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March 6, 2020

Senator P. Page Cortez, President
Louisiana Senate
Via e-mail: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2019-17 ~ Pharmacy Records

Dear Senator Cortez:

As we indicated in our first report to your office on November 8, 2019, the Board is amending 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.

Subsequent to the publication of our *Notice of Intent* in the November 2019 edition of the Louisiana Register, we conducted a public hearing on December 27, 2019 to receive comments and testimony on the proposed amendment. We received no comments or testimony on the proposed rule changes. During their subsequent meeting on February 5, 2020, the Board considered the absence of substantive comments and determined no revisions were necessary. The Occupational Licensing Review Commission approved the continuation of the promulgation process during their February 28, 2020 meeting. In connection with this regulatory project, you should find the following documents in this package:

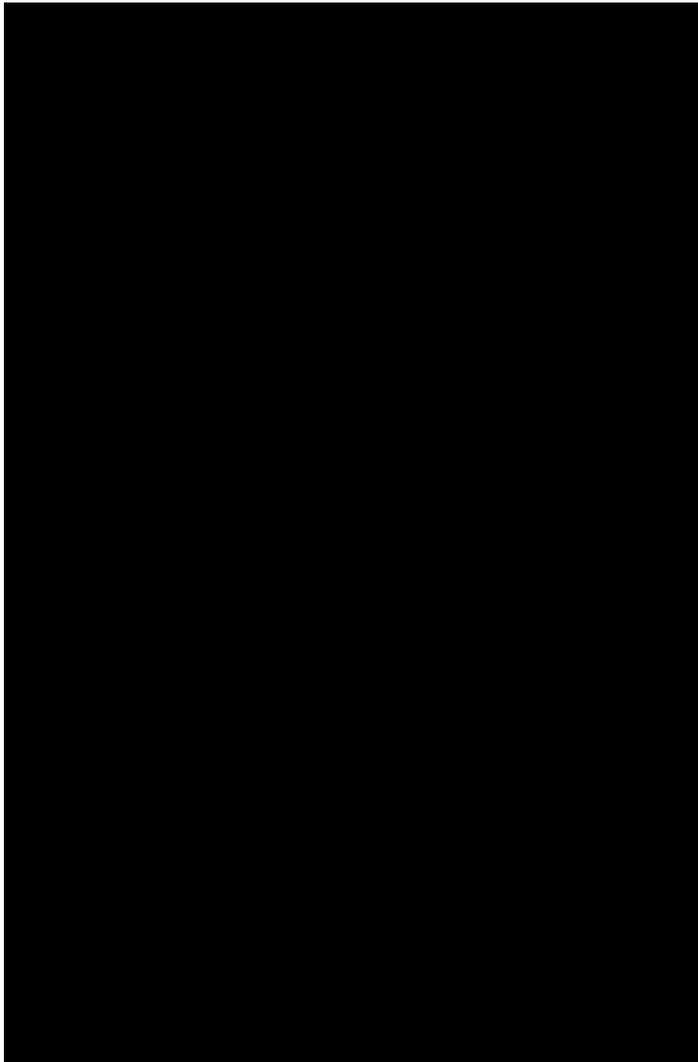
- *Notice of Intent*, as published in the November 2019 Louisiana Register Page 02
- Record from the December 27, 2019 Public Hearing Page 12
- Full text of proposed rule Page 46

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposal without amendment as a *Rule* in the April 20, 2020 edition of the Louisiana Register with an immediate effective date. If you have any questions about the enclosed information or our procedures, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm J. Broussard
Executive Director

cc: Chair, Senate Committee on Health and Welfare – APA.S-H&W@legis.la.gov
Speaker, House of Representatives – APA.HouseSpeaker@legis.la.gov
Chair, House Committee on Health and Welfare – APA.H-HW@legis.la.gov
Editor, Louisiana Register – Reg.Submission@la.gov
Reference File



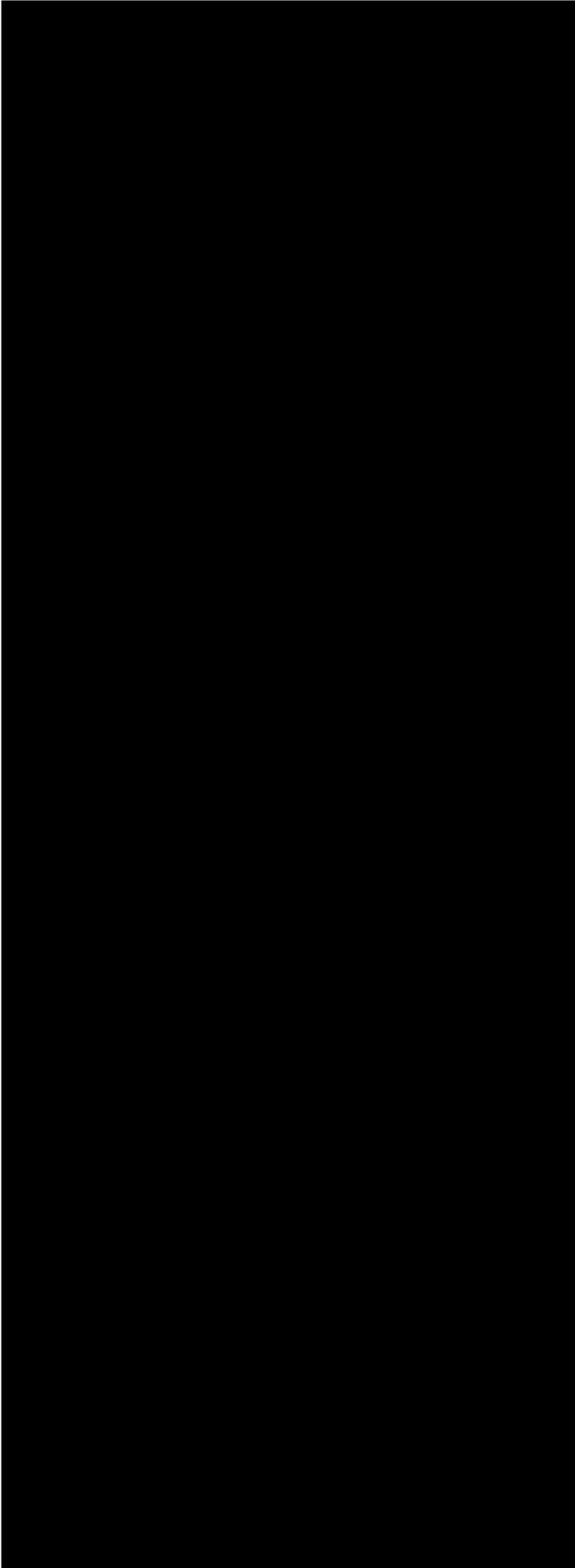
NOTICE OF INTENT

**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.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 11. Pharmacies

Subchapter A. General Requirements

§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 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 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 30 inches in width.

F. - J. ...

K. References. 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 46:

§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 document shall be submitted to the board for inclusion in the 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 46:

§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 46:

§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 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 46:

§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 46:

§1119. Definitions

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

Chart Order—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—the Louisiana Department of Health or its successor.

Medical Order—a lawful order of a practitioner that may or may not include a prescription.

* * *

Prescription or Prescription Drug Order—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 46:

§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 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 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 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 46:

§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, 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 this Part, and the pharmacist responsible for dispensing;

10. ...

11. the refill history of the prescription as defined in 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 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 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 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. ...

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 46:

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

A. Definitions

* * *

Positive Identification—

a. has the same meaning as defined in Section 1119 of 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:

i. - v. ...

