any controlled dangerous substance(s) from the EDK;
 8. The pharmacist at the provider pharmacy shall receive and retain all completed usage records for a minimum of two years;
 9. When the EDK is opened:
 - a. The pharmacist shall be notified by the facility within 24 hours; and
 - b. Shift counts shall be performed by the nursing staff on all controlled dangerous substances until the kit is resealed by the pharmacist.
 10. Shift counts of the controlled dangerous substances contained in the EDK shall not be required when the EDK is sealed;
 11. The pharmacist shall check the controlled dangerous substances in the EDK at least monthly and so document that check inside the kit.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004, amended LR 39:312 (February 2013), [amended by Department of Health, Board of Pharmacy, LR](#).

Subchapter C. Drug Abuse Treatment Center Pharmacies

§1715. Purpose

- A. The board may issue a pharmacy permit for a drug abuse treatment center operating in the state of Louisiana where drugs are dispensed and pharmacy primary care is provided.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

§1717. Cross References

- A. For all regulations that apply to drug abuse treatment center pharmacies concerning pharmacy practices not specifically stated in this subchapter, refer to Chapter 11 [of this Part](#).

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in [yellow](#) proposed by LTC Stakeholders; coding highlighted in [blue](#) proposed by staff.

1852 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
1853 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096
1854 (October 2003), effective January 1, 2004, amended by Department of Health, Board of Pharmacy, LR.
1855

1856 §1719. Definitions

- 1857 A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this
1858 section:
1859 *Administer or Administration* – means the direct application of a drug to the body of a patient or
1860 research subject by injection, inhalation, ingestion, or any other means.
1861 *Authorized Personnel* – means individuals who, within the scope of their authority granted by mutual
1862 agreement of the drug abuse treatment center’s pharmacist-in-charge and director, are granted access to
1863 the drug abuse treatment center’s pharmacy department as part of his duties.
1864 *Dispense or Dispensing* – means the interpretation, evaluation, and implementation of a prescription
1865 drug order, including the preparation and delivery of a drug or device to a patient or patient’s agent in a
1866 suitable container appropriately labeled for subsequent administration to, or use by, a patient.
1867 “Dispense” necessarily includes a transfer of possession of a drug or device to the patient or the
1868 patient’s agent.
1869 *Drug Abuse Treatment Center* – means any establishment, facility, or institution, public or private,
1870 whether operated for profit or not, which primarily offers, or purports to offer, maintain, or operate
1871 facilities for the residential or outpatient diagnosis, care, treatment, or rehabilitation of two or more
1872 non-related individuals, who are patients as defined herein, excluding, however, any hospital or mental
1873 hospital otherwise licensed by the Department of Health and Hospitals.
1874 *Patient or Client* – means a person who is dependent on, or otherwise suffering physically or mentally
1875 from the use of, or abuse of, controlled dangerous substances and who requires continuing care of a
1876 drug abuse treatment center.
1877 *Perpetual Inventory* – means a computer record of inventory kept continuously up to date by detailed
1878 entries of all incoming and outgoing items. This includes inventory on hand, purchases, and
1879 dispensing.

1880 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
1881 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096
1882 (October 2003), effective January 1, 2004, amended by Department of Health, Board of Pharmacy, LR.
1883
1884

1885 §1721. Drug Abuse Treatment Center Pharmacy Permit

- 1886 A. A drug abuse treatment center pharmacy permit shall be required to operate a pharmacy
1887 department located within a drug abuse treatment facility for patients of that facility. The permit shall
1888 be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations
1889 this Part.

1890 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
1891 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097
1892 (October 2003), effective January 1, 2004, amended by Department of Health, Board of Pharmacy, LR.
1893
1894

1895 §1723. Minimum Security Controls for Drug Abuse Treatment Centers

- 1896 A. Persons enrolled in a drug abuse treatment center shall wait for their prescriptions in an area physically
1897 separated from the controlled dangerous substance (CDS) storage and dispensing area. This
1898 requirement shall be enforced by the drug abuse treatment center physician(s), pharmacist(s), and
1899 employees.
1900 B. All CDS used in a drug abuse treatment center shall be securely locked and accessible to authorized
1901 personnel within that facility only.
1902

1903 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1904 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097
 1905 (October 2003), effective January 1, 2004.
 1906

1907 §1725. Records and Reports of Drug Abuse Treatment Centers

- 1908 A. All persons licensed by the Department of Health ~~and Hospitals~~ to operate a drug abuse treatment
 1909 center and who possess a Drug Enforcement Administration (DEA) registration to purchase, possess,
 1910 and use CDS shall keep the following records:
- 1911 1. records of CDS received by approved persons, including date of receipt, name and address of
 1912 distributor, type and quantity of such drugs received, and the signature of the individual
 1913 receiving the CDS. A duplicate invoice or separate itemized list furnished by the distributor
 1914 will be sufficient to satisfy this record requirement, provided it includes all required
 1915 information and is maintained in a separate file. In addition, duplicate copies of federal order
 1916 forms for CDS listed in Schedule II must be retained; and
 - 1917 2. records of CDS administered or dispensed, including date of administration or dispensing,
 1918 name of patient, signature of person administering or dispensing, type and quantity of drug,
 1919 and such other information as may be required by state and federal laws and regulations.
- 1920 B. Records of perpetual inventories shall be kept at the permitted site as prescribed by law.
 1921

1922 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

1923 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097
 1924 (October 2003), effective January 1, 2004, ~~amended by Department of Health, Board of Pharmacy, LR.~~
 1925

