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Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

Subchapter B. Pharmacy Records

§1119. ~~Availability and Inspection Definitions~~

- ~~A. Pharmacy records shall be available and readily retrievable upon request for board inspection and review.~~
~~B. All records required by the laws and regulations of the board shall be provided to the board, or its agents, within seventy two (72) hours of request, unless a shorter period is required, as determined by the board or its agent.~~
- A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:
- “Department” means the Louisiana Department of Health and Hospitals or its successor.
“Password” means a private identification that is created by a user to obtain access to an electronic pharmacy information system.
“Personal identifier” means a unique user name or number for identifying and tracking a specific user’s access to a pharmacy information system such as social security number, user identification number, or employee number.
“Positive identification” means a method of identifying an individual who prescribes, administers, or dispenses a prescription drug.
1. A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:
 - a. A manual signature on a hard copy record;
 - b. A magnetic card reader;
 - c. A bar code reader;
 - d. A thumbprint reader or other biometric method;
 - e. A proximity badge reader;
 - f. A register in which each individual pharmacist dispensing a prescription shall sign a log each day, attesting to the fact that the information entered into the electronic record keeping system has been reviewed that day, and is correct as stated.
 - g. A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the prescription drug. The printout must be maintained for two years and made available on request to an agent of the board.
 2. A method relying on a magnetic card reader, a bar code reader, or a proximity badge reader must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

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

§1121. ~~General Record Keeping Requirements~~

- A. ~~Requirements. A pharmacy shall maintain complete, accurate, and readily retrievable prescription drug records. All prescription drug records shall be available for board review upon request.~~
1. All records relating to the practice of pharmacy shall be uniformly maintained for a period of two years, be readily available, and promptly produced upon request for inspection by an agent of the board during regular business hours.

- 54 2. All records required by the laws and regulations of the board shall be provided to the board, or its
 55 agents, within seventy-two (72) hours of request, unless a shorter period is required, as
 56 determined by the board or its agent.
 57 3. The failure to produce any pharmacy records requested by the board or its agent within seventy-
 58 two (72) hours of such request shall substantiate a violation of R.S. 37:1241(A)(22).
 59 B. Accountability. The holder of the pharmacy permit and the pharmacist-in-charge shall account for all
 60 prescription drug transactions, consisting of:
 61 1. Acquisition records – invoice receipts of drugs acquired;
 62 2. Disposition records – ~~prescription orders dispensed or drugs sold,~~ drugs dispensed pursuant to
 63 prescription orders, administered pursuant to medical orders, or distributed pursuant to purchase
 64 orders, and
 65 3. Inventory records – drugs in current possession.
 66 C. Retention. Except as provided in Section 1123, all records required in by this Chapter and by Louisiana
 67 law shall be retained for a minimum of two years from the most recent transaction. The failure to retain
 68 such records for at least two years shall substantiate a violation of R.S. 37:1229.
 69

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

71 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312
 72 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR
 73