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

i. - 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 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 this Chapter.

c. A record of all drugs compounded or prepackaged for use only within 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 46:

§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 46:

§1147. Starter Doses for Patients in Licensed Healthcare Facilities

A. Definitions

Starter Dose Order—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—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—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 46:

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 46:

§1503. Definitions

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

Hospital Off-Site Satellite Pharmacy—a pharmacy located within a hospital licensed by the Louisiana Department of Health, 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.

Positive Identification—

1. has the same meaning as defined in Section 1119 of 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 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 46:

§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 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 46:

§1507. Repealed.

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 46:

§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 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 of this Part.

1. When the pharmacy uses an electronic product verification process as described in Section 1217 of 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 46:

§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 this Part.

6. - 6.b....

7. The hospital off-site satellite pharmacy shall comply with the recordkeeping provisions identified in Chapter 11 of 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 46:

§1527. Repealed.

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 46:

Chapter 17. Institutional Pharmacy
Subchapter A. General Requirements

§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 46:

§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.

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 46:

§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 this Part.

B. Pharmacies operated within a hospital shall be operated in accordance with Chapter 15 of this Part.

C. Pharmacies operated within a correctional center shall be operated in accordance with Chapter 18 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 29:2095 (October 2003), effective January 1, 2004, amended LR 39:313 (February 2013), amended by Department of Health, Board of Pharmacy, LR 46:

Subchapter B. Emergency Drug Kits

§1711. Emergency Drug Kit Permit

A. - B.5. ...

6. The original EDK permit shall be 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 10 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 46:

§1713. Emergency Drug Kit Requirements

A. - H. ...

I. Inspection.

1. The provider pharmacy shall inspect the EDK every 30 days, plus or minus five 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 46:

Subchapter C. Drug Abuse Treatment Center Pharmacies

§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 46:

§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—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.

* * *

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 46:

§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 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 46:

§1725. Records and Reports of Drug Abuse Treatment Centers

A. All persons licensed by the Department of Health 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 46:

Chapter 25. Prescriptions, Drugs, and Devices

Subchapter A. General Requirements

§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 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 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 46:

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—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 forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed above.

D. - E.1. ...

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 46:

§2513. 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 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 46:

§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 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 46:

§2521. Emergency Refills

A. Using sound professional judgment, a pharmacist may refill adequate medication for a 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 46:

Family Impact Statement

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.

1. The Effect on the Stability of the Family. The proposed Rule amendment will have no effect on the stability of the family.

2. The Effect on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed Rule amendment will have no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The Effect on the Functioning of the Family. The proposed Rule amendment will have no effect on the functioning of the family.

4. The Effect on Family Earnings and Family Budget. The proposed Rule amendment will have no effect on family earnings or family budget.

5. The Effect on the Behavior and Personal Responsibility of Children. The proposed Rule amendment will have no effect on the behavior and personal responsibility of children.

6. The Ability of the Family or a Local Government to Perform the Function as Contained in the Proposed Rule. The proposed Rule amendment 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

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.

1. The Effect on Household Income, Assets, and Financial Security. The proposed Rule amendment will have no effect on household income, assets, or financial security.

2. The Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed Rule amendment will have no effect on early

childhood development or preschool through postsecondary education development.

3. The Effect on Employment and Workforce Development. The proposed Rule amendment will have no effect on employment or workforce development.

4. The Effect on Taxes and Tax Credits. The proposed Rule amendment will have no effect on taxes or tax credits.

5. The Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. The proposed Rule amendment will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

Small Business Analysis

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:

1. The Establishment of Less Stringent Compliance or Reporting Requirements for Small Businesses. There are no reporting requirements in the proposed Rule amendment.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. There are no specific schedules for deadlines in the proposed Rule amendment.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. There are no specific reporting requirements in the proposed Rule amendment.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed Rule amendment will simplify recordkeeping requirements in all pharmacies.

5. 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.

Provider Impact Statement

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:

1. The Effect on the Staffing Level Requirements or Qualifications Required to Provide the Same Level of Service. The proposed Rule amendment will have no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.

2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed Rule amendment will have no effect on the cost to the provider to provide the same level of service.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed Rule amendment will have no effect on the ability of the provider to provide the same level of service.

Public 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, LA 70809-1700. He is responsible for responding to inquiries regarding the proposed Rule amendment.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule amendment is scheduled for 9 a.m. on Friday, December 27, 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 p.m. 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

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Pharmacy Records

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT 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 NONGOVERNMENTAL 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.

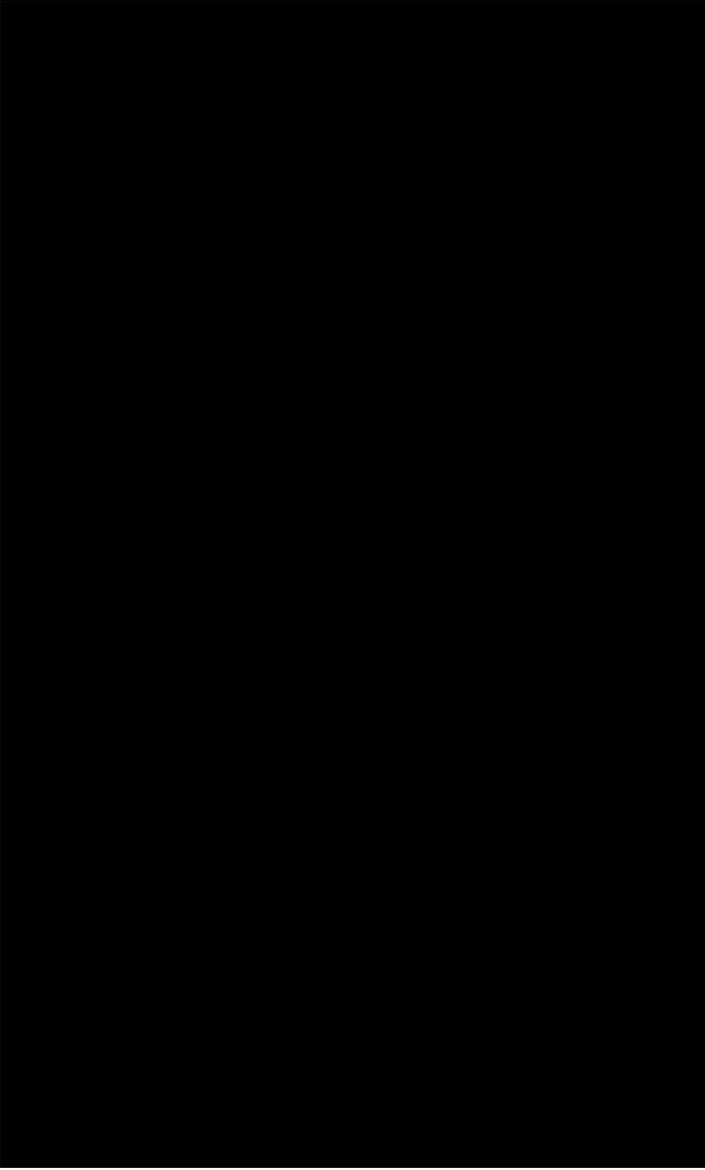
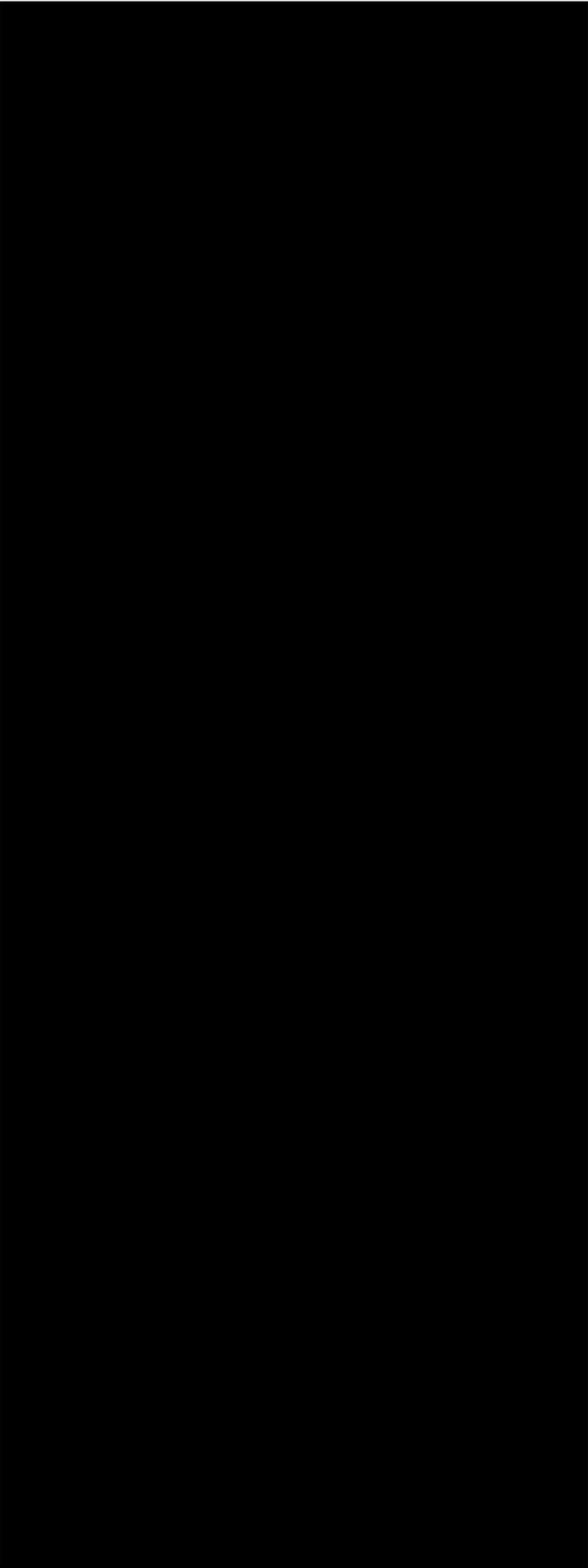
The removal of the notarization requirement for the form used by the pharmacist-in-charge of a pharmacy may reduce operational costs for the pharmacy. The proposed rule change requiring EDK permits to be readily available rather than conspicuously displayed may result in a marginal savings for facilities 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
Executive Director
1911#051