1926 Chapter 25. Prescriptions, Drugs, and Devices

1927 Subchapter A. General Requirements

1928 §2501. Prescription Drugs and Devices

- 1931 A. Prescription Drugs or Devices. A prescription drug or device is a medication or mechanism that may
 1932 only be dispensed by a pharmacist on the order of a licensed practitioner and shall bear the "Rx Only"
 1933 notation or any other designation of similar import required by law on the label of a commercial
 1934 container.
 1935
- 1936 1. Dispensing. Prescription drugs or devices shall be dispensed only by a Louisiana-licensed
 1937 pharmacist.
 - 1938 2. Possession. Prescription drugs or devices shall be procured and possessed in the course of the
 1939 practice of pharmacy by a permitted pharmacy.
 - 1940 3. Storage. Prescription drugs or devices shall be stored in a permitted pharmacy under the
 1941 immediate control and responsibility of a pharmacist.
- 1942 B. Misbranded Drugs.
- 1943 1. Misbranded drugs are:
 - 1944 a. those drugs whose labeling is false or misleading in any particular manner; or
 - 1945 b. those drugs whose label does not bear the name and address of the manufacturer,
 1946 packer, or distributor, and does not have an accurate statement of the quantities of
 1947 the active ingredients; or
 - 1948 c. those drugs without an accurate monograph; or
 - 1949 d. those drugs meeting the qualifications for misbranded drugs as noted in the
 1950 Federal Food, Drug, and Cosmetic Act, or its successor.
 - 1951 2. It is unlawful to possess or dispense misbranded drugs.
- 1952 C. Adulterated Drugs.
- 1953 1. Adulterated drugs are contaminated medicinal substances having deleterious foreign or
 1954 injurious materials, which fail to meet safety, quality, and/or purity standards.
 - 1955 2. It is unlawful to possess or dispense adulterated drugs.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

1956
1957
1958
1959
1960
1961
1962
1963
1964
1965
1966
1967
1968
1969
1970
1971
1972
1973
1974
1975
1976
1977
1978
1979
1980
1981
1982
1983
1984
1985
1986
1987
1988
1989
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007

- D. Expired Drugs. Expired drugs shall not be dispensed and shall be removed from the pharmacy drug inventory.
- E. Recalled Drugs. Recalled drugs shall be removed from the pharmacy inventory immediately upon notice. Recalls are classified as:
 1. Class I – a situation in which there is a strong likelihood that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
 2. Class II – a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
 3. Class III – a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2503. Drug Returns

- A. Drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004.

§2505. Investigational Drugs

- A. All investigational drugs stored or dispensed by any pharmacy shall conform to appropriate and applicable federal and state laws and regulations pertaining to their use.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004.

§2507. Veterinary Prescription Drugs

- A. Veterinary prescription drugs are prescription medications for animal use prescribed by a licensed veterinarian pursuant to a valid veterinarian-client-patient relationship and dispensed by a licensed pharmacist to the veterinarian’s client, for a legitimate medical purpose, that are unsafe for unsupervised use as defined in 21 CFR §201.105, or its successor.
- B. Dispensing Requirements. Veterinary prescription drugs shall be exclusively dispensed by a duly licensed pharmacist upon the order of a licensed veterinarian, unless otherwise provided by law.
- C. Labeling Requirements. Veterinary prescription drugs shall be dispensed in an appropriate container, and in addition to the labeling requirements in Chapter 11 of ~~these regulations this Part~~, shall contain the following information:
 1. the commercial label inscription “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian”; and
 2. the client’s name and patient’s animal species.
- D. Prescription Form Requirements. Prescriptions issued by a licensed veterinarian shall conform to ~~§ Section 2511 of these regulations this Part~~.
- E. Storage. Veterinary prescription drugs shall be maintained in the prescription department of a pharmacy, and shall be kept separate and apart from drugs intended for human use.

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

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion. Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

2008 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
2009 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004,
2010 amended by Department of Health, Board of Pharmacy, LR.
2011

2012 **§2509. Prescription Devices**

- 2013 A. In the interest of public health, safety, and welfare, the board may, from time to time, restrict the sale
- 2014 of certain devices to be dispensed only by a licensed pharmacist after a legitimate medical need has
- 2015 been demonstrated. A legitimate medical need includes the prevention of the transmission of
- 2016 communicable diseases.
- 2017 B. Pharmacy Device. A pharmacy device is an instrument, apparatus, implement, machine, contrivance,
- 2018 implant, in vitro reagent, or other similar or related article, including any component or accessory,
- 2019 which is required under federal law to bear the label "Caution: Federal or State law requires dispensing
- 2020 by or on the order of a physician." and/or "Rx Only", or other designation of similar import.
- 2021 1. Hypodermic Apparatus. Hypodermic means any syringe, needle, instrument, device, or
- 2022 implement intended or capable of being adopted for the purpose of administering drugs by
- 2023 subcutaneous, intramuscular, or intravenous injection.
- 2024 a. Sale. Hypodermic syringes and/or needles shall be sold or distributed only by a
- 2025 licensed pharmacist, physician, dentist, veterinarian, podiatrist, embalmer, drug
- 2026 wholesaler, surgical supplier, or other legally authorized distributor.
- 2027 b. Storage. Hypodermic syringes and/or needles shall be stored in the prescription
- 2028 department or in another secure area.
- 2029

2030 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2031 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
2032 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004.
2033

