



Louisiana Board of Pharmacy

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November 8, 2019

Senator John A. Alario, Jr, President
Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2019-17 ~ Pharmacy Records

Dear Senator Alario:

The Board has initiated the rulemaking process to amend four chapters of rules relative to pharmacy records, primarily to implement the provisions of Act 602 of the 2018 Legislature, and to make a significant number of technical revisions relating to editorial style. The legislation authorized the use of chart orders in pharmacies, and the substantive rule amendments implement that new authority. In connection with this regulatory project, the following documents are attached.

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| • Approval from Occupational Licensing Review Commission | Page 2 |
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As indicated in the solicitation, we will convene a public hearing on December 27, 2019 to receive public comments and testimony on these proposed rule changes. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information about this project, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm J. Broussard
Executive Director

cc: Chair, Senate Health & Welfare Committee
Via Email: APA.S-H&W@legis.la.gov
Speaker, House of Representatives
Via Email: APA.HouseSpeaker@legis.la.gov
Chair, House Health & Welfare Committee
Via Email: APA.H-HW@legis.la.gov
Director, Community Outreach Services, La. Economic Development
Via Email: Pat.Witty@la.gov
Editor, *Louisiana Register*
Via Email: Reg.Submission@la.gov
Reference File



WHEREAS, it is necessary for the Occupational Licensing Review Commission (OLRC) to issue a resolution regarding the approval or denial of specific occupational regulations submitted for its review:

NOW, THEREFORE, BE IT RESOLVED BY THE OCCUPATIONAL LICENSING REVIEW COMMISSION, that the following occupational regulations, as defined by Louisiana Revised Statutes 37:43(7), shall be known to have been approved by the OLRC at a duly called meeting of its members on August 29, 2019. The OLRC finds that these occupational regulations comply with the state policy set forth in Louisiana Revised Statutes 37:44 and authorizes the respective occupational licensing boards to initiate promulgation of the regulations in accordance with the Administrative Procedure Act.

A. Louisiana Behavior Analyst Board

- i. LAC 46: VIII.501-517 Supervision

B. Louisiana Board of Examiners for Speech Language Pathology and Audiology

- i. LAC 46: LXXV.103. Definitions
- ii. LAC 46: LXXV.107. Qualifications for Licensure
- iii. LAC 46: LXXV.109. Licensure Application Procedure
- iv. LAC 46: LXXV.121. Duties
- v. LAC 46: LXXV.125. Renewals
- vi. LAC 46: LXXV.127. Continuing Education Requirements
- vii. LAC 46: LXXV.501. Investigation of Complaints

C. State Board of Certified Public Accountants of Louisiana

- i. LAC 46: XIX.505.F.1.b

D. Louisiana State Board of Embalmers and Funeral Directors

- i. LAC 46: XXXVII.701. Renewal and Reinstatement
- ii. LAC 46: XXXVII.905. Application; Fee
- iii. LAC 46: XXXVII.1701. Reports on Prepaid Funeral Services or Merchandise
- iv. LAC 46: XXXVII.1901. Survivors Clause
- v. LAC 46: XXXVII.1902. Heirship Clause
- vi. LAC 46: XXXVII.2001. Procedure to Follow

E. Louisiana State Board of Dentistry

- i. LAC 46: XXXIII.1503
- ii. LAC 46: XXXIII.1607
- iii. LAC 46: XXXIII.1615.

F. State Board of Architectural Examiners

- i. LAC 46: I.1101. Registration Information
- ii. LAC 46: I.1105. Licenses
- iii. LAC 46: I.1301. Renewal Practices

G. Louisiana State Board of Social Work Examiners

- i. LAC 46: XXV.503. LMSWs Seeking the LCSW Credential

H. Louisiana Licensed Professional Counselors Board of Examiners

- i. LAC 46: LX.3105. Definitions for Licensed Marriage and Family Therapists and Provisional Licensed Marriage and Family Therapists
- ii. LAC 46: LX.3309. Academic Requirements for MFT Licensure or Provisional Licensure
- iii. LAC 46: LX.3315. Application, Practice, and Renewal Requirements for Provisional Licensed Marriage and Family Therapists
- iv. LAC 46: LX. 3317. Qualifications of the LMFT-Approved Supervisor, LMFT-Registered Supervisor Candidate, Board-Approved Supervisor, and Registered Supervisor Candidate.
- v. LAC 46: LX.3319. Responsibilities of the Provisional Licensed Marriage and Family Therapist

I. Louisiana Liquefied Petroleum Gas Commission

- i. LAC 55: IX.105. Applications
- ii. LAC 55: IX.107. Requirements
- iii. LAC 55: IX.109. Compliance with Rules
- iv. LAC 55: IX.113. Classes of Permits and Registrations
- v. LAC 55: IX.133. Shall Purchase Containers Manufactured by Manufacturers Acceptable to the Authority Having Jurisdiction
- vi. LAC 55: IX.177. Appliance Installation and Connections
- vii. LAC 55: IX.181. National Fire Protection Association Pamphlet Numbers 54 and 58
- viii. LAC 55: IX.205. Installation of Liquefied Petroleum Gas Systems Used as Engine Fuel System for School Bus/Mass Transit Vehicles
- ix. LAC 55: IX.1513. Classes of Permits