Evan Brasseaux
Staff Director
Legislative Fiscal Office





Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov



Public Hearing Record

December 27, 2019

Louisiana Board of Pharmacy

Public Hearing Attendance Record ~ December 27, 2019

Regulatory Projects 2019-1B through 2019-18

| Name | Address | E-mail | Group or Agency Represented |
|----------------|----------------------------------|-------------------|---|
| 1. TJ Woodward | 2450 Cottonwood Ave BR, LA 70808 | tj@rxstogeaux.com | Capital Wellness Solutions/Prescriptions to Geaux |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |

In The Matter Of:
STATE OF LOUISIANA PARISH OF EAST BATON ROUGE
LOUISIANA BOARD OF PHARMACY

Public Hearing
December 27, 2019

Associated Reporters, Inc.
2431 South Acadian Thruway
Suite 550
Baton Rouge, La. 70808

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STATE OF LOUISIANA
PARISH OF EAST BATON ROUGE
LOUISIANA BOARD OF PHARMACY

An Public Hearing was held by the
Louisiana Board of Pharmacy, on Friday,
December 27, 2019, at their office located
at 3388 Brentwood, Baton Rouge, Louisiana
70809 beginning at 9:00 a.m.

BEFORE:

Susan Erkel
Certified Court Reporter
In and For the State of
Louisiana

P R O C E E D I N G S

1
2 MR. FINALET:

3 Good morning. Today is Friday,
4 December 27, 2019. The time is 9:00
5 a.m. We're assembled in the Boardroom
6 at the Louisiana Board of Pharmacy
7 located at 3388 Brentwood Drive in Baton
8 Rouge, Louisiana. My name is Carlos
9 Finalet. I serve the Board of Pharmacy
10 as its General Counsel. In his absence,
11 the Board President, Carol Aron, has
12 requested that I moderate this hearing.
13 I now call this Public Hearing to order.

14 As a courtesy to everyone else in the
15 room, please take time to silence your
16 cell phones or other electronic devices.
17 Further, should you find it necessary to
18 take or make a telephone call, please
19 step outside the meeting room to do so.

20 For your safety, the emergency exit
21 path from this room is through the door
22 into the lobby and through the front
23 door through which you entered the
24 building. For your comfort, the
25 restrooms are located in the lobby --

1 ladies on the opposite side of the
2 lobby, just past the receptionist's
3 window, and gentlemen just outside the
4 door to this room.

5 In addition, we have a water cooler
6 in this room. Please help yourself.
7 For your peace of mind, please ensure
8 that you did not park in one of the
9 three spaces between this building and
10 the back of the building in front of
11 this one, or in front of the building in
12 front of this one. Those parking spaces
13 do not belong to the Board, and tow
14 trucks are regular visitors to that
15 area. Additional parking is available
16 at the rear of the Perlis clothing store
17 on Jefferson Highway, and there is a
18 stairway connecting that parking lot to
19 the Board's parking area in front of our
20 building.

21 This hearing is held in accordance
22 with Administrative Procedures Act and
23 the Open Meetings Law. As required by
24 these laws, this hearing is convened
25 pursuant to public notice and notice has

1 been properly posted.

2 The purpose of today's hearing is to
3 receive public comments and testimony on
4 the 17 regulatory projects listed on the
5 agenda for today's hearing. The Board
6 published its Notices of Intent for all
7 these projects in November 2019 edition
8 of the Louisiana Register. Further, the
9 Board filed its first reports with the
10 legislative oversight committees on
11 November 8 and then distributed
12 electronic Notice of Rulemaking Activity
13 on November 9, 2019 to its electronic
14 List of Interested Parties, as well as
15 all its licensees.

16 As indicated in the Notices, the
17 Board has convened this public hearing
18 to receive public comments and testimony
19 on all 17 of these regulatory projects.
20 The Board will consider the comments and
21 testimony offered today during their
22 next meeting on February 5, 2020, to
23 determine whether any revisions to the
24 proposed rule amendments are necessary.
25 We will reply to your comments as soon

1 as possible thereafter.

2 Prior to making any comments today,
3 we ask that you sign the guest register
4 for this event. Copies of today's
5 agenda and the notices are available at
6 the registration desk or rather,
7 actually right in front of you. The
8 proposed rule amendments are also
9 available in the Public Library section
10 of the Board's website, as well as the
11 website of the Louisiana Register.

12 While we may answer questions to
13 clarify language or interpretation, it
14 is not our intent to debate any issues
15 today. Again, the purpose of this
16 hearing is to receive your comments and
17 testimony for the Board's consideration.
18 As indicated in the notices, the
19 deadline for all comments and testimony
20 on these proposed rules amendments is
21 12:00 noon today.

22 We are now prepared to receive your
23 comments and testimony. As you begin
24 your comments, we ask that you identify
25 yourself and any organization that you

1 may represent. Please identify which
2 regulatory topic for which you are
3 submitting comments or testimony.

4 Before we take any oral statements, I
5 do want to enter into the record two
6 written comments that were submitted to
7 the Board Office, one on December 23,
8 2019 from the National Association of
9 Chain Drug Stores, specifically by its
10 representative Steven C. Anderson,
11 President and its CEO. And then the
12 second written comment was submitted on
13 December 26, 2019 by Albertsons
14 Companies, specifically by its
15 representative, Pharmacist Robert
16 Geddes, Director of Pharmacy,
17 Legislative and Regulatory Affairs.