2034
2035 **Subchapter B. Prescriptions and Chart Orders**

2036
2037 **§2511. Prescriptions and Chart Orders**

- 2038 A. Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in
- 2039 this Section:
- 2040 "**Chart Order**" is a lawful order entered on the electronic or paper chart or medical record of an
- 2041 inpatient or resident of an institutional facility by a practitioner or his licensed healthcare designee for
- 2042 a drug or device and shall be considered a prescription drug order provided it contains the following:
- 2043 (a) Full name of the patient.
- 2044 (b) Date of issuance.
- 2045 (c) Name, strength, and dosage form of the drug prescribed.
- 2046 (d) Directions for use.
- 2047 (e) Name of the prescribing practitioner.
- 2048 (f) The prescribing practitioner's written or electronic signature or the written or electronic signature
- 2049 of the practitioner's licensed healthcare designee, who shall be a licensed nurse, pharmacist, or
- 2050 physician practicing in a long-term care facility. The licensed healthcare designee shall be
- 2051 authorized to document a chart order in the patient's medical record on behalf of the prescribing
- 2052 practitioner pending the prescribing practitioner's signature, or to communicate a prescription to a
- 2053 pharmacy whether telephonically, by facsimile transmission, or electronically.

2054 *Electronic Prescription* – a prescription transmitted in electronic form.

2055 *Practice Affiliation* – a practice relationship, collaboration, or practice under the supervision of a

2056 physician licensed to practice medicine.

2057 *Prescription or Prescription Drug Order* – an order from a practitioner authorized by law to prescribe

2058 for a drug or device that is patient specific and is communicated by any means to a pharmacist in a

2059 permitted pharmacy, and is to be preserved on file as required by law or regulation.
2060

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 2061 B. Requirements. A prescription shall contain the following data elements:
- 2062 1. Prescriber's name, licensure designation, address, telephone number, and if for a controlled
- 2063 substance, the Drug Enforcement Administration (DEA) registration number;
- 2064 2. Patient's name, and if for a controlled substance, address;
- 2065 3. Date prescription issued by the prescriber;
- 2066 4. Name of drug or device, and if applicable, strength, and quantity to be dispensed;
- 2067 5. Directions for use;
- 2068 6. Signature of prescriber; and
- 2069 7. Refill instructions, if any. In the absence of refill instructions on the original prescription, the
- 2070 prescription shall not be refilled.
- 2071 C. Written Prescriptions. A written prescription shall conform to the following format:
- 2072 1. The prescription form shall be of a size not less than 4 inches by 5 inches, and shall bear a
- 2073 single printed signature line.
- 2074 2. The prescription form shall clearly indicate the authorized prescriber's name, licensure
- 2075 designation, address, telephone number, and, if for a controlled substance, the Drug
- 2076 Enforcement Administration (DEA) registration number. In the event that multiple
- 2077 practitioners are identified on the prescription form, the authorizing prescriber's specific
- 2078 identity shall be clear and unambiguous. This identification may be indicated by any means,
- 2079 including but not limited to, a marked check box next to, or circling, the authorizing
- 2080 prescriber's printed name.
- 2081 3. No prescription form shall contain more than four prescription drug orders. Each prescription
- 2082 drug order on the form shall provide the following:
- 2083 a. check box labeled "Dispense as Written", or "DAW", or both; and
- 2084 b. the number of refills, if any.
- 2085 4. The prescription shall be written with ink or indelible pencil, typewriter, or printed on a
- 2086 computer printer and shall be manually signed by the practitioner on the date issued and in the
- 2087 same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith).
- 2088 Examples of invalid signatures include rubber stamps, signatures of anyone other than the
- 2089 prescriber, and computer generated signatures.
- 2090 5. Facsimile Prescription
- 2091 a. The receiving facsimile machine of a prescription transmitted by facsimile shall be
- 2092 located within the pharmacy department.
- 2093 b. The prescription transmitted by facsimile shall be on a non-fading legible medium.
- 2094 c. All requirements applicable to written prescriptions in this Subsection shall apply
- 2095 to facsimile prescriptions, except Subparagraph C.7.c.
- 2096 d. The provisions of this Section notwithstanding, a prescription for a medication not
- 2097 listed as a controlled substance which is received in a pharmacy by facsimile and
- 2098 which bears an electronic signature of the prescriber shall be construed as a
- 2099 validly-formatted prescription; however, this temporary allowance shall expire at
- 2100 midnight on December 31, 2016.
- 2101 6. Forms used by pharmacists to record telephoned or transferred prescriptions are exempt from
- 2102 the format requirements listed above.
- 2103 D. Oral Prescriptions.
- 2104 1. Upon the receipt of an oral prescription from an authorized prescriber, the pharmacist or
- 2105 pharmacy intern or pharmacy technician shall reduce the order to a written form prior to
- 2106 dispensing the medication. As an alternative to recording such prescriptions on paper forms,
- 2107 a pharmacist may enter the prescription information directly into the pharmacy's dispensing
- 2108 information system. In the event a pharmacy intern or pharmacy technician transcribes such a
- 2109 prescription, the supervising pharmacist shall initial or countersign the prescription form prior
- 2110 to processing the prescription.
- 2111 E. Electronic Prescriptions.
- 2112 1. The prescription shall clearly indicate the authorized prescriber's name, licensure designation,
- 2113 address, telephone number, and if for a controlled substance, the DEA registration number.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 2114 F. Exclusion. The provisions of this Section shall not apply to medical chart orders written for patients in
2115 facilities licensed by the Department of Health or its successor.
2116