74 §1123. Records

- 75 ~~A. Acquisition Records. Prescription drug acquisition records shall be required, and shall consist of~~
 76 ~~documented invoices from manufacturers, wholesalers, distributors, brokers, or other sources of supply.~~
 77 ~~B. Inventory Records. Accurate and readily retrievable records regarding prescription drug acquisition~~
 78 ~~invoices, distribution, and inventories shall be maintained and available for accountability and retained at~~
 79 ~~the pharmacy premises. Inventories of controlled dangerous substances shall be required, where~~
 80 ~~applicable, and maintained at the pharmacy.~~
 81 ~~C. Prescription Records.~~
 82 1. ~~Dispensing Prescription Files. Dispensed prescription orders shall be required and maintained for~~
 83 ~~a minimum of two years from the last transaction/fill date by the pharmacy, constituting proof of~~
 84 ~~dispensing by adequate prescription files properly documented with the proper medical~~
 85 ~~practitioner's authority and the following information:~~
 86 1. ~~patient's name, address, and telephone number;~~
 87 2. ~~prescriber's name, address, telephone number, and if applicable, the Drug~~
 88 ~~Enforcement Administration (DEA) registration number and signature;~~
 89 3. ~~drug name, dosage form, strength, and quantity prescribed, as well as quantity~~
 90 ~~dispensed when in variance with the original order;~~
 91 4. ~~number of prescription refills authorized by the prescriber;~~
 92 5. ~~prescription number;~~
 93 6. ~~original dispensing date; and~~
 94 7. ~~pharmacist's name or initials.~~
 95 2. ~~Prescription Refill Records. The following information shall be readily retrievable from the~~
 96 ~~electronic record keeping system:~~
 97 1. ~~date of refill;~~
 98 2. ~~quantity dispensed when in variance with original order; and~~
 99 3. ~~pharmacist's name, initials, or identification code.~~
 100 ~~D. Electronic Record Keeping System. An electronic record keeping system shall be utilized in a pharmacy~~
 101 ~~and shall be a complete, accurate, readily retrievable prescription record keeping and storage system. An~~
 102 ~~electronic record keeping system shall meet the following requirements:~~
 103 1. ~~Retrieval. The system shall provide on line retrieval via screen or hard copy printout of original~~
 104 ~~prescription order information for those prescription orders that are currently authorized for~~
 105 ~~refilling.~~
 106 2. ~~Summary. The system shall be capable of producing a daily hard copy summary of controlled~~
 107 ~~dangerous substance transactions.~~
 108 3. ~~Refills. The system shall be capable of recording and providing the dates of prescription refills~~
 109 ~~and the identity of the pharmacist refilling those prescriptions.~~

- 110 4. ~~Patient Profile. The system shall be capable of producing a patient profile that shall contain the~~
 111 ~~following minimum information: patient's name and address/location, name of drug, dosage~~
 112 ~~form, strength, route and frequency of administration, and pharmacist's identification.~~
 113 5. ~~Original Prescription Records. The prescription hard copy shall represent the original written~~
 114 ~~order or original oral prescription reduced to written form manually or electronically produced by~~
 115 ~~the pharmacist, and shall meet the record keeping requirements of this chapter.~~
 116 6. ~~Maintenance. The original written prescription, or the written form of an oral prescription, shall~~
 117 ~~be retained on file, in numerical order, for a minimum of two years from the date of dispensing or~~
 118 ~~the date of the last refill dispensed.~~
 119 7. ~~Prescription Refill Information. Records of refills shall be entered into the electronic record~~
 120 ~~keeping system.~~
 121 8. ~~Record. A report of all original or refilled prescriptions dispensed shall be maintained, and shall~~
 122 ~~include the following:~~
 123 ~~1. prescription number;~~
 124 ~~2. date of initial dispensing of the original prescription and the date(s) of refilling;~~
 125 ~~3. total number of prescription refills dispensed to date or retrievable refill history on a~~
 126 ~~visual mode of display as an alternative to appearing on the hard copy printout;~~
 127 ~~4. patient's name;~~
 128 ~~5. patient's address, if required;~~
 129 ~~6. the authorized prescriber's name;~~
 130 ~~7. authorized prescriber's address, if required;~~
 131 ~~8. the name, strength, dosage form, and quantity of the drug dispensed; and~~
 132 ~~9. the last name and initial of the dispensing pharmacist.~~
 133 9. ~~Backup Support System. The electronic record keeping system shall be capable of being~~
 134 ~~reconstructed in the event of an electronic or computer malfunction or unforeseen accident~~
 135 ~~resulting in the destruction of the system or the information contained therein. To prevent the~~
 136 ~~accidental loss of electronic records, an adequate backup system shall be maintained. Backup~~
 137 ~~support systems shall be updated at least once daily.~~
- 138 E. ~~Digital Imaging of Prescriptions~~
 139 1. ~~In lieu of filing the actual original hard copy prescription, a pharmacy may use an electronic~~
 140 ~~imaging recordkeeping system, if:~~
 141 ~~1. the system is capable of capturing, storing, and reproducing the exact image of a~~
 142 ~~prescription, including the reverse side of the prescription~~
 143 ~~2. any notes of clarification of and alterations to a prescription shall identify the author~~
 144 ~~and shall be directly associated with the electronic image of the prescription;~~
 145 ~~3. the prescription image and any associated notes of clarification to or alterations to a~~
 146 ~~prescription are retained for a period not less than two years from the date the~~
 147 ~~prescription is last dispensed;~~
 148 ~~4. policies and procedures for the use of an electronic imaging recordkeeping system are~~
 149 ~~developed, implemented, reviewed, and available for board inspection; and~~
 150 ~~5. the prescription is not for a Schedule II controlled dangerous substance.~~
 151 2. ~~In this capacity the pharmacy may retain the hard copy prescriptions in order of date scanned in~~
 152 ~~lieu of numerical order.~~
- 153
 154 A. There shall be positive identification of the pharmacist or pharmacists, intern, technician, or technician
 155 candidate responsible for performing all activities related to the practice of pharmacy including, but not
 156 limited to:
 157 1. Prescription information entered into the pharmacy information system;
 158 2. Prospective drug utilization review;
 159 3. Prescription dispensing;
 160 4. Administration of immunizations.
- 161 B. A pharmacy may use one of the following types of pharmacy information systems:
 162 1. A system that utilizes the original hard copy prescription to document the initial dispensing of a
 163 prescription, but utilizes a computerized system to dispense refills that does not document the
 164 positive identification of the pharmacist responsible for the practice of pharmacy. In order to