18 So if there are any oral statements,
19 comments that the public would like to
20 make, now is would be the time.

21 MR. WOODARD:

22 I guess I might as well just to get
23 everything on the record, Carlos. TJ
24 Woodard here representing Capitol
25 Wellness Solutions. I notice the first

1 item on the agenda, Licensing Marijuana
2 Pharmacies, and I'm not sure exactly how
3 this pertains to us or if I'm even -- if
4 this is the right venue to bring things
5 up, but there's a few things that we've
6 noticed over the first few months of
7 establishing, opening, running, and now
8 we've done it for several months so we
9 kind of have a feel of what's working
10 and what's not working.

11 And I guess maybe just bullet points
12 to bring up at a future meeting with
13 Board Members to discuss, there are kind
14 of three, well four critical issues that
15 I think we're -- kind of prohibit our
16 growth and the effective running of our
17 marijuana pharmacies. The first I would
18 say, delivery, and I don't know exactly
19 what mechanism, if it's me as the
20 pharmacist in charge of delivery, and if
21 it's a third-party company delivery.

22 We have several patients that we've
23 seen and we've established a
24 relationship with that are truly bed
25 bound and don't have transportation,

1 that don't have anyone that can access
2 medication for them, I would be happy to
3 deliver it to their home if that were
4 allowed and legal so maybe just some
5 guidance on even an extreme situations,
6 you know.

7 I don't think this is a scenario like
8 I deliver in my traditional pharmacy
9 downtown where we deliver everything,
10 but just to have that option would be
11 helpful.

12 The second and I think it's been
13 discussed is, we, personally speaking
14 for Capitol Wellness, we have two great
15 technicians that are kind of
16 underutilized. They can perform certain
17 duties, data entry, but really beyond
18 that, as far as the filling -- filling
19 of the medication, they can't do now.
20 The pharmacist is the only one in my
21 understanding that can touch the product
22 and you know, essentially stick a label
23 on a box, if you will.

24 Sometimes that creates a logjam. We
25 spend most of our time counseling

1 patients so if I'm in the back
2 counseling a patient and we have three
3 additional patients come in, everything
4 is stopped waiting on me, where at a
5 minimum, they could enter it, fill it,
6 label it for me to check and review, as
7 we do in the traditional pharmacy I
8 guess. So in my mind, if they can fill,
9 you know, a Percocet in a traditional
10 pharmacy, I can count behind them and
11 check it and then dispense it.

12 It would be helpful if they could do
13 that in our world. There just seems to
14 be this firewall between technicians and
15 the product that I don't see any issue
16 whatsoever with it professionally
17 because I'm still checking behind it and
18 the things we traditionally do. So
19 that's another thing.

20 The -- another big one and I don't
21 know, there's a fine line between we're
22 really -- I don't know all the specifics
23 in the law, but we're really prohibited
24 from advertising. And I don't know that
25 advertising is in a sense of you know,

1 we need to put up a billboard that we
2 sell medical marijuana here, but it
3 would help one, communicate with doctors
4 and patients kind of what we do and what
5 we can do.

6 We do that some for education now
7 with physicians. We don't really have a
8 way to reach the patients unless they
9 call us. But the main reason there is a
10 medical marijuana recommending facility
11 adjacent to our location and we're
12 commonly confused with them. So we're
13 on Picardy off of Essen. They're on the
14 corner of Picardy and Essen. You know
15 they have some flag out with some
16 marijuana paraphernalia type things.
17 People regularly think that's us. We
18 would like a way just to let them know
19 that it's not.

20 I mean, for instance, our location
21 just has on the outside, it just says
22 "Capitol" and our logo. So especially
23 with elderly folks, they're constantly
24 confused with how to get to us, what we
25 do, who we are. So again, I'm not

1 asking for anything specifically, more
2 so just to start the conversation with
3 how could we do this efficiently and
4 professionally to communicate what we're
5 doing with the general public in a
6 professional way.

7 I don't think we want to, you know,
8 have the blow up people dancing on the
9 roads saying, you know, medical
10 marijuana here, but it's really been a -
11 - and I think its inhibited the growth
12 statewide for folks. We still have
13 physicians and patients that have
14 literally no idea what it is that we do.
15 In about six months now that we've been
16 open, there have been some lives that
17 have truly been changed so I can
18 honestly say that I think we're going in
19 the right direction.

20 We're taking it slowly and doing it
21 very controlled and very well. These
22 are just some things that I've seen in
23 practice that I think would help every
24 marijuana pharmacy without hurting the
25 public in any way. Actually, quite the

1 opposite. But again, I'm not asking for
2 anything specifically. Just maybe at
3 some future meeting we could discuss it.

4 So I don't even know if this is the
5 right forum for that but just to kind of
6 get that down in the public comment.

7 MR. FINALET:

8 And you had a forth point, maybe?

9 MR. WOODARD:

10 Well, the fourth point and I'm
11 skipping over, I see at the bottom,
12 number 3, letter Q, Cannabis Metered
13 Dose Inhaler. I don't know remotely
14 what that's about. I will just say, one
15 of the biggest issues we have is getting
16 this product into a patient's system as
17 quickly as possible for various reasons,
18 whether it's acute pain, whether it's an
19 anxiety attack secondary to PTSD.

20 That's still the fastest way to get this
21 medication into someone's body, through
22 the lungs.

23 So, you know, again, I'm not here
24 saying we should, you know, have flower
25 or vaporization. I don't know. This is

1 one thing that's come up, metered dose
2 inhaler. I will just say from the
3 clinical perspective, I couldn't support
4 something like this more. I don't know
5 what it looks like. I don't know if it's
6 an ILERA and southern product or it's a
7 GB -- well, it's not GB anymore,
8 Wellcanna, an LSU product, but that's
9 been a real issue with us is we need
10 some mechanism to get instant relief for
11 some patients.

12 That's one of the biggest complaints
13 we've had is that, you know, we have the
14 tinctures. They're faster than an oral
15 product. They work. They work very
16 well. There's still a 15 to 30 to an
17 hour gap there so if someone's having an
18 acute anxiety attack, I have nothing for
19 them.

20 MR. FINALET:

21 And I think that was the purpose of
22 that both legislatively and regulation.

23 MR. WOODARD:

24 So just to -- and this is me speaking
25 personally as a pharmacist and on behalf

1 of Capitol, that's something that we
2 support. There is a need for it.

3 MR. FINALET:

4 And to answer your question about if
5 this was the proper forum, I don't think
6 it's improper. You know you definitely
7 addressed that one aspect of the inhaler
8 which was appropriate. The other items
9 are appropriate insofar as they'll be
10 part of the comment review that the
11 Board's going to make at the February
12 meeting.

13 MR. WOODARD:

14 Okay.

15 MR. FINALET:

16 And my feeling is that the Board
17 President's going to delegate that to
18 Regulation Revision Committee.

19 MR. WOODARD:

20 Okay.

21 MR. FINALET:

22 And so there should be a very lively
23 chain of meetings thereafter --

24 MR. WOODARD:

25 Right.

1 MR. FINALET:

2 -- on all these aspects. And as you
3 know, the projects evolving and we
4 expected it to evolve and frankly, want
5 it to evolve to address a lot of the
6 concerns you had about educating
7 appropriately.

8 MR. WOODARD:

9 Right, right.

10 MR. FINALET:

11 And informing the public and getting
12 the right patients to you.

13 MR. WOODARD:

14 And I think we've all -- I will say
15 that speaking with people kind of from
16 other states, speaking with folks at
17 Pennington, speaking with folks at LSU,
18 I think we did it the right way. It's
19 much, you know, much different than in
20 California or Colorado model, but it's
21 well controlled and we can actually use
22 that to our benefit in a lot of ways. I
23 mean we're talking about doing clinical
24 trials now which is kind of
25 groundbreaking.