2117 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2118 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
2119 (October 1988), amended LR 29:2102 (October 2003), effective January 1, 2004, amended LR 41:98 (January
2120 2015), amended LR 41:2147 (October 2015), amended by the Department of Health, Board of Pharmacy, LR
2121 43:2162 (November 2017), amended by Department of Health, Board of Pharmacy, LR.
2122

2123 **§2513. Prescription Receipt and Verification of Prescription Drug Orders and Chart**
2124 **Orders**

- 2125 A. Receipt of a Prescription
2126 1. Written. A pharmacist may receive and dispense a prescription drug order or chart order that
2127 has been written and/or signed by the practitioner.
2128 2. Oral. A pharmacist may receive and dispense a prescription drug order or chart order that has
2129 been orally communicated by the practitioner when the prescription order has been reduced to
2130 hard copy.
2131 3. Electronic Transmission. A pharmacist may receive a prescription via electronic or other
2132 means, and then reduce to hard copy, if necessary.
2133 B. Verification. Verification of the accuracy and authenticity of any prescription drug order or chart order
2134 is the responsibility of the pharmacist.
2135

2136 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2137 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
2138 (October 1988), effective January 1, 1989, amended LR 29:2103 (October 2003), effective January 1, 2004,
2139 amended by Department of Health, Board of Pharmacy, LR.
2140

2141 **§2515. Prescriptions Based Upon Electronic Questionnaires**

- 2142 A. A prescription issued solely on the results of answers to an electronic questionnaire, in the absence of a
2143 documented patient evaluation including a physical examination, is issued outside the context of a
2144 valid physician-patient relationship, and is not a valid prescription.
2145 B. If a pharmacist has reasons to suspect that a prescription was authorized solely on the results of an
2146 electronic questionnaire and in the absence of a documented patient evaluation including a physical
2147 examination, the pharmacist shall ascertain if that practitioner's standard of practice allows that
2148 practitioner to authorize a prescription under such circumstances. Reasons to suspect that a
2149 prescription may have been authorized in the absence of a valid physician-patient relationship, or in
2150 violation of the practitioner's standard of practice, include:
2151 1. the number of prescriptions authorized on a daily basis by the practitioner;
2152 2. the manner in which the prescriptions are authorized by the practitioner or received by the
2153 pharmacy, i.e., electronically;
2154 3. the geographical distance between the practitioner and the patient(s);
2155 4. knowledge by the pharmacist that the prescription was issued solely as a result of answers to
2156 an electronic questionnaire; or
2157 5. knowledge by the pharmacist that the pharmacy he works for directly or indirectly participates
2158 in an internet site that markets prescription drugs to the public.
2159 C. A pharmacist who has reasons to suspect that a prescription may have been authorized in the absence
2160 of a valid physician-patient relationship, or otherwise in violation of the prescriber's standard of
2161 practice, shall not fill such prescription until he has obtained proof to a reasonable certainty of the
2162 validity of such prescription.
2163 D. A pharmacist who dispenses prescription drugs in violation of this Section is not acting in the best
2164 interest of the patient and is dispensing outside the course of the professional practice of pharmacy.
2165

2166 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

2167 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
 2168 (October 1988), effective January 1, 1989, amended LR 29:2103 (October 2003), effective January 1, 2004.
 2169

2170 **§2517. Prescription Dispensing**

- 2171 A. Prescription dispensing means the issuance, by a licensed pharmacist, of one or more doses of
 2172 medication in a suitable container, properly labeled for subsequent administration, and shall consist of
 2173 the following procedures or practices:
- 2174 1. receiving and interpretation of the prescription order;
 - 2175 2. assembling the drug products and an appropriate container;
 - 2176 3. preparing the prescription by compounding, mixing, counting, or pouring;
 - 2177 4. affixing the proper label to the final container;
 - 2178 5. patient counseling as required; and
 - 2179 6. transfer of possession.
- 2180 B. Equivalent Drug Product Interchange
- 2181 1. The pharmacist shall not select an equivalent drug product when the prescriber prohibits
 2182 interchange by any one of the following methods:
 - 2183 a. On a prescription generated in written form, the prescriber shall handwrite a mark
 2184 in a check box labeled "Dispense as Written", or the abbreviation "DAW", or
 2185 both, and shall manually signed the prescription form.
 - 2186 i. For prescriptions reimbursable by the state Medicaid program, the
 2187 prescriber shall handwrite the words "Brand Necessary" or "Brand
 2188 Medically Necessary" on the prescription form or on a sheet of paper
 2189 attached to the prescription form.
 - 2190 b. On a prescription generated in oral or verbal form, the prescriber (or the
 2191 prescriber's agent) shall indicate a specific brand name drug or product is ordered
 2192 by the practitioner, and the pharmacist shall note such information on the file copy
 2193 of the prescription.
 - 2194 c. On a prescription generated in electronic form, the prescriber shall indicate
 2195 "Dispense as Written", "DAW", or "Brand Medically Necessary."
 - 2196 2. Where the prescriber has indicated that an equivalent drug product interchange is prohibited,
 2197 then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as
 2198 to a patient's desire for an equivalent drug product interchange.
 - 2199 3. In the event the prescriber has not prohibited equivalent drug product interchange in the
 2200 manner described above, the pharmacist may select an equivalent drug product for dispensing,
 2201 provided the patient has been informed of, and has consented to, the proposed cost saving
 2202 interchange.
 - 2203 4. When the pharmacist selects a biological product rated as interchangeable for the product
 2204 ordered by the prescriber, the dispensing pharmacist (or his designee) shall communicate to
 2205 the prescriber – by any means, but no later than five business days following the dispensing
 2206 date – the specific product dispensed to the patient, including the name of the product and the
 2207 manufacturer. However, no such communication to the prescriber is required when:
 - 2208 a. The prescriber prohibited interchange in the manner described above;
 - 2209 b. There is no product rated as interchangeable or therapeutically equivalent; or
 - 2210 c. The product dispensed is a refill not changed from the product dispensed on the
 2211 prior filling of the prescription.
- 2212 C. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for
 2213 return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed
 2214 from the pharmacy premises where they were dispensed.
 2215