- 165 document positive identification, this system shall require the manual signature or initials of a
 166 pharmacist on a hard copy record as specified in Paragraph E of this Section.
 167 2. An electronic recordkeeping system that complies with the provisions of 21 CFR 1311 and
 168 documents the positive identification of the pharmacist responsible for the practice of pharmacy.
 169 Such systems shall provide for routine backups at least once per day.
 170 C. All pharmacy information systems shall be capable of providing immediate retrieval (via display and hard
 171 copy printout or other mutually agreeable transfer media) of patient profile information for all
 172 prescriptions dispensed within the previous two years. This information shall include the following
 173 minimum data:
 174 1. The original prescription number;
 175 2. Date of issuance of the original prescription order by the prescriber;
 176 3. Date of dispensing by the pharmacist;
 177 4. Full name and address of the patient;
 178 5. Full name and address of the prescriber;
 179 6. Directions for use;
 180 7. The name, strength, dosage form, and quantity of the drug prescribed;
 181 8. The quantity dispensed if different from the quantity prescribed;
 182 9. The pharmacist responsible for prescription information entered into the computer system, the
 183 pharmacist responsible for prospective drug utilization review as defined in §515 of these rules,
 184 and the pharmacist responsible for dispensing;
 185 10. The total number of refills authorized by the prescriber; and
 186 11. The refill history of the prescription as defined in Paragraph D of this Section.
 187 D. The refill history of the prescription record maintained in the pharmacy information system shall include,
 188 but is not limited to:
 189 1. The prescription number;
 190 2. The name and strength of the drug dispensed;
 191 3. The date of the refill or partial fill;
 192 4. The quantity dispensed;
 193 5. The pharmacist responsible for prospective drug utilization review as defined in §515 of these
 194 rules, and the pharmacist responsible for dispensing each refill;
 195 6. The total number of refills or partial fills dispensed to date for that prescription order
 196 E. The hard copy documentation required pursuant to Paragraph (B)(1) of this Section shall be provided by
 197 each individual pharmacist who makes use of such system by signing a statement attesting to the fact that
 198 the prescription information entered into the computer is correct as displayed.
 199 F. Backup Support System
 200 1. The pharmacy information system shall be capable of being reconstructed in the event of an
 201 electronic or computer malfunction or unforeseen accident resulting in the destruction of the
 202 system or the information contained therein. To prevent the accidental loss of electronic records,
 203 an adequate backup system shall be maintained. Backup support systems shall be updated at least
 204 once daily.
 205 2. In the event the pharmacy information system experiences down time, a record of all refills
 206 dispensed during such time shall be recorded and then entered into the pharmacy information
 207 system as soon as it is available for use. During the time the pharmacy information system is not
 208 available, prescriptions may only be refilled if, in the professional judgment of the pharmacist,
 209 the number of refills authorized by the prescriber has not been exceeded.
 210 G. A pharmacy purging a pharmacy information system of prescription records shall develop a method of
 211 recordkeeping capable of providing retrieval (via display, hard copy printout, or other mutually agreeable
 212 transfer media) of prescription order information for all prescriptions filled or refilled within the previous
 213 two years. This information shall include, at a minimum, the following data:
 214 1. Pharmacy name and address;
 215 2. Original prescription number;
 216 3. Date of issuance of the original prescription order by the prescriber;
 217 4. Date of original dispensing by the pharmacist;
 218 5. Full name and address of the patient;
 219 6. Full name and address of the prescriber;
 220 7. Directions for use;