1 But, you know, we've got to start
2 and then I think it's, you know,
3 postmortem review of what's working,
4 what's not working and just speaking --
5 we're in close contact with the other
6 pharmacies in the state and it's kind of
7 the same things that keep coming up. So
8 I don't intend to be the spokesperson
9 for everyone, but I'm happy to answer
10 questions specifically, you know,
11 patient based, what is working and
12 what's not.

13 MR. FINALET:

14 And I can tell you that the Board
15 will really want all of your input --

16 MR. WOODARD:

17 Okay.

18 MR. FINALET:

19 -- as to what you do because y'all
20 are on the front lines.

21 MR. WOODARD:

22 Yeah.

23 MR. FINALET:

24 Y'all know what is needed and then
25 they could figure out what we can work

1 with.

2 MR. WOODARD:

3 Perfect. So board meeting February
4 at Xavier.

5 MR. FINALET:

6 At Xavier and I believe the starting
7 time is 9:00.

8 MR. WOODARD:

9 And will the Regulations Committee be
10 before that or after that?

11 MR. FINALET:

12 After that.

13 MR. WOODARD:

14 So they'll be --

15 MR. FINALET:

16 There is a Regulations Committee
17 meeting in January 23rd I think. But
18 that -- nothing marijuana related I
19 don't think is on that agenda. But they
20 wouldn't be discussing this anyway. The
21 Board has to delegate it to the
22 committee.

23 MR. WOODARD:

24 Okay.

25 MR. FINALET:

1 The committee does take up issues on
2 their own. There's a process for it.

3 MR. WOODARD:

4 That's what Malcolm said. I haven't
5 brought it up myself yet to be delegated
6 that because I wasn't quite ready. But
7 maybe at the Board, do I ask for it to
8 be delegated?

9 MR. FINALET:

10 Well, what I'm going to suggest to
11 Malcolm when he's preparing the
12 comments, is you know, for the Board's
13 Digest is to itemize your comments and
14 concerns.

15 MR. WOODARD:

16 Okay.

17 MR. FINALET:

18 And that would give the Board
19 President a vehicle to delegate that at
20 that time.

21 MR. WOODARD:

22 Okay. Perfect.

23 MR. FINALET:

24 If you want to check before the
25 meeting, you can always just submit a

1 request for that and then I'm not sure
2 which part of the meeting it would be
3 considered. It might be one of the
4 actual agenda items or it might be part
5 of the Executive Committee report.

6 MR. WOODARD:

7 Okay.

8 MR. FINALET:

9 I'm not sure. Why don't we do this.
10 Malcolm gets back on the 2nd. You know,
11 between now and then, maybe you shoot
12 him an e-mail just asking that question.

13 MR. WOODARD:

14 And it's -- and he has told me that
15 and given me that guidance that the
16 proper procedure like you just said.
17 It's got to go the Regulations
18 Committee. That's where this will be
19 hashed out. And that's really all we
20 want is just to have the discussion.
21 And I'd love for everyone to ask us
22 questions because this was all so new
23 for everyone, what's working.

24 I will say, professionally speaking,
25 it's worked much more than I thought it

1 was. You know, we never really knew,
2 you're going to flip the lights on if
3 this is going to be like some, you know,
4 shady, fly-by-night deal and it's just
5 not that at all.

6 MR. FINALET:

7 And I've heard that your particular
8 location is doing very well.

9 MR. WOODARD:

10 Yeah.

11 MR. FINALET:

12 And I've hear good things about it.

13 MR. WOODARD:

14 Okay. Thank you, Carlos. I think
15 that's it.

16 MR. FINALET:

17 Give Lisa my hello.

18 MR. WOODARD:

19 I will.

20 MR. FINALET:

21 I might come by soon.

22 MR. WOODARD:

23 Thank you again for your help. I've
24 talked to Kerry so I think we have a
25 good plan.

1 MR. FINALET:

2 Good deal. Take care. Happy new
3 year.

4 MR. WOODARD:

5 You too.

6 MR. FINALET:

7 Thank you.

8 (No public comments were received
9 from 9:17 a.m. until 11:59 a.m.)

10 MR. FINALET:

11 The time is now 12:00 noon. This
12 public hearing is adjourned.

13

14 (THE HEARING ADJOURNED AT 12:00 P.M.)

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1 C E R T I F I C A T E

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3 transcript accompanied by my original signature
4 and official seal on this page.