2216 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2217 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
 2218 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004,
 2219 amended by the Department of Health, Board of Pharmacy, LR 43:2162 (November 2017).
 2220

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

§2519. Prescription Refills; Medication Synchronization and Refill Consolidation

- 2221
2222
2223
2224
2225
2226
2227
2228
2229
2230
2231
2232
2233
2234
2235
2236
2237
2238
2239
2240
2241
2242
2243
2244
2245
- A. Refill Authorization. Prescription refills may be dispensed only with the prescriber's authorization, as indicated on the original prescription order. In the absence of the authorized practitioner's instructions on the original prescription, the prescription shall be considered non-refillable. When all refills authorized on the original prescription have been dispensed, then authorization from the prescribing practitioner shall be obtained prior to dispensing; when such authorization has been received, a new prescription shall be prepared and it shall be issued a different prescription number.
 - B. Controlled Dangerous Substances.
 - 1. The refilling of a prescription for a drug listed in Schedule II is prohibited.
 - 2. A prescription for a drug listed in Schedule III, IV, or V may be refilled up to five times, if so indicated at the time issued.
 - C. Medication Synchronization and Refill Consolidation. These terms refer to a service which a pharmacist may perform for his patient, at the request of the patient, wherein he may proactively adjust the medication dispensing quantity and/or the refill schedule of a prescription in order to manage the patient's medication therapy, with the goal of improved medication adherence by the patient.
 - 1. For the performance of this service, the pharmacist may adjust the dispensing quantity and/or the refill schedule originally ordered by the prescriber; however, the pharmacist shall not exceed the total quantity prescribed [dispensing quantity multiplied by the total number of fills authorized (original plus refills)], or what is otherwise allowed by law.
 - 2. With respect to prescriptions for controlled substances where refills have been authorized, pharmacists may utilize partial fills, as described in § Section 2747.C.5 of the board's rules this Part, but may not exceed the dispensing quantity noted on the original prescription.

2246 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2247 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
2248 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004,
2249 amended LR 33:1133 (June 2007), amended LR 42:1519 (September 2016), amended by the Department of Health,
2250 Board of Pharmacy, LR.

§2521. Emergency Refills

- 2251
2252
2253
2254
2255
2256
- A. Using sound professional judgment, a pharmacist may refill adequate medication for a seventy-two
{72} hour regimen when an emergency for medication has been adequately demonstrated and the
prescribing practitioner is not available.

2257 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2258 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
2259 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004,
2260 amended by the Department of Health, Board of Pharmacy, LR.

§2523. Transfer of Prescription Information

- 2261
2262
2263
2264
2265
2266
2267
2268
2269
2270
2271
- A. Prescription Transfer Requirements
 - 1. Prescriptions for Controlled Dangerous Substances
 - a. The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization, whether or not the pharmacy from which the prescription is transferred is open for business. Transfers are subject to the following requirements:

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

2272
2273
2274
2275
2276
2277
2278
2279
2280
2281
2282
2283
2284
2285
2286
2287
2288
2289
2290
2291
2292
2293
2294
2295
2296
2297
2298
2299
2300
2301
2302
2303
2304
2305
2306
2307
2308
2309
2310
2311
2312
2313
2314
2315
2316
2317
2318
2319
2320
2321
2322
2323
2324
2325

- i. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
 - (a) Invalidation of the prescription.
 - (b) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.
 - (c) Record the date of the transfer and the name of the pharmacist transferring the information.
 - b. The pharmacist receiving the transferred prescription information shall reduce to writing the following:
 - i. Indication of the transferred nature of the prescription.
 - ii. Provide all information required for a prescription for a controlled substance (full name and address of patient; drug name, strength, and dosage form; quantity prescribed and directions for use; and the name, address, and DEA registration number of the prescriber) and include:
 - (a) date of issuance of original prescription;
 - (b) original number of refills authorized on original prescription;
 - (c) date of original dispensing;
 - (d) number of valid refills remaining and date(s) and location(s) of previous refill(s);
 - (e) pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;
 - (f) name of pharmacist who transferred the prescription; and
 - (g) pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled.
 - iii. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.
 - c. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.
2. Prescriptions for Drugs Other Than Controlled Dangerous Substances
- a. The transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies, subject to the following requirements:
 - i. Prescriptions may be transferred up to the maximum number of refills permitted by the prescriber on the original prescription.
 - ii. The transferring pharmacist, intern or certified technician shall record the information itemized in Clause 1.a.i above, with the exception of DEA registration numbers.
 - iii. The receiving pharmacist, intern or certified technician shall record the information itemized in Subparagraph 1.b above, with the exception of DEA registration numbers.
 - b. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.
 - c. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.
- B. Pharmacies Using Common Electronic Files
- 1. Pharmacies using a common electronic file are not required to physically or electronically transfer prescriptions for information dispensing purposes between or among pharmacies participating in the same common prescription file; provided, however, any such common file must contain complete and adequate records of such prescriptions, and further, that a hard