- 221 8. Name, strength, dosage form, and quantity of the drug prescribed;
222 9. Quantity dispensed if different from the quantity prescribed;
223 10. Total number of refills authorized by the prescriber;
224 11. Total number of refills dispensed to date for that prescription order;
225 12. Date of each refill;
226 13. Name or initials of each individual dispensing pharmacist.
- 227 H. A log shall be maintained of all changes made to a prescription record after the prescription has been
228 dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being
229 altered in any way. At a minimum, the log shall contain the following information:
- 230 1. Date and time of change;
231 2. Change(s) made;
232 3. Pharmacist making the change.
- 233 I. Prescriptions entered into a pharmacy information system but not dispensed shall meet all of the following
234 requirements:
- 235 1. The complete prescription information shall be entered in the computer system;
236 2. The information shall appear in the patient's profile; and
237 3. There is positive identification, in the pharmacy information system or on the hard copy
238 prescription, of the pharmacist who is responsible for entering the prescription information into
239 the system.
- 240 J. With respect to oral prescriptions received in the pharmacy and then transcribed to written form in the
241 pharmacy, or written prescriptions received by facsimile in the pharmacy, or written prescriptions
242 presented to the pharmacy, a pharmacy may use an electronic imaging system to preserve such
243 prescriptions, but only if:
- 244 1. The system is capable of capturing, storing, and reproducing the exact image of a prescription,
245 including the reverse side of the prescription form;
246 2. Any notes of clarification of and alterations to a prescription shall identify the author and shall be
247 directly associated with the electronic image of the prescription form;
248 3. The image of the prescription form and any associated notes of clarification to or alterations to a
249 prescription are retained for a period of not less than two years from the date the prescription is
250 last dispensed;
251 4. Policies and procedures for the use of an electronic imaging system are developed, implemented,
252 reviewed, and available for board inspection; and
253 5. The prescription is not for a controlled dangerous substance listed in Schedule II
- 254 K. Filing and Retention of Prescription Forms
- 255 1. Written prescription forms (including transcriptions of verbal prescriptions received in the
256 pharmacy, prescriptions received by facsimile in the pharmacy, as well as written prescription
257 forms presented to the pharmacy) shall be assembled and stored in prescription number sequence.
258 Prescriptions for controlled dangerous substances listed in Schedule II shall be filed separately
259 from all other prescriptions. Where multiple medications are ordered on a single prescription
260 form and includes one or more controlled dangerous substances listed in Schedule II, then such
261 forms shall be filed with other Schedule II prescriptions. These original hard copy prescription
262 forms shall be retained in the prescription department for a minimum of two years following the
263 most recent transaction.
- 264 2. For those pharmacies utilizing an electronic imaging system as described in Paragraph J of this
265 Section, written prescription forms may be assembled and stored in prescription number
266 sequence, or in the alternative, a date scanned sequence. Further, these original hard copy
267 prescriptions shall be retained in the prescription department for a minimum of one year
268 following the most recent transaction.
- 269 3. Prescription forms received as an electronic image or electronic facsimile directly within the
270 pharmacy information system shall be retained within the information system for a minimum of
271 two years following the most recent transaction. Further, the pharmacy may produce a hard copy
272 of the prescription form but shall not be required to do so merely for recordkeeping purposes.
- 273 4. Electronic prescriptions – those generated electronically by the prescriber, transmitted
274 electronically to the pharmacy, and then received electronically directly into the pharmacy
275 information system – shall be retained within the information system for a minimum of two years