J. Louisiana State Board of Optometry Examiners

- i. LAC 46: LI.301. Continuing Education
- ii. LAC 46: LI.303. Continuing Education Requirement for Controlled Dangerous Substances
- iii. LAC 46: LI.501. Professional Conduct
- iv. LAC 46: LI.503. License to Practice Optometry
- v. LAC 46: LI.505. Prescriptions for Eyeglasses or Contact Lenses
- vi. LAC 46: LI.611. Mandatory Access and Review of Prescription Monitoring Program Data; Exceptions

K. Louisiana Professional Engineering and Land Surveying Board

- i. LAC 46: LXI.105. Definitions
- ii. LAC 46: LXI.2305. Supervising Professional

L. Louisiana Board of Professional Geoscientists

- i. LAC 46: XXXI.1501. Use of Seals

M. Louisiana Manufactured Housing Commission

- i. LAC 55: V.553. Definitions
- ii. LAC 55: V.555. Repair Requirements

N. Louisiana Board of Pharmacy

- i. LAC 46: LIII.1103, 1105, 1109, 1113, 1115, 1119, 1121, 1123, 1124, 1145, 1147, 1501, 1503, 1505, 1507, 1509, 1525, 1527, 1701, 1703, 1705, 1711, 1713, 1717, 1719, 1721, 1725, 2507, 2511, 2513, 2519, 2521. **Pharmacy Records**
- ii. LAC 46: LIII.2447. Licensure of Marijuana Pharmacies
- iii. LAC 46: LIII.2425. Telepharmacy Dispensing Sites
- iv. LAC 46: LIII.503, 903. Delays of Licensure Examinations
- v. LAC 46: LIII.903, 905. License Transfer for Pharmacy Technicians
- vi. LAC 46: LIII.507. Continuing Education Records
- vii. LAC 46: LIII.1503, 1519, 2503, 2517, 2701, 2749. Drug Disposal by Pharmacies
- viii. LAC 46: LIII.2535. Pharmacy Compounding

O. Louisiana State Board of Nursing

- i. LAC 46: XLVII.3303
- ii. LAC 46: XLVII.3307

This Resolution was ADOPTED by unanimous vote of the Commission on August 29, 2019.


Erin Monroe Wesley, Chair

Notice of Intent

Department of Health Board of Pharmacy

Pharmacy Records (LAC 46:LIII.Chapters 11, 15, 17, and 25)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend portions of four chapters of its rules, primarily with respect to pharmacy records, but also with a large number of technical revisions relating to editorial style. The impetus for the new rules is Act 602 of the 2018 Legislature, which added the term “chart order” to the pharmacy law and authorizes their use in pharmacies.

The proposed substantive changes in Chapter 11 include deletion of the requirement for pharmacies to maintain printed versions of the Louisiana Board of Pharmacy Laws and Regulations in §1103.K, deletion of the requirement for the pharmacist-in-charge affidavit to be notarized in §1105.J, insertion of the term “chart order” and its statutory definition in §1119, insertion of provisions authorizing use of chart orders in various types of pharmacy records in §1123 and §1124, deletion of Subsection M in §1123 and the terms “inpatient prescription” and “dispensing of drug pursuant to an inpatient prescription” in §1124, all of which had been necessary due to the absence of chart orders in the Board’s rules, insertion of a new §1145 enabling remote access to prescription records and chart orders in pharmacies, and insertion of a new §1147 enabling a pharmacy to share chart orders with certain pharmacies.

The proposed substantive changes in Chapter 15 include deletion of the term “hospital prescription” and “dispensing of a drug pursuant to a hospital prescription”, both of which had been necessary due to the absence of chart orders in the Board’s rules, deletion of §1507 which is now duplicative of the same two-year practice requirement for pharmacists-in-charge for all pharmacies and now found in §1105, and deletion of §1527 relative to remote access to medical orders, the content of which is being relocated to the new §1145 in Chapter 11.

The proposed substantive changes in Chapter 17 removes the requirement in §1711 for the emergency drug kit (EDK) permit to be conspicuously displayed at the provider pharmacy as long as it is readily retrievable, and insertion of a new Subsection E in §1711 enabling the relinquishment of an EDK permit when the pharmacy intends to cancel it prior to the next renewal.

The proposed substantive changes in Chapter 25 inserts the term “chart orders” and its statutory definition in §2511, makes provisions for the use of chart orders in pharmacy records in §2511 and §2513, and inserts a new Subsection F in §2511 enabling procedures for pharmacists to record changes in incomplete prescriptions and chart orders.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

* * *

§1103. Prescription Department Requirements

- A. – B. ...
- 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)~~ 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)~~ 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)~~ inches in width.
- F. – J. ...
- K. References. ~~A printed copy~~ The current edition of the *Louisiana Board of Pharmacy Laws and Regulations* shall be maintained and readily available within the prescription department of a pharmacy. The pharmacy shall maintain access to current and appropriate reference materials pertinent to the pharmacy practice, including but not limited to, pharmacology, drug interactions, dosing, toxicity, and patient counseling.

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

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

§1105. Pharmacist-in-Charge

- A. – I.3. ...
- J. Affidavit of Responsibility and Duties. The designated pharmacist-in-charge shall sign an affidavit on a form supplied by the board indicating his understanding and acceptance of the duties and responsibilities of a pharmacist-in-charge. This ~~notarized~~ document shall be submitted to the board for inclusion in the ~~pharmacy's~~ pharmacist's record in the board office.
- K. ...

