LAC 46:XLIX.1105 relative to the administration of nursing facility administrators and their licensure to amend the refusal, suspension and revocation of license policy to include administrators-in-training, to add an additional violation complaint category, and to expand the disciplinary action options available to the board.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XLIX. Nursing Facility Administrators
Chapter 11. Licenses
§1105. Refusal, Suspension and Revocation of License

A. Board Review; Notice of Hearing

1. Upon the determination that a licensee or administrator-in-training applicant has violated one or more provisions of this Part the board may suspend, revoke, or refuse to issue a license or certificate of registration for nursing home administrator found in violation of this Part. In addition, the board may place a licensed administrator on probation, and/or in remedial training, and/or officially reprimand or otherwise discipline a licensee or administrator-in-training applicant, including but not limited to the imposition of a fine as set forth in this Part.

2. Once a complaint under the categories that follow has been received by the board, the board shall provide licensee or administrator-in-training applicant with adequate notice and an opportunity to respond as provided in Chapter 13 of this Part.

a. Category One

i. - x. ...

xi. has used alcohol, narcotics, or other drugs in a manner that interferes with the actual ability to practice as a nursing facility administrator or train as a administrator-in-training applicant.

b. - e. ...

3. Disciplinary Action

a. Category One. A fine of not less than $500 nor more than $2,000, and/or probation not to exceed three years, and/or suspension of license for not less than 30 days nor more than three years, denial of licensure and/or remedial training, counseling or revocation of license.

A.3.a.i. - C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:2504, R.S. 37:2509 and R.S. 37:2510.

HISTORICAL NOTE: Adopted by the Department of Health and Human Resources, Board of Examiners of Nursing Home Administrators, April 1970, amended and promulgated LR 6:276 (June 1980), amended LR 9:461 (July 1983), LR 12:366 (June 1986), amended by Department of Health and Hospitals, Board of Examiners of Nursing Home Administrators, LR 15:195 (March 1989), repealed and repromulgated LR 18:181 (February 1992), amended by the Board of Examiners of Nursing Facility Administrators, LR 37:595 (February 2011), LR 39:1046 (April 2013), LR 41:97 (January 2015).

Mark A. Hebert
Executive Director

1501#001

RULE

Department of Health and Hospitals
Board of Pharmacy

Pharmacy Compounding (LAC 46:LIII.Chapter 25)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy has amended Chapter 25, Prescriptions, Drugs and Devices, and more specifically, Subchapter C, Compounding of Drugs, of its rules. The Rule changes are intended to harmonize the board's rules on this topic with recently enacted federal legislation, the Drug Quality and Security Act of 2013.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 25. Prescriptions, Drugs, and Devices
Subchapter C. Compounding of Drugs
§2531. Purpose and Scope

A. Purpose. The rules of this Subchapter describe the requirements of minimum current good compounding practices for the preparation of drug formulations by Louisiana-licensed pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates for dispensing and/or administration to patients.

B. Scope. These requirements are intended to apply to all compounded preparations, sterile and non-sterile, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or practitioner's office.

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

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

§2533. Definitions

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

* * *

Preparation—a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations.

* * *

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

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

§2535. General Standards

A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.

1. A pharmacy shall have written procedures as necessary for the compounding of drug preparations to assure that the finished preparations have the identity, strength, quality, and purity they are represented to possess.

2. All compounding activities shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, as well as the Federal Food, Drug and Cosmetic Act of 1938 as subsequently amended, most recently in November 2013 (FDCA), the 2014 edition of title 21 of the *Code of Federal Regulations* (CFR), and all relevant chapters of the 2014 edition of the United States Pharmacopeia-National Formulary (USP 37-NF 32).

a. The compounding of sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of section 503A of the FDCA and USP chapter 797.

b. The compounding of non-sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of section 503A of the FDCA and USP chapter 795.

c. The compounding of preparations for veterinary use shall comply with the provisions of section 530 of Title 21 of the CFR.

d. The compounding of positron emission tomography (PET) drugs shall comply with the provisions of section 212 of title 21 of the CFR.

3. Products or duplicates of products removed from the market for the purposes of safety shall not be used to compound prescriptions for human use.

B. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the compounding of sterile preparations shall notify the board and shall receive approval from the board prior to beginning that practice.

C. Training and Education. All individuals compounding sterile preparations shall:

1. obtain practical and/or academic training in the compounding and dispensing of sterile preparations;

2. complete a minimum of one hour of Accreditation Council for Pharmacy Education (ACPE) accredited or board-approved continuing education, on an annual basis, related to sterile drug preparation, dispensing, and utilization;

3. use proper aseptic technique in compounding of all sterile preparations, as defined by the pharmacy practice site's policy and procedure manual;

4. qualify through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such persons will be assigned to use to make and dispense sterile preparations; and

5. maintain in the pharmacy practice site a written record of initial and subsequent training and competency evaluations. The record shall contain the following minimum information:

a. name of the individual receiving the training/evaluation;

b. date of the training/evaluation;

c. general description of the topics covered;

d. signature of the individual receiving the training/evaluation; and

e. name and signature of the individual providing the training/evaluation.