276 following the most recent transaction. The pharmacy may produce a hard copy of the
 277 prescription, but shall not be required to do so merely for recordkeeping purposes.

278 L. Patient Profiles

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

281 1. The dispensing pharmacist shall be responsible for ensuring that a reasonable effort has been
 282 made to obtain, document, and maintain at least the following records:

283 a. The patient's data record, which should consist of, but is not limited to, the following
 284 information:

285 i. Full name of the patient for whom the drug is intended;

286 ii. Residential address and telephone number of the patient;

287 iii. Patient's date of birth;

288 iv. Patient's gender;

289 v. A list of current patient specific data consisting of at least the following:

290 (aa) Known drug related allergies,

291 (bb) Previous drug reactions,

292 (cc) History of or active chronic conditions or disease states,

293 (dd) Other drugs and nutritional supplements, including nonprescription
 294 drugs used on a routine basis, or devices.

295 vi. The pharmacist's comments relevant to the individual patient's drug
 296 therapy, including any other necessary information unique to the specific
 297 patient or drug.

298 b. The patient's drug therapy record, which shall contain at least the following information
 299 for all the prescriptions that were filled at the pharmacy:

300 i. Name and strength of the drug or device;

301 ii. Prescription number;

302 iii. Quantity dispensed;

303 iv. Date dispensed;

304 v. Name of the prescriber;

305 vi. Directions for use.

306 2. Any information that is given to the pharmacist by the patient or caregiver to complete the patient
 307 data record shall be presumed to be accurate, unless there is reasonable cause to believe the
 308 information is inaccurate.

309 M. Exceptions

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

311 1. Pharmacies permitted as hospital pharmacies by the board shall comply with the provisions of
 312 Chapter 15 of these rules.

313 2. Other pharmacies providing medications and services to patients within facilities other than
 314 hospitals licensed by the department shall comply with the provisions of Section 1123.1 of these
 315 rules for those activities.

316
 317 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

318 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312
 319 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR 36:755 (April 2010),
 320 amended LR

321
 322 **§1123.1 Records of Pharmacy Services for Patients in Licensed Healthcare Facilities Other**
 323 **than Hospitals**

324 A. Definitions

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

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

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

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

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

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

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

- 348 1. adequate audit controls are in place to detect and deter drug diversion;
- 349 2. adequate access controls are in place to assure the identity of the user and to assign
 350 accountability of the user for any drug transaction;
- 351 3. adequate safeguards are in place to prevent and detect the unauthorized use of an
 352 individual’s password and personal identifier;
- 353 4. an ongoing quality assurance program is in place to ensure that (a) through (c) of this
 354 term are being fulfilled and reviewed; and
- 355 5. appropriate policies and procedures are in place to address items (a) through (d) of this
 356 term.

357 All of the above notwithstanding, however, positive identification as defined in Section 1119 of these
 358 rules shall always be used to document the:

- 359 a. Dispensing, compounding, or prepackaging of a drug;
- 360 b. Removal and possession of a controlled substance to administer to a patient; and
- 361 c. Waste of a controlled substance.