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

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

* * *

§1109. Pharmacist Temporary Absence

- A. – E. ...
- F. If at any time the pharmacist deems it necessary to leave the on-site facility, the pharmacy shall be closed in accordance with § Section 1111 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 23:1311 (October 1997), amended LR 27:2237 (December 2001) effective January 1, 2002, amended LR 29:2088 (October 2003), effective January 1, 2004, amended by Department of Health, Board of Pharmacy, LR.

* * *

§1113. Mechanical Drug Dispensing Devices

- A. Dispensing of prescription drugs directly to a patient or caregiver by mechanical devices or machine is prohibited. This prohibition shall not apply to automated medication systems as defined and provided for in Chapter 12 of ~~these regulations~~ 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 23:1311 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, amended by Department of Health, Board of Pharmacy, LR.

§1115. Advertising

- A. False, fraudulent, deceptive, or misleading advertising as prohibited by R.S. 37:1241 of the Pharmacy Practice Act and this Section shall include, but is not limited to, any public misrepresentation done or made with the knowledge, whether actual or constructive, that is untrue or illegal, or is said to be done falsely when the meaning is that the party is in fault for its error. Actual or constructive knowledge as used in this context shall include intentionally, negligently, mistakenly, or accidentally representing an untrue fact.
- B. – C. ...
- D. No advertising shall include any reference, direct or indirect, to any controlled dangerous substance as provided for in Schedules II, III, IV, or V of R.S. 40:964. The provision of coupons or vouchers for controlled substances through authorized prescribers, which accompany legitimate prescriptions for such controlled substances issued to patients, shall not be prohibited by 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 23:1311 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007), amended by the Department of Health, Board of Pharmacy, LR

* * *

§1119. Definitions

- A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:
- “Chart order” means a lawful order entered on the electronic or paper chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his licensed healthcare designee for a drug or device and shall be considered a prescription drug order provided it contains the following:
1. Full name of the patient.
 2. Date of issuance.
 3. Name, strength, and dosage form of the drug prescribed.
 4. Directions for use.
 5. Name of the prescribing practitioner.
 6. The prescribing practitioner’s written or electronic signature or the written or electronic signature of the practitioner’s licensed healthcare designee, who shall be a licensed nurse, pharmacist, or physician practicing in a long-term care facility. The licensed healthcare designee shall be authorized to document a chart order in the patient’s medical record on behalf of the prescribing practitioner pending the prescribing practitioner’s signature, or to communicate a prescription to a pharmacy whether telephonically, by facsimile transmission, or electronically.

“Department” means the Louisiana Department of Health and Hospitals or its successor.

“Medical order” means a lawful order of a practitioner that may or may not include a prescription.

* * *

“Prescription” or “prescription drug order” means an order from a practitioner authorized by law to prescribe for a drug or device that is patient-specific and is communicated by any means to a pharmacist in a permitted pharmacy, and is to be preserved on file as required by law or regulation.

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 40:2252 (November 2014), effective January 1, 2015, amended by the Department of Health, Board of Pharmacy, LR

§1121. General Requirements

- A. – A.1. ...
2. 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.
 3. The failure to produce any pharmacy records requested by the board or its agent within ~~seventy-two (72)~~ hours of such request shall substantiate a violation of R.S. 37:1241(A)(22).
- B. – B.1. ...
2. Disposition records – drugs dispensed pursuant to prescription drug orders or chart orders, administered pursuant to medical orders, or distributed pursuant to purchase orders, and
 3. Inventory records – drugs in current possession.
- C. Retention. Except as provided in Section 1123 of this Part, all records required by this ~~Chapter Part~~ and by Louisiana law shall be retained for a minimum of two years from the most recent transaction. The failure to retain such records for at least two years shall substantiate a violation of R.S. 37:1229.

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 40:2252 (November 2014), effective January 1, 2015, amended by the Department of Health, Board of Pharmacy, LR

§1123. Records of Prescription Drug Orders and Chart Orders

- A. – A.4. ...
- 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. ...
 2. Date of issuance of the original prescription drug order or chart order by the prescriber;
 3. – 8. ...
 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. ...
 11. The refill history of the prescription as defined in ~~Paragraph Subsection~~ Paragraph Subsection 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:
- D.1. – D.4. ...
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;
- D.6 – E. ...
- F. Backup Support System
1. ...
 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 orders filled or refilled within the previous two years. This information shall include, at a minimum, the following data:

1. – 2. ...

3. Date of issuance of the original prescription drug order or chart order by the prescriber;

4. – 10. ...

11. Total number of refills dispensed to date for that prescription drug order or chart order;

G.12. – H.3. ...

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

I.1. – I.3. ...

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

1. The system is capable of capturing, storing, and reproducing the exact image of a prescription, including the reverse side of the prescription form and its annotations;

2. – 5. ...

K. Filing and Retention of Prescription Forms

1. Written prescription drug order or chart order forms (including transcriptions of verbal prescriptions received in the pharmacy, prescriptions drug orders or chart orders received by facsimile in the pharmacy, as well as written prescription drug order or chart order forms presented to the pharmacy shall be assembled and stored in prescription number sequence. Prescriptions for controlled dangerous substances listed in Schedule II shall be filed separately from all other prescriptions. Where multiple medications are ordered on a single prescription form and includes one or more controlled dangerous substances listed in Schedule II, then such forms shall be filed with other Schedule II prescriptions. These original hard copy prescription drug order and chart order forms shall be retained in the prescription department for a minimum of two years following the most recent transaction.