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion. Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 2326 copy of each prescription transferred or accessed for purposes of refilling shall be generated
2327 and maintained at the pharmacy refilling the prescription or to which the prescription is
2328 transferred.
2329 2. This accommodation shall comply with all state and federal laws and regulations regarding
2330 controlled dangerous substance prescription transfers.
2331

2332 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2333 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
2334 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004,
2335 amended LR 33:1133 (June 2007), amended LR 36:756 (April 2010).
2336

2337 §2525. Prescription Expiration

- 2338 A. A prescription for a drug other than a controlled dangerous substance shall expire one year after the
2339 date written.
2340 B. A prescription for a controlled dangerous substance shall expire:
2341 1. 90 days after the date of issue if the drug is listed in Schedule II; or
2342 2. 6 months after the date of issue if the drug is listed in Schedule III, IV, or V.
2343 C. Expired prescriptions shall not be refillable or renewable.
2344

2345 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2346 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
2347 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004,
2348 amended by the Department of Health, Board of Pharmacy, LR 42:1090 (July 2016).
2349

2350 §2527. Prescription Labeling

- 2351 A. An appropriate label shall be affixed to a proper container, and shall bear the following minimum
2352 information:
2353 1. pharmacy's name, address, and telephone number;
2354 2. prescription number;
2355 3. authorized prescriber's name;
2356 4. patient's name;
2357 5. date dispensed;
2358 6. drug name and strength;
2359 7. directions for use, as indicated;
2360 8. pharmacist's name or initials; and
2361 9. cautionary auxiliary labels, if applicable.
2362

2363 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2364 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
2365 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.
2366

2367 §2529. Pharmacy Prepackaging

- 2368 A. *Prepackaging* is the preparation of medication in a unit-of-use container by a pharmacist in a
2369 pharmacy prior to the receipt of a prescription for ultimate prescription dispensing by a pharmacist in
2370 Louisiana.
2371 B. Labeling. The label on the prepackaged container shall contain the following minimum information:
2372 1. drug name;
2373 2. dosage form;
2374 3. strength;
2375 4. quantity;
2376 5. name of manufacturer and/or distributor;
2377 6. manufacturer's lot or batch number;
2378 7. date of preparation;

- 2379 8. pharmacist's initials; and
 2380 9. expiration date according to United States Pharmacopeia (USP) guidelines.
 2381

2382 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2383 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
 2384 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004.
 2385
 2386

2387 Subchapter C. Compounding of Drugs 2388

2389 §2531. Purpose and Scope

- 2390 A. Purpose. The rules of this Subchapter describe the requirements of minimum current good
 2391 compounding practices for the preparation of drug formulations by Louisiana-licensed pharmacists,
 2392 pharmacy interns, pharmacy technicians, and pharmacy technician candidates for dispensing and/or
 2393 administration to patients.
 2394 B. Scope. These requirements are intended to apply to all compounded preparations, sterile and non-
 2395 sterile, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or
 2396 practitioner's office.
 2397

2398 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2399 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
 2400 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004,
 2401 amended LR 41:97 (January 2015).
 2402

2403 §2533. Definitions

- 2404 A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this
 2405 Section:
 2406 *Biological Safety Cabinet* – a containment unit suitable for the preparation of low to moderate risk
 2407 agents where there is a need for protection of the product, personnel, and environment, according to
 2408 National Sanitation Foundation (NSF) Standard 49, or its successor.
 2409 *Class 100 Environment* – an atmospheric environment that contains fewer than 100 particles, of the
 2410 size 0.5 microns or less in diameter, per cubic foot of air, according to Federal Standard 209E, or its
 2411 successor.
 2412 *Component* – any ingredient used in the compounding of a drug product.
 2413 *Compounding* – the preparation, mixing, assembling, packaging, or labeling of a drug or device by a
 2414 pharmacist for his patient as the result of a practitioner's prescription drug order or initiative based on
 2415 the practitioner/patient/pharmacist relationship in the course of professional practice, or including the
 2416 preparation of drugs or devices in anticipation of prescription orders to be received by the
 2417 compounding pharmacist based on routine, regularly observed prescribing patterns. Compounding
 2418 does not include the compounding of drug products that are essentially copies of a commercially
 2419 available product.
 2420 *Cytotoxic* – any pharmaceutical that has the capability of killing living cells.
 2421 *Practitioner Administered Compounds* – products compounded by a licensed pharmacist upon the
 2422 medical order of a licensed prescriber for administration by a prescriber for diagnostic or therapeutic
 2423 purposes.
 2424 *Preparation* – a compounded drug dosage form or dietary supplement or a device to which a
 2425 compounder has introduced a drug. This term will be used to describe compounded formulations.
 2426 *Sterile Compounding* – compounding performed using established aseptic technique and utilizing a
 2427 laminar air flow hood or other device capable of providing a sterile compounding environment. Sterile
 2428 compounding shall be used when compounding parenteral medications or products, ophthalmic
 2429 preparations, or any other preparation requiring sterile techniques.
 2430 *Sterile Product* – any dosage form devoid of viable microorganisms including, but not limited to,
 2431 parenterals, injectables, and ophthalmics.

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
 Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

2432
2433
2434
2435
2436
2437

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR 41:97 (January 2015).