362 **B. Drug Distribution and Control**

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

- 365 1. Procedure Manual. The pharmacist-in-charge shall maintain defined procedures for the safe and
 366 efficient distribution of medications and pharmacy care. A current copy of the manual shall be
 367 available for board inspection upon request.
- 368 2. Inventories. The pharmacist-in-charge shall be responsible for the performance of an annual
 369 inventory of all controlled dangerous substances within his span of control, in compliance with
 370 the provisions of Section 2733 of these rules.
- 371 3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:
 372 a. A record of all drugs procured, the quantity received, and the name, address and
 373 wholesale distributor license number of the person from whom the drugs were procured.
 374 b. All drug orders and records relating to the practice of pharmacy.
 375 i. Records of drugs dispensed shall include, but are not limited to:
 376 (aa) The name, strength, and quantity of drugs dispensed;
 377 (bb) The date of dispensing;
 378 (cc) The name of the inpatient to whom, or for whose use, the drug was
 379 dispensed; and
 380 (dd) Positive identification of all pharmacists involved in the dispensing.
 381 ii. All other records relating to the practice of pharmacy other than dispensing
 382 shall include, but are not limited to:
 383 (aa) The name of the inpatient to whom, or for whose benefit, the activity
 384 was performed;
 385 (bb) The nature of the pharmacy practice activity performed;
 386 (cc) The results of the activity, if applicable; and

- 387 (dd) Positive identification of all pharmacists involved in the activity;
 388 identifying the function performed by each pharmacist.
 389 iii. Records of drugs dispensed to patients for use outside the facility shall be
 390 maintained in compliance with Section 1123 of these rules.
 391 c. A record of all drugs compounded or prepackaged for use only within that facility,
 392 which shall include at least the following:
 393 i. Name of drug, strength, quantity, and dosage form;
 394 ii. Manufacturer's or distributor's control number (except for patient-specific
 395 sterile compounded preparations);
 396 iii. Manufacturer's or distributor's name, if a generic drug is used;
 397 iv. Pharmacy control number;
 398 v. Manufacturer's or distributor's expiration date (except for patient-specific
 399 sterile compounded preparations);
 400 vi. Pharmacy's expiration date or beyond-use date;
 401 vii. Positive identification of the licensed person responsible for the
 402 compounding or prepackaging of the drug.
 403 d. A record of the distribution of drugs to patient care areas and other areas of the facility
 404 held for administration, which shall include at least the following:
 405 i. The name, strength, dosage form, and amount of the drug distributed;
 406 ii. The area receiving the drug;
 407 iii. The date distributed;
 408 iv. Positive identification of the individual receiving the drug if it is a
 409 controlled dangerous substance;
 410 v. The area of the facility receiving the controlled dangerous substance shall
 411 make a record of all such drugs administered to patients. Such records
 412 shall include at least the following:
 413 (aa) Name of the patient;
 414 (bb) Name, dosage form, and strength when applicable of the drug;
 415 (cc) Date and time the drug was administered;
 416 (dd) Quantity administered;
 417 (ee) Positive identification of the personnel administering the drug.
 418 e. A log that shall be maintained of all changes made to a drug record in an electronic drug
 419 recordkeeping system after a drug transaction has been made. The log shall contain at
 420 least, but is not limited, to the following:
 421 i. Date and time of change;
 422 ii. Changes made;
 423 iii. Person making the change.

424
 425 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

426 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR
 427

428 **§1125. Security and Confidentiality**

- 429 A. The electronic record keeping system shall provide adequate safeguards against improper, illegal, or
 430 unauthorized manipulation or alteration. The holder of the pharmacy permit shall provide adequate
 431 safeguards against improper, illegal, or unauthorized manipulation or alteration of any records in the
 432 pharmacy information system.
 433 B. A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to
 434 confidential information. If confidential health information is not transmitted directly between a
 435 pharmacist and a practitioner, but is transmitted through a data communications device, the confidential
 436 health information may not be accessed, maintained, or altered by the operator of the data communications
 437 device. Confidential information is privileged and may be released only subject to federal privacy laws
 438 and regulations, and subject to applicable Louisiana statutes.
 439