2. For those pharmacies utilizing an electronic imaging system as described in ~~Paragraph~~ Subsection 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 as an electronic image or electronic facsimile directly within the pharmacy information system shall be retained within the information system 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.

L. – L.1.a.vi. ...

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:

L.1.b.i – L.1.c. ...

~~M. – Exceptions~~

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

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

~~2. Other pharmacies providing medications and services to patients within facilities other than hospitals licensed by the department shall comply with the provisions of Section 1124 of these rules for those activities.~~

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.~~

* * *

~~*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.~~

* * *

Positive identification –

a. has the same meaning as defined in Section 1119 of ~~these rules~~ this Chapter, 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:

a.i. – a. v. ...

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

b.i. – b.iii. ...

B. – B.1. ...

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.

B.3. – B.3.b.ii.(d) ...

iii. Records of drugs dispensed to patients for use outside the facility shall be maintained in compliance with Section 1123 of ~~these rules~~ this Chapter.

c. A record of all drugs compounded or prepackaged for use only within ~~that a~~ a healthcare facility, which shall include at least the following:

B.3.c.i – B.3.e.iii. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 40:2255 (November 2014), effective January 1, 2015, amended by Department of Health, Board of Pharmacy, LR.

* * *

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

A. Notwithstanding any provision of rules to the contrary, nothing shall prohibit a Louisiana-licensed pharmacist who is an employee of or under contract with a pharmacy in Louisiana from accessing that pharmacy's dispensing information system from a location other than the pharmacy in order to process prescription drug orders, medical orders, or chart orders, but only when all of the following conditions are satisfied:

1. The pharmacy establishes controls to protect the privacy and security of confidential records;

2. The pharmacist does not engage in the receiving of written prescription drug orders or medical orders or chart orders or the maintenance of such orders; and

3. No part of the pharmacy's dispensing information system is duplicated, downloaded, or removed from the pharmacy's dispensing information system.

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

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

§1147. Starter Doses for Patients in Licensed Healthcare Facilities

A. Definitions

“Starter dose order” means a prescription drug order or chart order transmitted by a vendor pharmacy to a starter dose pharmacy for the purpose of obtaining medication for a patient in a licensed health care facility.

“Starter dose pharmacy” means a Louisiana-licensed pharmacy that dispenses a starter dose of medication to a patient in a licensed health care facility pursuant to a starter dose order.

“Vendor pharmacy” means a Louisiana-licensed pharmacy which has a contract with a licensed health facility to dispense medications to patients within that facility.

- B. A vendor pharmacy may share a chart order with a starter dose pharmacy without the necessity of transferring such order, for the purpose of authorizing the starter dose pharmacy to dispense starter doses of medication to a patient in a licensed health care facility under the following circumstances:
1. The vendor pharmacy has secured authorization from the facility to utilize a starter dose pharmacy;
 2. The vendor pharmacy is in possession of a valid chart order and is unable to furnish the medication ordered in a timely manner; and
 3. The vendor pharmacy and starter dose pharmacy maintain records of all chart orders and starter dose orders for a period of not less than two years following date of transmission of such orders.

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

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

* * *

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 meaning 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.~~

* * *

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

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

* * *

Positive identification –

1. has the same meaning as defined in Section 1119 of ~~these rules~~ this Part, except that a specific hospital 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:

- 1.a. – 1.e. ...
2. 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:
- 2.a. – 2.c. ...

* * *

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, amended LR 33:1132 (June 2007), amended LR 39:1282 (May 2013), amended LR 40:2256 (November 2014), effective January 1, 2015, amended LR 41:2147 (October 2015), amended by Department of Health, Board of Pharmacy, LR.

§1505. Hospital Pharmacy Permit

- A. A hospital pharmacy permit shall be required to operate a pharmacy department located within a hospital for registered patients in a hospital. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of ~~these regulations~~ 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 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, amended LR 33:1132 (June 2007), amended by Department of Health, Board of Pharmacy, LR.

§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.~~

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

§1509. Drug Distribution Control

- A. – A.3.b.ii.(d) ...
 - 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.
- A.3.c. – A.3.e.iii. ...
- 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. ...

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

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

* * *

§1525. Hospital Off-Site Satellite Pharmacy

A. – B.4. ...

5. When the hospital off-site satellite pharmacy is closed or there is no pharmacist on duty, other individuals shall not have access to the hospital off-site satellite pharmacy except for temporary absences as provided for in Chapter 11 of ~~these rules~~ this Part.
6. – 6.b. ...
7. The hospital off-site satellite pharmacy shall comply with the recordkeeping provisions identified in Chapter 11 of ~~these rules~~ this Part.
8. ...

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

A. ~~Notwithstanding any provision of rules to the contrary, nothing shall prohibit a Louisiana licensed pharmacist who is an employee of or under contract with a hospital pharmacy in Louisiana from accessing that pharmacy's dispensing information system from a location other than the pharmacy in order to process prescription drug orders or medical orders, but only when all of the following conditions are satisfied:~~

1. ~~The pharmacy establishes controls to protect the privacy and security of confidential records;~~
2. ~~The pharmacist does not engage in the receiving of written prescription drug orders or medical orders or the maintenance of prescription drug orders or medical orders; and~~
3. ~~No part of the pharmacy's dispensing information system is duplicated, downloaded, or removed from the pharmacy's dispensing information 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 41:2147 (October 2015), repealed by the Department of Health, Board of Pharmacy, LR

Chapter 17. Institutional Pharmacy

§1701. Cross References

A. For all regulations that apply to permitted institutional pharmacies concerning pharmacy practices and records not specifically stated in this chapter, refer to Chapter 11 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 14:708 (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

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

* * *

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

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.