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|--|---|---|---|--|
| <p>absence (1) 3:10</p> <p>access (1) 9:1</p> <p>accordance (1) 4:21</p> <p>Act (1) 4:22</p> <p>Activity (1) 5:12</p> <p>actual (1) 20:4</p> <p>actually (3) 6:7;12:25;16:21</p> <p>acute (2) 13:18;14:18</p> <p>addition (1) 4:5</p> <p>Additional (2) 4:15;10:3</p> <p>address (1) 16:5</p> <p>addressed (1) 15:7</p> <p>adjacent (1) 11:11</p> <p>adjourned (2) 22:12,14</p> <p>Administrative (1) 4:22</p> <p>advertising (2) 10:24,25</p> <p>Affairs (1) 7:17</p> <p>Again (5) 6:15;11:25;13:1,23; 21:23</p> <p>agenda (5) 5:5;6:5;8:1;18:19; 20:4</p> <p>Albertsons (1) 7:13</p> <p>allowed (1) 9:4</p> <p>always (1) 19:25</p> <p>amendments (3) 5:24;6:8,20</p> <p>Anderson (1) 7:10</p> <p>anxiety (2) 13:19;14:18</p> <p>anymore (1) 14:7</p> <p>appropriate (2) 15:8,9</p> <p>appropriately (1) 16:7</p> <p>area (2) 4:15,19</p> | <p>Aron (1) 3:11</p> <p>aspect (1) 15:7</p> <p>aspects (1) 16:2</p> <p>assembled (1) 3:5</p> <p>Association (1) 7:8</p> <p>attack (2) 13:19;14:18</p> <p>available (3) 4:15;6:5,9</p> | <p>box (1) 9:23</p> <p>Brentwood (1) 3:7</p> <p>bring (2) 8:4,12</p> <p>brought (1) 19:5</p> <p>building (5) 3:24;4:9,10,11,20</p> <p>bullet (1) 8:11</p> | <p>17:7</p> <p>comment (3) 7:12;13:6;15:10</p> <p>comments (15) 5:3,18,20,25;6:2,16, 19,23,24;7:3,6,19; 19:12,13;22:8</p> <p>Committee (7) 15:18;18:9,16,22; 19:1;20:5,18</p> <p>committees (1) 5:10</p> <p>commonly (1) 11:12</p> <p>communicate (2) 11:3;12:4</p> <p>Companies (1) 7:14</p> <p>company (1) 8:21</p> <p>complaints (1) 14:12</p> <p>concerns (2) 16:6;19:14</p> <p>confused (2) 11:12,24</p> <p>connecting (1) 4:18</p> <p>consider (1) 5:20</p> <p>consideration (1) 6:17</p> <p>considered (1) 20:3</p> <p>constantly (1) 11:23</p> <p>contact (1) 17:5</p> <p>controlled (2) 12:21;16:21</p> <p>convened (2) 4:24;5:17</p> <p>conversation (1) 12:2</p> <p>cooler (1) 4:5</p> <p>Copies (1) 6:4</p> <p>corner (1) 11:14</p> <p>Counsel (1) 3:10</p> <p>counseling (2) 9:25;10:2</p> <p>count (1) 10:10</p> <p>courtesy (1) 3:14</p> <p>creates (1) 9:24</p> <p>critical (1) 8:14</p> | <p>dancing (1) 12:8</p> <p>data (1) 9:17</p> <p>deadline (1) 6:19</p> <p>deal (2) 21:4;22:2</p> <p>debate (1) 6:14</p> <p>December (3) 3:4;7:7,13</p> <p>definitely (1) 15:6</p> <p>delegate (3) 15:17;18:21;19:19</p> <p>delegated (2) 19:5,8</p> <p>deliver (3) 9:3,8,9</p> <p>delivery (3) 8:18,20,21</p> <p>desk (1) 6:6</p> <p>determine (1) 5:23</p> <p>devices (1) 3:16</p> <p>different (1) 16:19</p> <p>Digest (1) 19:13</p> <p>direction (1) 12:19</p> <p>Director (1) 7:16</p> <p>discuss (2) 8:13;13:3</p> <p>discussed (1) 9:13</p> <p>discussing (1) 18:20</p> <p>discussion (1) 20:20</p> <p>dispense (1) 10:11</p> <p>distributed (1) 5:11</p> <p>doctors (1) 11:3</p> <p>done (1) 8:8</p> <p>door (3) 3:21,23;4:4</p> <p>Dose (2) 13:13;14:1</p> <p>down (1) 13:6</p> <p>downtown (1) 9:9</p> |
| | <p>B</p> <p>back (3) 4:10;10:1;20:10</p> <p>based (1) 17:11</p> <p>Baton (1) 3:7</p> <p>bed (1) 8:24</p> <p>begin (1) 6:23</p> <p>behalf (1) 14:25</p> <p>behind (2) 10:10,17</p> <p>belong (1) 4:13</p> <p>benefit (1) 16:22</p> <p>beyond (1) 9:17</p> <p>big (1) 10:20</p> <p>biggest (2) 13:15;14:12</p> <p>billboard (1) 11:1</p> <p>blow (1) 12:8</p> <p>Board (16) 3:6,9,11;4:13;5:5,9, 17,20;7:7;8:13;15:16; 17:14;18:3,21;19:7, 18</p> <p>Boardroom (1) 3:5</p> <p>Board's (5) 4:19;6:10,17;15:11; 19:12</p> <p>body (1) 13:21</p> <p>both (1) 14:22</p> <p>bottom (1) 13:11</p> <p>bound (1) 8:25</p> | <p>California (1) 16:20</p> <p>call (3) 3:13,18;11:9</p> <p>can (11) 9:1,16,21;10:8,10; 11:5;12:17;16:21; 17:14,25;19:25</p> <p>Cannabis (1) 13:12</p> <p>Capitol (4) 7:24;9:14;11:22; 15:1</p> <p>care (1) 22:2</p> <p>Carlos (3) 3:8;7:23;21:14</p> <p>Carol (1) 3:11</p> <p>cell (1) 3:16</p> <p>CEO (1) 7:11</p> <p>certain (1) 9:16</p> <p>Chain (2) 7:9;15:23</p> <p>changed (1) 12:17</p> <p>charge (1) 8:20</p> <p>check (3) 10:6,11;19:24</p> <p>checking (1) 10:17</p> <p>clarify (1) 6:13</p> <p>clinical (2) 14:3;16:23</p> <p>close (1) 17:5</p> <p>clothing (1) 4:16</p> <p>Colorado (1) 16:20</p> <p>comfort (1) 3:24</p> <p>coming (1)</p> | | |

| | | | | |
|---|--|---|---|---|
| Drive (1) 3:7 | exit (1) 3:20 | four (1) 8:14 | hello (1) 21:17 | items (2) 15:8;20:4 |
| Drug (1) 7:9 | expected (1) 16:4 | fourth (1) 13:10 | help (4) 4:6;11:3;12:23; 21:23 | J |
| during (1) 5:21 | extreme (1) 9:5 | frankly (1) 16:4 | helpful (2) 9:11;10:12 | January (1) 18:17 |
| duties (1) 9:17 | F | Friday (1) 3:3 | Highway (1) 4:17 | Jefferson (1) 4:17 |
| E | facility (1) 11:10 | front (7) 3:22;4:10,11,12,19; 6:7;17:20 | home (1) 9:3 | K |
| edition (1) 5:7 | far (1) 9:18 | Further (2) 3:17;5:8 | honestly (1) 12:18 | keep (1) 17:7 |
| educating (1) 16:6 | faster (1) 14:14 | future (2) 8:12;13:3 | hour (1) 14:17 | Kerry (1) 21:24 |
| education (1) 11:6 | fastest (1) 13:20 | G | hurting (1) 12:24 | kind (9) 8:9,13,15;9:15; 11:4;13:5;16:15,24; 17:6 |
| effective (1) 8:16 | February (3) 5:22;15:11;18:3 | gap (1) 14:17 | I | knew (1) 21:1 |
| efficiently (1) 12:3 | feel (1) 8:9 | GB (2) 14:7,7 | idea (1) 12:14 | L |
| elderly (1) 11:23 | feeling (1) 15:16 | Geddes (1) 7:16 | identify (2) 6:24;7:1 | label (2) 9:22;10:6 |
| electronic (3) 3:16;5:12,13 | few (2) 8:5,6 | General (2) 3:10;12:5 | ILERA (1) 14:6 | ladies (1) 4:1 |
| else (1) 3:14 | figure (1) 17:25 | gentlemen (1) 4:3 | improper (1) 15:6 | language (1) 6:13 |
| e-mail (1) 20:12 | filed (1) 5:9 | gets (1) 20:10 | indicated (2) 5:16;6:18 | Law (2) 4:23;10:23 |
| emergency (1) 3:20 | fill (2) 10:5,8 | given (1) 20:15 | informing (1) 16:11 | laws (1) 4:24 |
| ensure (1) 4:7 | filling (2) 9:18,18 | Good (4) 3:3;21:12,25;22:2 | Inhaler (3) 13:13;14:2;15:7 | legal (1) 9:4 |
| enter (2) 7:5;10:5 | FINALET (27) 3:2,9;13:7;14:20; 15:3,15,21;16:1,10; 17:13,18,23;18:5,11, 15,25;19:9,17,23; 20:8;21:6,11,16,20; 22:1,6,10 | great (1) 9:14 | inhibited (1) 12:11 | legislative (2) 5:10;7:17 |
| entered (1) 3:23 | find (1) 3:17 | groundbreaking (1) 16:25 | input (1) 17:15 | legislatively (1) 14:22 |
| entry (1) 9:17 | fine (1) 10:21 | growth (2) 8:16;12:11 | insofar (1) 15:9 | letter (1) 13:12 |
| especially (1) 11:22 | firewall (1) 10:14 | guess (3) 7:22;8:11;10:8 | instance (1) 11:20 | Library (1) 6:9 |
| Essen (2) 11:13,14 | first (4) 5:9;7:25;8:6,17 | guest (1) 6:3 | instant (1) 14:10 | licensees (1) 5:15 |
| essentially (1) 9:22 | flag (1) 11:15 | guidance (2) 9:5;20:15 | intend (1) 17:8 | Licensing (1) 8:1 |
| established (1) 8:23 | flip (1) 21:2 | H | Intent (2) 5:6;6:14 | lights (1) 21:2 |
| establishing (1) 8:7 | flower (1) 13:24 | happy (3) 9:2;17:9;22:2 | Interested (1) 5:14 | line (1) 10:21 |
| even (3) 8:3;9:5;13:4 | fly-by-night (1) 21:4 | hashed (1) 20:19 | interpretation (1) 6:13 | lines (1) 17:20 |
| event (1) 6:4 | folks (4) 11:23;12:12;16:16, 17 | hear (1) 21:12 | into (4) 3:22;7:5;13:16,21 | Lisa (1) 21:17 |
| everyone (4) 3:14;17:9;20:21,23 | forth (1) 13:8 | heard (1) 21:7 | issue (2) 10:15;14:9 | List (1) 5:14 |
| evolve (2) 16:4,5 | forum (2) 13:5;15:5 | hearing (10) 3:12,13;4:21,24; 5:2,5,17;6:16;22:12, 14 | issues (4) 6:14;8:14;13:15; 19:1 | listed (1) 5:4 |
| evolving (1) 16:3 | | held (1) 4:21 | item (1) 8:1 | literally (1) 12:14 |
| exactly (2) 8:2,18 | | | itemize (1) 19:13 | |
| Executive (1) 20:5 | | | | |