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

441 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23.1312,
 442 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, amended LR

443
 444 **§1127. Register**
 445 A. ~~The pharmacy shall maintain a register in which each individual pharmacist dispensing a prescription shall~~
 446 ~~sign a log each day, attesting to the fact that the information entered into the electronic record keeping~~
 447 ~~system has been reviewed that day, and is correct as stated.~~

448 Repealed.

449
 450 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
 451 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312
 452 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, repealed LR
 453

454 **§1129. Confidentiality**

455 A. ~~A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to~~
 456 ~~confidential information. If confidential health information is not transmitted directly between a~~
 457 ~~pharmacist and a practitioner, but is transmitted through a data communications device, the confidential~~
 458 ~~health information may not be accessed, maintained, or altered by the operator of the data communications~~
 459 ~~device. Confidential information is privileged and may be released only subject to federal privacy laws~~
 460 ~~and regulations, and subject to applicable Louisiana statutes.~~

461 Repealed.

462
 463 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
 464 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091
 465 (October 2003), effective January 1, 2004, repealed LR
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469 **Chapter 12. Automated Medication Systems**

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473 **§1213. Records**

- 474 A. Records and/or electronic data kept by the system shall meet the following requirements:
- 475 1. ...
 - 476 2. In the event controlled substances are stored in the system, the records shall include the positive
 477 identification (as defined in Section 1119 of the Board’s rules) of the personnel retrieving and
 478 administering the controlled substance to the patient.
 - 479 3. ...

480
 481 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
 482 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June
 483 2000), effective July 1, 2000, amended LR
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487 **Chapter 15. Hospital Pharmacy**

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491 **§1503. Definitions**

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

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

501 Hospital Patient – a person receiving health care services within a hospital facility.

502 Hospital Pharmacy – ...

503 Hospital Prescription – a written, electronic or oral order for a drug for use in treating a hospital
 504 patient.

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

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

510 Positive identification – has the same meaning as defined in Section 1119 of these rules, except that a
 511 specific hospital having a closed electronic drug record keeping system may be permitted to use
 512 identifiers utilizing both a password combined with a personal identifier to document the positive
 513 identification of each user for the prescribing and administration of a drug, provided the pharmacist-
 514 in-charge has determined:

515 1. adequate audit controls are in place to detect and deter drug diversion;

516 2. adequate access controls are in place to assure the identity of the user and to assign
 517 accountability of the user for any drug transaction;

518 3. adequate safeguards are in place to prevent and detect the unauthorized use of an
 519 individual’s password and personal identifier;

520 4. an ongoing quality assurance program is in place to ensure that all three provisions cited
 521 above in this definition are being fulfilled and reviewed; and

522 5. appropriate policies and procedures are in place to address all four provisions cited above
 523 in this definition.

524 All of the above notwithstanding, however, positive identification as defined in Section 1119 of these
 525 rules shall always be used to document the:

526 a. Dispensing, compounding, or prepackaging of a drug;

527 b. Removal and possession of a controlled substance to administer to a patient; and

528 c. Waste of a controlled substance.

529 Remote Processing Services – the processing of a medical order or prescription by one pharmacy on
 530 behalf of another pharmacy, including:

531 1. receiving, interpreting, or clarifying a medical order;

532 2. entering data and transferring medical order information;

533 3. interpreting clinical data;

534 4. performing therapeutic intervention relative to medication therapy; and

535 5. providing drug information concerning a patient’s drug therapy; provided, however,
 536 that remote processing does not include the physical preparation or physical transfer of
 537 drugs.

538 Remote Processor – a permitted hospital pharmacy in Louisiana which provides remote processing
 539 services for another permitted hospital pharmacy in Louisiana;

540 Unit Dose – ...

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

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

546
 547 ...