§1705. Institutional Pharmacy Permit

A. An institutional pharmacy permit shall be required to operate a pharmacy department located within an institutional facility, other than a hospital or penal institution, for residents or patients of that

- institutional facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of ~~these regulations~~ this Part.
- B. Pharmacies operated within a hospital shall be operated in accordance with Chapter 15 of ~~these regulations~~ this Part.
 - C. Pharmacies operated within a ~~penal institution~~ correctional center shall be operated in accordance with Chapter 18 of ~~these regulations~~ 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 14:708 (October 1988), effective January 1, 1989, amended LR 29:2095 (October 2003), effective January 1, 2004, amended LR 39:313 (February 2013), amended by Department of Health, Board of Pharmacy, LR.

* * *

§1711. Emergency Drug Kit Permit

A. – B.5. ...

- 6. The original EDK permit shall be ~~conspicuously displayed~~ readily retrievable at the provider pharmacy. A copy of the EDK permit shall be maintained in the room where the EDK is located.

C. – D. ...

E. Cancellation Prior to Renewal. In the event the facility or provider pharmacy elects to cancel the permit prior to the renewal date, the pharmacy shall relinquish the permit to the board office no later than ten days following the date of cancellation.

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

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

§1713. Emergency Drug Kit Requirements

A. – H. ...

I. Inspection.

- 1. The provider pharmacy shall inspect the EDK every ~~thirty (30)~~ thirty (30) days, plus or minus five (5) days. Proper documentation of these inspections, EDK inventory, and all records of use shall be maintained and made available to the board upon request.

I.2 – J.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 29:2096 (October 2003), effective January 1, 2004, amended LR 39:312 (February 2013), amended by Department of Health, Board of Pharmacy, LR.

* * *

§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.

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 by Department of Health, Board of Pharmacy, LR.

§1719. Definitions

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

* * *

Drug Abuse Treatment Center – means any establishment, facility, or institution, public or private, whether operated for profit or not, which primarily offers, or purports to offer, maintain, or operate facilities for the residential or outpatient diagnosis, care, treatment, or rehabilitation of two or more non-related individuals, who are patients as defined herein, excluding, however, any hospital or mental hospital otherwise licensed by the Department of Health ~~and Hospitals~~.

* * *

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 by Department of Health, Board of Pharmacy, LR.

§1721. Drug Abuse Treatment Center Pharmacy Permit

- A. A drug abuse treatment center pharmacy permit shall be required to operate a pharmacy department located within a drug abuse treatment facility for patients of that facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of ~~these regulations~~ 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 29:2097 (October 2003), effective January 1, 2004, amended by Department of Health, Board of Pharmacy, LR.

* * *

§1725. Records and Reports of Drug Abuse Treatment Centers

- A. All persons licensed by the Department of Health ~~and Hospitals~~ to operate a drug abuse treatment center and who possess a Drug Enforcement Administration (DEA) registration to purchase, possess, and use CDS shall keep the following records:

A.1. – B. ...

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

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

* * *

Chapter 25. Prescriptions, Drugs, and Devices

* * *

§2507. Veterinary Prescription Drugs

A. – B. ...

- 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:

C.1. – C.2. ...

- D. Prescription Form Requirements. Prescriptions issued by a licensed veterinarian shall conform to § Section 2511 of these regulations this Chapter.

E. ...

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

* * *

Subchapter B. Prescriptions and Chart Orders

§2511. Prescriptions and Chart Orders

- A. Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:

“Chart Order” is a lawful order entered on the electronic or paper chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his licensed healthcare designee for a drug or device and shall be considered a prescription drug order provided it contains the following:

1. Full name of the patient.
2. Date of issuance.
3. Name, strength, and dosage form of the drug prescribed.

4. Directions for use.
5. Name of the prescribing practitioner.
6. The prescribing practitioner's written or electronic signature or the written or electronic signature of the practitioner's licensed healthcare designee, who shall be a licensed nurse, pharmacist, or physician practicing in a long-term care facility. The licensed healthcare designee shall be authorized to document a chart order in the patient's medical record on behalf of the prescribing practitioner pending the prescribing practitioner's signature, or to communicate a prescription to a pharmacy whether telephonically, by facsimile transmission, or electronically.

* * *

B. – C.5.d. ...

6. Chart orders and Fforms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed above.

D. – E.1. ...

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

F. Completion of Prescription Orders and Chart Orders. In the event a pharmacist receives a prescription order or chart order lacking certain required information, the pharmacist may consult with the prescriber to clarify the prescriber's intent. Following a consultation with the prescriber and the appropriate documentation thereof on the order:

1. A pharmacist may add the following data elements on the order:
 - a. Patient's address; or
 - b. Drug dosage form or
2. A pharmacist may record changes in the following data elements on the order:
 - a. Patient's address;
 - b. Drug strength;
 - c. Quantity prescribed; or
 - d. Directions for use.
3. A pharmacist shall never add or make changes to the following data elements on the order:
 - a. Patient's name;
 - b. Date of issue;
 - c. Drug name (except for generic interchange as permitted by law); or
 - d. Prescriber signature

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), amended LR 29:2102 (October 2003), effective January 1, 2004, amended LR 41:98 (January 2015), amended LR 41:2147 (October 2015), amended by the Department of Health, Board of Pharmacy, LR 43:2162 (November 2017), amended by Department of Health, Board of Pharmacy, LR.