2438 **§2535. General Standards**

- 2439 A. Compounding Practices. Compounded medications may be prepared using prescription medications,
2440 over-the-counter medications, chemicals, compounds, or other components.
- 2441 1. A pharmacy shall have written procedures as necessary for the compounding of drug
2442 preparations to assure that the finished preparations have the identity, strength, quality, and
2443 purity they are represented to possess.
 - 2444 2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices,
2445 and equipment, as well as the Federal Food, Drug and Cosmetic Act of 1938 as subsequently
2446 amended, most recently in November 2013 (FDCA), the 2016 edition of Title 21 of the *Code*
2447 *of Federal Regulations (CFR)*, and all relevant chapters of the 2014 edition of the United
2448 States Pharmacopeia-National Formulary (USP 37 – NF 32).
 - 2449 a. The compounding of sterile preparations pursuant to the receipt of a patient-
2450 specific prescription shall comply with the provisions of Section 503-A of the
2451 FDCA and USP Chapter 797.
 - 2452 b. The compounding of non-sterile preparations pursuant to the receipt of a patient-
2453 specific prescription shall comply with the provisions of Section 503-A of the
2454 FDCA and USP Chapter 795.
 - 2455 c. The compounding of preparations for veterinary use shall comply with the
2456 provisions of Section 530 of Title 21 of the CFR.
 - 2457 d. The compounding of positron emission tomography (PET) drugs shall comply
2458 with the provisions of Section 212 of Title 21 of the CFR.
 - 2459 3. Products or duplicates of products removed from the market for the purposes of safety shall
2460 not be used to compound prescriptions for human use.
- 2461 B. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the
2462 compounding of sterile preparations shall notify the board and shall receive approval from the board
2463 prior to beginning that practice.
- 2464 C. Training and Education. All individuals compounding sterile preparations shall:
- 2465 1. Obtain practical and/or academic training in the compounding and dispensing of sterile
2466 preparations;
 - 2467 2. Complete a minimum of one hour of Accreditation Council for Pharmacy Education (ACPE)
2468 accredited or board-approved continuing education, on an annual basis, related to sterile drug
2469 preparation, dispensing, and utilization;
 - 2470 3. Use proper aseptic technique in compounding of all sterile preparations, as defined by the
2471 pharmacy practice site's policy and procedure manual;
 - 2472 4. Qualify through an appropriate combination of specific training and experience to operate or
2473 manipulate any item of equipment, apparatus, or device to which such persons will be
2474 assigned to use to make and dispense sterile preparations; and
 - 2475 5. Maintain in the pharmacy practice site a written record of initial and subsequent training and
2476 competency evaluations. The record shall contain the following minimum information:
 - 2477 a. Name of the individual receiving the training/evaluation;
 - 2478 b. Date of the training/evaluation;
 - 2479 c. General description of the topics covered;
 - 2480 d. Signature of the individual receiving the training/evaluation; and
 - 2481 e. Name and signature of the individual providing the training/evaluation.
- 2482 D. Anticipated Use Preparations. The pharmacist shall label any excess compounded preparation so as to
2483 reference it to the formula used and the assigned lot number and estimated beyond use date based on
2484 the pharmacist's professional judgment and/or other appropriate testing or published data.
- 2485 E. Veterinarian Administered Compounds, also referred to as Pharmacy-Generated Drugs

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

- 2486
2487
2488
2489
2490
2491
2492
2493
2494
2495
2496
2497
2498
2499
2500
2501
2502
2503
2504
2505
2506
2507
2508
2509
2510
2511
2512
2513
2514
2515
2516
2517
2518
2519
2520
2521
2522
2523
2524
2525
2526
2527
2528
2529
2530
2531
2532
2533
1. Upon receipt of a valid non-patient-specific medical order from a licensed veterinarian, the pharmacy may compound a preparation intended for administration to an animal patient by the veterinarian.
 2. These preparations may not be distributed to any third party by the pharmacy, nor may these preparations be further re-sold or distributed by the veterinarian ordering the preparation from the pharmacy.
 3. This authorization is primarily intended to facilitate the preparation of medication needed for emergency use in a veterinary office practice. Given the limited application of this authorization, which allows these products to be prepared using less rigorous standards applicable to compounding as opposed to the more rigorous standards applicable to manufacturing processes, the compounding pharmacy preparing these products shall be limited in the amount of such products they can prepare.
 - a. No Louisiana-licensed pharmacy may distribute any amount of practitioner administered compounds in excess of five percent of the total amount of drug products dispensed and/or distributed from their pharmacy.
 - b. The five percent limitation shall be calculated on a monthly basis and shall reference the number of dosage units.
 - c. For those Louisiana-licensed pharmacies located outside Louisiana, the total amount distributed and/or dispensed shall reference the pharmacy's total business within the state of Louisiana.
 4. The provisions of this Paragraph E notwithstanding, pharmacists intending to engage in the compounding of veterinary preparations pursuant to non-patient-specific medical orders from veterinarians should be aware that federal law or rule may not permit such activity by a licensed pharmacy, and further, such pharmacists should be aware that the board's rules cannot legitimize an activity that is not permitted under federal law or rule, and further, such pharmacists should be aware that while this activity is permitted by the board, pharmacists engaging in this activity remain subject to the full force and effect of federal law enforcement
- F. Compounding Commercial Products not Available. A pharmacy may prepare a copy of a commercial product when that product is not available as evidenced by either of the following:
1. Products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health-System Pharmacists (ASHP).
 2. Products temporarily unavailable from manufacturers, as documented by invoice or other communication from the distributor or manufacturer.
- G. Labeling of Compounded Preparations.
1. For patient-specific compounded preparations, the labeling requirements of R.S. 37:1225, or its successor, as well as §2527 of this Chapter, or its successor shall apply.
 2. For veterinarian administered compounds, the label shall contain, at a minimum, the following data elements:
 - a. Pharmacy's name, address, and telephone number;
 - b. Veterinarian's name;
 - c. Name of preparation;
 - d. Strength and concentration;
 - e. Lot number;
 - f. Beyond use date;
 - g. Special storage requirements, if applicable;
 - h. Identification number assigned by the pharmacy; and
 - i. Name or initials of pharmacist responsible for final check of the preparation.