548 549 **§1509. Drug Distribution and Control**

550 A. The hospital pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt,
 551 distribution, control, accountability, and patient administration and management of drugs. The staff of the
 552 hospital pharmacy shall cooperate with the pharmacist-in-charge in meeting drug control requirements in
 553 ordering, administering, and accounting for pharmaceuticals.

- 554 1. Procedure Manual
 555 ...
 556 2. Inventories
 557 ...
 558 3. Records
 559 ~~The pharmacist in charge shall maintain adequate records regarding the use and accountability of~~
 560 ~~controlled dangerous substances. Proof of use records for controlled dangerous substances shall~~
 561 ~~be maintained separately and in such a manner as to be readily retrievable. These records shall~~
 562 ~~specify the following minimum information:~~
 563 ~~a. Drug name, strength, and quantity;~~
 564 ~~b. Dose;~~
 565 ~~c. Full name of patient;~~
 566 ~~d. Date and time of administration; and~~
 567 ~~e. Name of person administering the drug.~~
 568 The pharmacist-in-charge shall be responsible for maintaining the following records:
 569 a. A record of all drugs procured, the quantity received, and the name, address and
 570 wholesale distributor license number of the person from whom the drugs were procured.
 571 b. All drug orders and records relating to the practice of pharmacy.
 572 i. Records of drugs dispensed shall include, but are not limited to:
 573 (aa) The name, strength, and quantity of drugs dispensed;
 574 (bb) The date of dispensing;
 575 (cc) The name of the hospital patient to whom, or for whose use, the drug
 576 was dispensed; and
 577 (dd) Positive identification of all pharmacists involved in the dispensing.
 578 ii. All other records relating to the practice of pharmacy other than dispensing
 579 shall include, but are not limited to:
 580 (aa) The name of the hospital patient to whom, or for whose benefit, the
 581 activity was performed;
 582 (bb) The nature of the pharmacy practice activity performed;
 583 (cc) The results of the activity, if applicable; and
 584 (dd) Positive identification of all pharmacists involved in the activity;
 585 identifying the function performed by each pharmacist.
 586 iii. Records of drugs dispensed to patients for use outside the hospital shall be
 587 maintained in compliance with Section 1123 of these rules.
 588 c. A record of all drugs compounded or prepackaged for use only within that hospital,
 589 which shall include at least the following:
 590 i. Name of drug, strength, quantity, and dosage form;
 591 ii. Manufacturer's or distributor's control number (except for patient-specific
 592 sterile compounded preparations);
 593 iii. Manufacturer's or distributor's name, if a generic drug is used;
 594 iv. Pharmacy control number;
 595 v. Manufacturer's or distributor's expiration date (except for patient-specific
 596 sterile compounded preparations);
 597 vi. Pharmacy's expiration date or beyond-use date;
 598 vii. Positive identification of the pharmacist licensed person responsible for the
 599 compounding or prepackaging of the drug.
 600 d. A record of the distribution of drugs to patient care areas and other areas of the hospital
 601 held for administration, which shall include at least the following:
 602 i. The name, strength, dosage form, and amount of the drug distributed;
 603 ii. The area receiving the drug;
 604 iii. The date distributed;
 605 iv. Positive identification of the individual receiving the drug if it is a
 606 controlled dangerous substance;
 607 v. The area of the hospital receiving the controlled dangerous substance shall
 608 make a record of all such drugs administered to patients. Such records
 609 shall include at least the following:

- 610 (aa) Name of the patient;
- 611 (bb) Name, dosage form, and strength when applicable of the drug;
- 612 (cc) Date and time the drug was administered;
- 613 (dd) Quantity administered;
- 614 (ee) Positive identification of the personnel administering the drug.
- 615 e. A log that shall be maintained of all changes made to a drug record in an electronic drug
- 616 recordkeeping system after a drug transaction has been made. The log shall contain at
- 617 least, but is not limited, to the following:
- 618 i. Date and time of change;
- 619 ii. Changes made;
- 620 iii. Person making the change.
- 621

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

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

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