§2513. Prescription Receipt and Verification of Prescription Drug Orders and Chart Orders

- A. Receipt of a Prescription
 1. Written. A pharmacist may receive and dispense a prescription drug order or chart order that has been written and/or signed by the practitioner.
 2. Oral. A pharmacist may receive and dispense a prescription drug order or chart order that has been orally communicated by the practitioner when the prescription order has been reduced to hard copy.
 3. ...
- B. Verification. Verification of the accuracy and authenticity of any prescription drug order or chart order is the responsibility of the pharmacist.

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 29:2103 (October 2003), effective January 1, 2004, amended by Department of Health, Board of Pharmacy, LR.

* * *

§2519. Prescription Refills; Medication Synchronization and Refill Consolidation

A. – C.1. ...

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.

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 29:2104 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007), amended LR 42:1519 (September 2016), amended by the Department of Health, Board of Pharmacy, LR.

§2521. Emergency Refills

- 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.

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 29:2104 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR.

FAMILY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on the stability of the family.

The proposed rule changes will have no effect on the stability of the family.

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

The proposed rule changes will have no effect on the authority and rights of parents regarding the education and supervision of their children.

III. The effect on the functioning of the family.

The proposed rule changes will have no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

The proposed rule changes will have no effect on family earnings or family budget.

V. The effect on the behavior and personal responsibility of children.

The proposed rule changes will have no effect on the behavior and personal responsibility of children.

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

The proposed rule changes will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.

POVERTY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the rule proposed for adoption, repeal, or amendment.

I. The effect on household income, assets, and financial security.

The proposed rule changes will have no effect on household income, assets, or financial security.

II. The effect on early childhood development and preschool through postsecondary education development.

The proposed rule changes will have no effect on early childhood development or preschool through postsecondary education development.

III. The effect on employment and workforce development.

The proposed rule changes will have no effect on employment or workforce development.

IV. The effect on taxes and tax credits.

The proposed rule changes will have no effect on taxes or tax credits.

V. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

The proposed rule changes will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

PROVIDER IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

I. The effect on the staffing level requirements or qualifications required to provide the same level of service.

The proposed rule changes will have no effect on the staffing level requirements or qualifications required to provide the same level of service.

II. The total direct and indirect effect on the cost to the provider to provide the same level of service.

The proposed rule changes will have no effect on the cost to the provider to provide the same level of service.

III. The overall effect on the ability of the provider to provide the same level of service.

The proposed rule changes will have no effect on the ability of the provider to provide the same level of service.

REGULATORY FLEXIBILITY ANALYSIS
FOR ADMINISTRATIVE RULES

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

There are no reporting requirements in the proposed rule changes.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no specific reporting requirements in the proposed rule changes.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

There are no specific reporting requirements in the proposed rule changes.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

The proposed rule changes will simplify recordkeeping requirements in all pharmacies.

V. The exemption of small businesses from all or any part of the requirements contained in the proposed rule.

There are no exemptions for small businesses.

SOLICITATION OF COMMENTS

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to Malcolm J Broussard, Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding the proposed rule amendment. A public hearing to solicit comments and testimony on the proposed rule amendment is scheduled for 9:00 a.m. on Tuesday, November 26, 2019. During the hearing, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day. To request reasonable accommodations for persons with disabilities, please call the Board office at 225.925.6496.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment:

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)

The proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, at a cost of \$5,000 for FY 20. Furthermore, the LBP anticipates a nominal reduction in printing costs from no longer having to provide printed copies of the pharmacy law book to pharmacies statewide free of charge, as the book is now available in electronic format on the LBP's website. For reference, the LBP only mails a printed copy of the pharmacy law book when a new pharmacy receives a permit and only issued 195 copies of the book in FY 19. Therefore, the LBP does not anticipate a significant cost savings.

In addition, the proposed rule changes update recordkeeping requirements to include chart orders, in compliance with Act 602 of 2018 and make provisions for the use of chart orders in various types of pharmacy records. The proposed rule amendments further enable remote access to such records from outside the pharmacy; remove the notarization requirement for affidavits signed by pharmacists-in-charge acknowledging acceptance of the position's duties; amend policies for the display and relinquishing of an emergency drug kit (EDK) permit; and make technical changes.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)

The proposed rule changes are not anticipated to affect revenue collections for state or local governmental units. While the proposed rule changes provide a process for the relinquishing of an EDK permit, the LBP does not anticipate the number of active EDK permits to significantly change as a result, as the relinquishing of a permit would only occur when switching from one EDK provider to another prior to permit renewal. For reference, EDK permits have an annual fee of \$25 paid to the LBP.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule changes update recordkeeping requirements to include chart orders for the dispensing of prescription medications in compliance with Act 602 of 2018. The use of chart orders allows hospitals and long-term care facilities to dispense medication without a hard copy prescription. The proposed changes include provisions for the use of chart orders in various types of pharmacy records, and further, enable remote access to such records from outside the pharmacy.