2534 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2535 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
2536 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October
2537 2003), effective January 1, 2004, amended LR 41:97 (January 2015), amended LR 42:891 (June 2016).
2538
2539

CODING: Underscored text is proposed for addition, and stricken text is proposed for deletion.
Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

2540 **§2537. Requirements for Compounding Sterile Products**

2541 Repealed.

2542

2543 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2544 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708

2545 (October 1988), effective January 1, 1989, amended LR 29:2106 (October 2003), effective January 1, 2004, repealed

2546 LR 41:98 (January 2015).

2547

2548

2549 **Subchapter D. Prescription Drugs**

2550

2551 **§2541. Standing Orders for Distribution of Naloxone and Other Opioid Antagonists**

2552 A. Given the current public health emergency relative to the misuse and abuse of opioid derivatives,

2553 public health officials have strongly recommended the widespread availability of naloxone and other

2554 opioid antagonists to addicts and their caregivers as well as first responders in the community.

2555 B. For as long as naloxone and other opioid antagonists remain classified as prescription drugs by the

2556 federal Food and Drug Administration, pharmacists must secure a prescription or order from a

2557 prescriber with the legal authority to prescribe the drug product in order to dispense or distribute the

2558 drug product.

2559 C. The Louisiana Legislature has adopted a number of laws designed to facilitate the distribution and

2560 dispensing of naloxone and other opioid antagonists beyond the person who would need the

2561 medication on an emergent basis to manage an opioid-related drug overdose, more specifically to first

2562 responders as well as caregivers and family and friends of potential patients.

2563 1. Act 253 of the 2014 Legislature authorized prescribers to issue prescriptions for naloxone and

2564 other opioid antagonists to first responders, and further, authorized pharmacists to recognize such

2565 prescriptions as legitimate orders for the dispensing and distribution of naloxone and other opioid

2566 antagonist drug products, and further, authorized first responders to have and hold those drug

2567 products ready for administration in emergent conditions to manage opioid-related drug

2568 overdoses.

2569 2. Act 192 of the 2015 Legislature authorized medical practitioners to prescribe naloxone or another

2570 opioid antagonist without having previously examined the individual to whom the medication

2571 would be administered, but only under certain conditions specified in the legislation, including the

2572 requirement for the prescriber to provide the recipient of the drug with all training and education

2573 required for the safe and proper administration of the drug product.

2574 3. Act 370 of the 2016 Legislature authorized medical practitioners to issue nonpatient-specific

2575 standing orders to pharmacists authorizing the distribution of naloxone and other opioid

2576 antagonists to anyone who might be in a position to assist a patient in the emergent management

2577 of an opioid-related drug overdose, but only in compliance with these rules.

2578 a. A nonpatient-specific standing order for the facilitated distribution of naloxone or other

2579 opioid antagonist issued by a medical practitioner licensed by the State of Louisiana shall

2580 expire one year after the date of issuance.

2581 b. A Louisiana-licensed pharmacist may distribute naloxone or other opioid antagonist

2582 according to the terms of the nonpatient-specific standing order issued by a Louisiana-

2583 licensed medical practitioner until the expiration date of the standing order. No pharmacist

2584 shall distribute naloxone or other opioid antagonist pursuant to a standing order more than one

2585 year after the date of issuance of the standing order.

2586 c. Before releasing the naloxone or other opioid antagonist drug product to the recipient, the

2587 pharmacist shall verify the recipient's knowledge and understanding of the proper use of the

2588 drug product, including, at a minimum:

2589 i. Techniques on how to recognize signs of an opioid-related drug overdose;

2590 ii. Standards and procedures for the storage and administration of the drug product; and

2591 iii. Emergency follow-up procedure including the requirement to summon emergency

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

Coding highlighted in yellow proposed by LTC Stakeholders; coding highlighted in blue proposed by staff.

2592 services either immediately before or immediately after administering the drug product to
2593 the individual experiencing the overdose.
2594 d. To comply with the recordkeeping requirements found elsewhere in the Board's rules, the
2595 pharmacist shall attach a copy of the standing order to the invoice or other record of sale or
2596 distribution, and further, shall store these transaction documents with the other distribution
2597 records in the pharmacy.
2598

2599 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

2600 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:958 (May 2017)

2601
2602

2603 **Chapter 27. Controlled Dangerous Substances**

2604

2605 LTC has posed a question about Section 2745.F.1.b.ii, relative to the allowance of facsimile forms for Schedule II
2606 prescriptions in long term care facilities [LTCF]. Specifically, does LTCF include assisted living facilities [ALF]?

2607

2608 LTCF is defined in the Practice Act: "*Long term care facility*" means a nursing home, retirement care, mental care,
2609 or other facility or institution that provides extended health care to a residential patient, including but not limited to
2610 health care facilities licensed by the Department of Health. [La. R.S. 37:1164(25)]

2611

2612 Staff suggests the definition is not so strictly written that ALF could not be construed as included in that definition,
2613 and further, that it would be appropriate to interpret that definition so as to include ALF.