| | | | | |
|---|--|--|--|--|
| <p>lively (1) 15:22</p> <p>lives (1) 12:16</p> <p>lobby (3) 3:22,25;4:2</p> <p>located (2) 3:7,25</p> <p>location (3) 11:11,20;21:8</p> <p>logjam (1) 9:24</p> <p>logo (1) 11:22</p> <p>looks (1) 14:5</p> <p>lot (3) 4:18;16:5,22</p> <p>Louisiana (4) 3:6,8;5:8;6:11</p> <p>love (1) 20:21</p> <p>LSU (2) 14:8;16:17</p> <p>lungs (1) 13:22</p> | <p>mind (2) 4:7;10:8</p> <p>minimum (1) 10:5</p> <p>model (1) 16:20</p> <p>moderate (1) 3:12</p> <p>months (3) 8:6,8;12:15</p> <p>more (3) 12:1;14:4;20:25</p> <p>morning (1) 3:3</p> <p>most (1) 9:25</p> <p>much (3) 16:19,19;20:25</p> <p>myself (1) 19:5</p> | <p>9:20</p> <p>Open (2) 4:23;12:16</p> <p>opening (1) 8:7</p> <p>opposite (2) 4:1;13:1</p> <p>option (1) 9:10</p> <p>oral (3) 7:4,18;14:14</p> <p>order (1) 3:13</p> <p>organization (1) 6:25</p> <p>out (3) 11:15;17:25;20:19</p> <p>outside (3) 3:19;4:3;11:21</p> <p>over (2) 8:6;13:11</p> <p>oversight (1) 5:10</p> <p>own (1) 19:2</p> | <p>perform (1) 9:16</p> <p>Perlis (1) 4:16</p> <p>personally (2) 9:13;14:25</p> <p>perspective (1) 14:3</p> <p>pertains (1) 8:3</p> <p>Pharmacies (3) 8:2,17;17:6</p> <p>Pharmacist (4) 7:15;8:20;9:20;14:25</p> <p>Pharmacy (7) 3:6,9;7:16;9:8;10:7,10;12:24</p> <p>phones (1) 3:16</p> <p>physicians (2) 11:7;12:13</p> <p>Picardy (2) 11:13,14</p> <p>plan (1) 21:25</p> <p>please (5) 3:15,18;4:6,7;7:1</p> <p>PM (1) 22:14</p> <p>point (2) 13:8,10</p> <p>points (1) 8:11</p> <p>possible (2) 6:1;13:17</p> <p>posted (1) 5:1</p> <p>postmortem (1) 17:3</p> <p>practice (1) 12:23</p> <p>prepared (1) 6:22</p> <p>preparing (1) 19:11</p> <p>President (3) 3:11;7:11;19:19</p> <p>President's (1) 15:17</p> <p>Prior (1) 6:2</p> <p>procedure (1) 20:16</p> <p>Procedures (1) 4:22</p> <p>process (1) 19:2</p> <p>product (6) 9:21;10:15;13:16;14:6,8,15</p> <p>professional (1) 12:6</p> | <p>professionally (3) 10:16;12:4;20:24</p> <p>prohibit (1) 8:15</p> <p>prohibited (1) 10:23</p> <p>projects (4) 5:4,7,19;16:3</p> <p>proper (2) 15:5;20:16</p> <p>properly (1) 5:1</p> <p>proposed (3) 5:24;6:8,20</p> <p>PTSD (1) 13:19</p> <p>Public (13) 3:13;4:25;5:3,17,18;6:9;7:19;12:5,25;13:6;16:11;22:8,12</p> <p>published (1) 5:6</p> <p>purpose (3) 5:2;6:15;14:21</p> <p>pursuant (1) 4:25</p> <p>put (1) 11:1</p> |
| M | N | P | Q | |
| <p>main (1) 11:9</p> <p>making (1) 6:2</p> <p>Malcolm (3) 19:4,11;20:10</p> <p>Marijuana (8) 8:1,17;11:2,10,16;12:10,24;18:18</p> <p>may (2) 6:12;7:1</p> <p>maybe (6) 8:11;9:4;13:2,8;19:7;20:11</p> <p>mean (2) 11:20;16:23</p> <p>mechanism (2) 8:19;14:10</p> <p>medical (3) 11:2,10;12:9</p> <p>medication (3) 9:2,19;13:21</p> <p>meeting (9) 3:19;5:22;8:12;13:3;15:12;18:3,17;19:25;20:2</p> <p>Meetings (2) 4:23;15:23</p> <p>Members (1) 8:13</p> <p>Metered (2) 13:12;14:1</p> <p>might (4) 7:22;20:3,4;21:21</p> | <p>name (1) 3:8</p> <p>National (1) 7:8</p> <p>necessary (2) 3:17;5:24</p> <p>need (3) 11:1;14:9;15:2</p> <p>needed (1) 17:24</p> <p>new (2) 20:22;22:2</p> <p>next (1) 5:22</p> <p>noon (2) 6:21;22:11</p> <p>notice (4) 4:25,25;5:12;7:25</p> <p>noticed (1) 8:6</p> <p>Notices (4) 5:6,16;6:5,18</p> <p>November (3) 5:7,11,13</p> <p>number (1) 13:12</p> | <p>paid (1) 13:18</p> <p>paraphernalia (1) 11:16</p> <p>park (1) 4:8</p> <p>parking (4) 4:12,15,18,19</p> <p>part (3) 15:10;20:2,4</p> <p>particular (1) 21:7</p> <p>Parties (1) 5:14</p> <p>past (1) 4:2</p> <p>path (1) 3:21</p> <p>patient (2) 10:2;17:11</p> <p>patients (8) 8:22;10:1,3;11:4,8;12:13;14:11;16:12</p> <p>patient's (1) 13:16</p> <p>peace (1) 4:7</p> <p>Pennington (1) 16:17</p> <p>People (3) 11:17;12:8;16:15</p> <p>Percocet (1) 10:9</p> <p>Perfect (2) 18:3;19:22</p> | <p>quickly (1) 13:17</p> <p>quite (2) 12:25;19:6</p> | |
| | O | | R | |
| | <p>off (1) 11:13</p> <p>offered (1) 5:21</p> <p>Office (1) 7:7</p> <p>one (12) 4:8,11,12;7:7;9:20;10:20;11:3;13:14;14:1,12;15:7;20:3</p> <p>only (1)</p> | | <p>rather (1) 6:6</p> <p>reach (1) 11:8</p> <p>ready (1) 19:6</p> <p>real (1) 14:9</p> <p>really (8) 9:17;10:22,23;11:7;12:10;17:15;20:19;21:1</p> <p>rear (1) 4:16</p> <p>reason (1) 11:9</p> <p>reasons (1) 13:17</p> <p>receive (4) 5:3,18;6:16,22</p> <p>received (1) 22:8</p> <p>receptionist's (1) 4:2</p> <p>recommending (1)</p> | |