The removal of the notarization requirement for the form used by the pharmacist-in-charge of a pharmacy may reduce operational costs for the pharmacy. The proposed rule change requiring EDK permits to be readily available rather than conspicuously displayed may result in a marginal savings for facilities and/or provider pharmacies. Furthermore, the proposed rule change allowing for relinquishing of an EDK permit prior to renewal is not anticipated to result in significant savings for pharmacies, as the LBP does not anticipate the number of active EDK permits to significantly change.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will not affect competition or employment.

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement:	Malcolm J. Broussard Executive Director	Dept.:	Health
Phone:	(225) 925-6481	Office:	Board of Pharmacy
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809	Title:	Pharmacy Records
		Effective Date of Rule:	Upon promulgation April 1, 2020 (est.)

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. **THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.**

**I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)**

The proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, at a cost of \$5,000 for FY 20. Furthermore, the LBP anticipates a nominal reduction in printing costs from no longer having to provide printed copies of the pharmacy law book to pharmacies statewide free of charge, as the book is now available in electronic format on the LBP's website. For reference, the LBP only mails a printed copy of the pharmacy law book when a new pharmacy receives a permit and only issued 195 copies of the book in FY 19. Therefore, the LBP does not anticipate a significant cost savings.

In addition, the proposed rule changes update recordkeeping requirements to include chart orders, in compliance with Act 602 of 2018 and make provisions for the use of chart orders in various types of pharmacy records. The proposed rule amendments further enable remote access to such records from outside the pharmacy; remove the notarization requirement for affidavits signed by pharmacists-in-charge acknowledging acceptance of the position's duties; amend policies for the display and relinquishing of an emergency drug kit (EDK) permit; and make technical changes.

**II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)**

The proposed rule changes are not anticipated to affect revenue collections for state or local governmental units. While the proposed rule changes provide a process for the relinquishing of an EDK permit, the LBP does not anticipate the number of active EDK permits to significantly change as a result, as the relinquishing of a permit would only occur when switching from one EDK provider to another prior to permit renewal. For reference, EDK permits have an annual fee of \$25 paid to the LBP.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule changes update recordkeeping requirements to include chart orders for the dispensing of prescription medications in compliance with Act 602 of 2018. The use of chart orders allows hospitals and long-term care facilities to dispense medication without a hard copy prescription. The proposed changes include provisions for the use of chart orders in various types of pharmacy records, and further, enable remote access to such records from outside the pharmacy.

The removal of the notarization requirement for the form used by the pharmacist-in-charge of a pharmacy may reduce operational costs for the pharmacy. The proposed rule change requiring EDK permits to be readily available rather than conspicuously displayed may result in a marginal savings for facilities and/or provider pharmacies. Furthermore, the proposed rule change allowing for relinquishing of an EDK permit prior to renewal is not anticipated to result in significant savings for pharmacies, as the LBP does not anticipate the number of active EDK

permits to significantly change.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will not affect competition or employment.

Malcolm J. Broussard
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

November 7, 2019
Date of Signature

Evan Brassy, Staff Director
Legislative Fiscal Officer or Designee

11/8/19
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The proposed rule changes incorporate chart orders into pharmacy records and makes provisions for their use in pharmacies, including remote access to such records. The requirement for a pharmacy to maintain a printed copy of the pharmacy law book is removed, and the notarization requirement for a form used by the pharmacist-in-charge is also removed. The proposed rule changes include a large number of technical revisions relative to editorial style.

- B. Summarize the circumstances that require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

Act 602 of the 2018 Legislature authorized the use of chart orders in pharmacies. The proposed rule changes incorporate chart orders into pharmacy records and provides for their use in pharmacies.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session:

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

The Board has allocated \$2,500 each for printing the Notice of Intent and the Final Rule. The Board operates on self-generated funds.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) Yes. If yes, attach documentation.

(b) No. If no, provide justification as to why this rule change should be published at this time.

The Board seeks to update its rules for pharmacy records to include chart orders as authorized by the 2018 Legislature.

- D. Compliance with Act 820 of the 2008 Regular Session

(1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of "small businesses", the Board is unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial

data. To the extent any pharmacy licensed by the Board would qualify as a small business, there are 2,003 pharmacies currently licensed.

- (2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

There are no specific reporting, recordkeeping or other administrative costs required by the proposed rule changes.

- (3) A statement of the probable effect on impacted small businesses.

To the extent a pharmacy has been developing 'work-arounds' relative to chart orders, the proposed rule changes will simplify their recordkeeping requirements and may reduce some of their operational costs. The removal of the notarization requirement for the form used by the pharmacist-in-charge may reduce some of their operational costs.

- (4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

There are no alternative methods for achieving the purpose of the proposed rule changes.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

<u>COSTS</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 5,000	\$ 0	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
TOTAL	\$ 5,000	\$ 0	\$ 0
POSITIONS (#)	0	0	0

2. Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, at a cost of \$5,000 for FY 20. Furthermore, the LBP anticipates a nominal reduction in printing costs from no longer having to provide printed copies of the pharmacy law book to pharmacies statewide free of charge, as the book is now available in electronic format on the LBP's website. For reference, the LBP only mails a printed copy of the pharmacy law book when a new pharmacy receives a permit and only issued 195 copies of the book in FY 19. Therefore, the LBP does not anticipate a significant cost savings.

In addition, the proposed rule changes update recordkeeping requirements to include chart orders, in compliance with Act 602 of 2018 and make provisions for the use of chart orders in various types of pharmacy records. The proposed rule amendments further enable remote access to such records from outside the pharmacy; remove the notarization requirement for affidavits signed by pharmacists-in-charge acknowledging acceptance of the position's duties; amend policies for the display and relinquishing of an emergency drug kit (EDK) permit; and make technical changes.

3. Sources of funding for implementing the proposed rule or rule change.

<u>SOURCE</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 5,000	\$ 0	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
TOTAL	\$ 5,000	\$ 0	\$ 0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

The Board has sufficient funds available to implement the proposed rule changes.

B. COST SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.
2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

To the extent a local governmental unit operates a pharmacy which has been developing 'work-arounds' relative to chart orders, the proposed rule changes will simplify their recordkeeping requirements and may reduce some of their operational costs. The removal of the notarization requirement for the form used by the pharmacist-in-charge may reduce some of their operational costs.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

- A. What increase (decrease) in revenues can be anticipated from the proposed action?

<u>SOURCE</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 0	\$ 0	\$ 0
DEDICATED FUNDS	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
LOCAL FUNDS	\$ 0	\$ 0	\$ 0
TOTAL	\$ 0	\$ 0	\$ 0

- B. Provide a narrative explanation of each increase or decrease in revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

The proposed rule changes are not anticipated to affect revenue collections for state or local governmental units. While the proposed rule changes provide a process for the relinquishing of an EDK permit, the LBP does not anticipate the number of active EDK permits to significantly change as a result, as the relinquishing of a permit would only occur when switching from one EDK provider to another prior to permit renewal. For reference, EDK permits have an annual fee of \$25.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule changes update recordkeeping requirements to include chart orders for the dispensing of prescription medications in compliance with Act 602 of 2018. The use of chart orders allows hospitals and long-term care facilities to dispense medication without a hard copy prescription. The proposed changes include provisions for the use of chart orders in various types of pharmacy records, and further, enable remote access to such records from outside the pharmacy.

The removal of the notarization requirement for the form used by the pharmacist-in-charge of a pharmacy may reduce operational costs for the pharmacy. The proposed rule change requiring EDK permits to be readily available rather than conspicuously displayed may result in a marginal savings for facilities and/or provider pharmacies. Furthermore, the proposed rule change allowing for relinquishing of an EDK permit prior to renewal is not anticipated to result in significant savings for pharmacies, as the LBP does not anticipate the number of active EDK permits to significantly change.

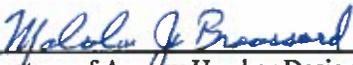
Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

The proposed rule changes will have no effect on receipts or revenue.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

The proposed rule changes will not affect competition or employment.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

November 7, 2019
Date of Signature

SENATE BILL NO. 477 (Substitute of Senate Bill No. 189 by Senator LaFleur)

BY SENATOR LAFLEUR

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AN ACT

To enact R.S. 37:1164(59) and 1226.4; relative to electronic prescribing of noncontrolled legend drugs; to provide for a definition of chart order; to provide for bidirectional transmission; to provide for authority to the Louisiana State Law Institute to alphabetize the definition list; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1164(59) and 1226.4 are hereby enacted to read as follows:

§1164. Definitions

As used in this Chapter, the following terms have the meaning ascribed to them by this Section:

* * *

(59) "Chart Order" is a lawful order entered on the electronic or paper chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his licensed healthcare designee for a drug or device and shall be considered a prescription drug order provided it contains the following:

- (a) Full name of the patient.**
- (b) Date of issuance.**
- (c) Name, strength, and dosage form of the drug prescribed.**
- (d) Directions for use.**
- (e) Name of the prescribing practitioner.**
- (f) The prescribing practitioner's written or electronic signature or the written or electronic signature of the practitioner's licensed healthcare designee, who shall be a licensed nurse, pharmacist, or physician practicing in a long-term care facility. The licensed healthcare designee shall be authorized to document a chart order in the patient's medical record on behalf of the**

1 prescribing practitioner pending the prescribing practitioner's signature, or to
2 communicate a prescription to a pharmacy whether telephonically, by facsimile
3 transmission, or electronically.

4 * * *

5 **§1226.4. Chart orders; bidirectional transmission; renewal**

6 **A. The institutional facility is the only party to the prescription drug**
7 **chart order that shall be required to maintain a copy of the prescriber's**
8 **signature unless otherwise required by federal law.**

9 **B. Bidirectional electronic transmission of chart orders between the**
10 **institutional facility and the pharmacy shall be permitted when transmission**
11 **occurs in a manner that complies with rules promulgated by the Centers for**
12 **Medicare and Medicaid Services and other federal rules or regulations.**

13 **C. Renewal of ongoing chart orders shall be signed by the prescriber at**
14 **the appropriate time interval based on facility type and federal regulation, state**
15 **law, or rule. Unless otherwise indicated, chart orders shall be ongoing until such**
16 **time as the practitioner discontinues the order and such discontinuation is**
17 **communicated to the pharmacy.**

18 **D. The board may promulgate rules to recognize and regulate the use of**
19 **chart orders that are not otherwise specifically provided for in this Section.**

20 Section 2. The Louisiana State Law Institute is hereby authorized and directed to
21 alphabetize the definitions contained in R.S. 37:1164.

PRESIDENT OF THE SENATE

SPEAKER OF THE HOUSE OF REPRESENTATIVES

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____