| | | | | |
|---|---|--|---|--|
| 11:10 record (2) 7:5,23 Register (3) 5:8;6:3,11 registration (1) 6:6 regular (1) 4:14 regularly (1) 11:17 regulation (2) 14:22;15:18 Regulations (3) 18:9,16;20:17 regulatory (4) 5:4,19;7:2,17 related (1) 18:18 relationship (1) 8:24 relief (1) 14:10 remotely (1) 13:13 reply (1) 5:25 report (1) 20:5 reports (1) 5:9 represent (1) 7:1 representative (2) 7:10,15 representing (1) 7:24 request (1) 20:1 requested (1) 3:12 required (1) 4:23 restrooms (1) 3:25 review (3) 10:6;15:10;17:3 Revision (1) 15:18 revisions (1) 5:23 right (9) 6:7;8:4;12:19;13:5; 15:25;16:9,9,12,18 roads (1) 12:9 Robert (1) 7:15 room (5) 3:15,19,21;4:4,6 Rouge (1) 3:8 rule (2) | 5:24;6:8 Rulemaking (1) 5:12 rules (1) 6:20 running (2) 8:7,16 | 4:9,12 speaking (7) 9:13;14:24;16:15, 16,17;17:4;20:24 specifically (5) 7:9,14;12:1;13:2; 17:10 specifics (1) 10:22 spend (1) 9:25 spokesperson (1) 17:8 stairway (1) 4:18 start (2) 12:2;17:1 starting (1) 18:6 state (1) 17:6 statements (2) 7:4,18 states (1) 16:16 statewide (1) 12:12 step (1) 3:19 Steven (1) 7:10 stick (1) 9:22 still (4) 10:17;12:12;13:20; 14:16 stopped (1) 10:4 store (1) 4:16 Stores (1) 7:9 submit (1) 19:25 submitted (2) 7:6,12 submitting (1) 7:3 suggest (1) 19:10 support (2) 14:3;15:2 sure (3) 8:2;20:1,9 system (1) 13:16 | technicians (2) 9:15;10:14 telephone (1) 3:18 testimony (7) 5:3,18,21;6:17,19, 23;7:3 thereafter (2) 6:1;15:23 third-party (1) 8:21 thought (1) 20:25 three (3) 4:9;8:14;10:2 tinctures (1) 14:14 TJ (1) 7:23 Today (5) 3:3;5:21;6:2,15,21 today's (3) 5:2,5;6:4 told (1) 20:14 topic (1) 7:2 touch (1) 9:21 tow (1) 4:13 traditional (3) 9:8;10:7,9 traditionally (1) 10:18 transportation (1) 8:25 trials (1) 16:24 trucks (1) 4:14 truly (2) 8:24;12:17 two (2) 7:5;9:14 type (1) 11:16 | 13:25 various (1) 13:17 vehicle (1) 19:19 venue (1) 8:4 visitors (1) 4:14 |
| | S | | | W |
| | safety (1) 3:20 same (1) 17:7 saying (2) 12:9;13:24 scenario (1) 9:7 second (2) 7:12;9:12 secondary (1) 13:19 section (1) 6:9 seems (1) 10:13 sell (1) 11:2 sense (1) 10:25 serve (1) 3:9 several (2) 8:8,22 shady (1) 21:4 shoot (1) 20:11 side (1) 4:1 sign (1) 6:3 silence (1) 3:15 situations (1) 9:5 six (1) 12:15 skipping (1) 13:11 slowly (1) 12:20 Solutions (1) 7:25 someone's (2) 13:21;14:17 Sometimes (1) 9:24 soon (2) 5:25;21:21 southern (1) 14:6 spaces (2) | | | waiting (1) 10:4 water (1) 4:5 way (6) 11:8,18;12:6,25; 13:20;16:18 ways (1) 16:22 website (2) 6:10,11 Wellcanna (1) 14:8 Wellness (2) 7:25;9:14 what's (6) 8:9,10;17:3,4,12; 20:23 whatsoever (1) 10:16 window (1) 4:3 without (1) 12:24 WOODARD (25) 7:21,24;13:9;14:23; 15:13,19,24;16:8,13; 17:16,21;18:2,8,13, 23;19:3,15,21;20:6, 13;21:9,13,18,22;22:4 work (3) 14:15,15;17:25 worked (1) 20:25 working (6) 8:9,10;17:3,4,11; 20:23 world (1) 10:13 written (2) 7:6,12 |
| | | T | | X |
| | | | U | Y |
| | | talked (1) 21:24 talking (1) 16:23 | underutilized (1) 9:16 unless (1) 11:8 up (8) 8:5,12;11:1;12:8; 14:1;17:7;19:1,5 use (1) 16:21 | |
| | | | V | |
| | | | vaporization (1) | y'all (2) 17:19,24 |

| | | | | |
|---|--|--|--|--|
| year (1) 22:3 | | | | |
| 1 | | | | |
| 11:59 (1) 22:9 12:00 (3) 6:21;22:11,14 15 (1) 14:16 17 (2) 5:4,19 | | | | |
| 2 | | | | |
| 2019 (5) 3:4;5:7,13;7:8,13 2020 (1) 5:22 23 (1) 7:7 23rd (1) 18:17 26 (1) 7:13 27 (1) 3:4 2nd (1) 20:10 | | | | |
| 3 | | | | |
| 3 (1) 13:12 30 (1) 14:16 3388 (1) 3:7 | | | | |
| 5 | | | | |
| 5 (1) 5:22 | | | | |
| 8 | | | | |
| 8 (1) 5:11 | | | | |
| 9 | | | | |
| 9 (1) 5:13 9:00 (2) 3:4;18:7 9:17 (1) 22:9 | | | | |



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Summary of Testimony & Public Comments
re
Regulatory Project 2019-17 ~ Pharmacy Records
at
December 27, 2019 Public Hearing

No comments or testimony received.

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 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 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 30 inches in width.
- F. – J. ...
- K. References. 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 document shall be submitted to the board for inclusion in the 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 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* – 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 – the Louisiana Department of Health or its successor.

Medical order – a lawful order of a practitioner that may or may not include a prescription.

* * *

Prescription or prescription drug order – 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 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 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.
- B. Retention. Except as provided in Section 1123 of this Part, all records required by this 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, 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 this Part, and the pharmacist responsible for dispensing;
 10. ...
 11. The refill history of the prescription as defined in 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 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, prescription 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 information for all prescription 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. Prescription 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 prescription drug orders or chart orders received by facsimile in the pharmacy, or written prescription 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, prescription 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 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 prescription 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 prescription 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 prescription drug orders and chart orders that were filled at the pharmacy:
- L.1.b.i – L.1.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 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

* * *

Positive identification –

- a. has the same meaning as defined in Section 1119 of 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 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 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 this Chapter.

b. A record of all drugs compounded or prepackaged for use only within 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.

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§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 – 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 – 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 – 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.

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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:

* * *

Hospital Off-Site Satellite Pharmacy – a pharmacy located within a hospital licensed by the Louisiana Department of Health, 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.

* * *

Positive identification –

1. has the same meaning as defined in Section 1119 of 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 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 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. Repealed.

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 this Part.

A.3.c. – A.3.e.iii. ...

A. Automated Medication Systems. A hospital pharmacy may use one or more automated medication systems in compliance with the provisions of Chapter 12 of this Part.

1. When the pharmacy uses an electronic product verification process as described in Section 1217 of 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 this Part.
6. – 6.b. ...
7. The hospital off-site satellite pharmacy shall comply with the recordkeeping provisions identified in Chapter 11 of 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. Repealed.

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.

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 this Part.
- B. Pharmacies operated within a hospital shall be operated in accordance with Chapter 15 of this Part.
- C. Pharmacies operated within a correctional center shall be operated in accordance with Chapter 18 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 29:2095 (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 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 10 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 30 days, plus or minus five 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.

* * *

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 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 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 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 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* – 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 forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed above.
- D. – E.1. ...
- 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. 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 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 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 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.