D. Anticipated Use Preparations. The pharmacist shall label any excess compounded preparation so as to reference it to the formula used and the assigned lot number and estimated beyond use date based on the pharmacist's professional judgment and/or other appropriate testing or published data.

E. Compounding Commercial Products not Available. A pharmacy may prepare a copy of a commercial product when that product is not available as evidenced by either of the following:

1. products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health-System Pharmacists (ASHP);

2. products temporarily unavailable from manufacturers, as documented by invoice or other communication from the distributor or manufacturer.

F. Labeling of Compounded Preparations

1. The labeling requirements of R.S. 37:1225, or its successor, as well as this Chapter, shall apply.

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

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

§2537. Requirements for Compounding Sterile Products

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 29:2106 (October 2003), effective January 1, 2004, repealed LR 41:98 (January 2015).

Malcolm J. Broussard
Executive Director

1501#009

RULE

Department of Health and Hospitals
Board of Pharmacy

Prescriptions (LAC 46:LIII.2511)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy has amended §2511, Prescriptions of its rules. The Rule updates the requirements for prescription forms and to codify contemporary practice standards for the minimum data set for prescriptions.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 25. Prescriptions, Drugs, and Devices
Subchapter B. Prescriptions
§2511. Prescriptions

A. …

* * *

B. Requirements. A prescription shall contain the following data elements:

1. prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the Drug Enforcement Administration (DEA) registration number;

2. patient's name, and if for a controlled substance, address;

3. date prescription issued by the prescriber;

4. name of drug or device, and if applicable, strength, and quantity to be dispensed;

5. directions for use;

6. signature of prescriber; and

7. refill instructions, if any. In the absence of refill instructions on the original prescription, the prescription shall not be refilled.

C. Written Prescriptions. A written prescription shall conform to the following format.

1. The prescription form shall be of a size not less than 4 inches by 5 inches, and shall bear a single printed signature line.

2. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and, if for a controlled substance, the Drug Enforcement Administration (DEA) registration number. In the event that multiple practitioners are identified on the prescription form, the authorizing prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling the authorizing prescriber's printed name.

3. No prescription form shall contain more than four prescription drug orders. Each prescription drug order recorded on the form shall provide the following:

a. check box labeled "Dispense as Written", or "DAW", or both; and

b. the number of refills, if any.

4. The prescription shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner on the date issued and in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). Examples of invalid signatures include rubber stamps, signatures of anyone other than the prescriber, and computer generated signatures.

5. Facsimile Prescription

a. The receiving facsimile machine of a prescription transmitted by facsimile shall be located within the pharmacy department.

b. The prescription transmitted by facsimile shall be on a non-fading legible medium.

c. All requirements applicable to written prescriptions in this Subsection shall apply to facsimile prescriptions, except Subparagraph B.7.c.

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

7. Equivalent Drug Product Interchange

a. The pharmacist shall not select an equivalent drug product when the prescriber handwrites a mark in the check box labeled "Dispense as Written", or "DAW", or both, and personally handwrites his signature on a printed single signature line. Otherwise, the pharmacist may select an equivalent drug product provided the patient has been informed of, and has consented to, the proposed cost saving interchange.

b. In the event an authorized prescriber has indicated that an equivalent drug product interchange is prohibited by handwriting a mark in the check box labeled "Dispense as Written" or "DAW" or both, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient's desire for an equivalent drug product interchange.

c. For prescriptions reimbursable by Medicaid, the authorized prescriber may only prohibit equivalent drug product interchange by handwriting the words "brand necessary" or "brand medically necessary" on the face of the prescription order or on a sheet attached to the prescription order.

D. Oral Prescriptions

1. Upon receipt of an oral prescription from an authorized prescriber, the pharmacist or pharmacy intern or pharmacy technician shall reduce the order to a written form prior to dispensing the medication. As an alternative to recording such prescriptions on paper forms, a pharmacist may enter the prescription information directly into the pharmacy's dispensing information system. In the event a pharmacy intern or pharmacy technicians transcribes such a prescription, the supervising pharmacist shall initial or countersign the prescription form prior to processing the prescription.

2. The pharmacist shall not select an equivalent drug product when the authorized prescriber or his agent has verbally indicated a specific brand name drug or product is ordered.

3. The pharmacist may select an equivalent drug product if the authorized prescriber or his agent has given his approval to the equivalent drug product interchange. The patient shall be informed of, and consent to, the proposed cost saving interchange.

E. Electronic Prescriptions

1. The prescription shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, DEA registration number.

2. The pharmacist shall not select an equivalent drug product when the prescriber indicates "Dispense as Written", "DAW" or "Brand Medically Necessary" and transmits his electronic signature. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and consents to, the proposed cost saving interchange.

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

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, LR 41:98 (January 2015).

Malcolm J. Broussard
Executive Director

1501#010

RULE

Department of Health and Hospitals
Board of Pharmacy

Special Event Pharmacy Permit
(LAC 46:LIII.Chapter 24)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy has amended Chapter 24, Limited Service Providers, of its rules by adding Subchapter B, Special Event Pharmacy Permit. The Rule is intended to authorize the issuance of a pharmacy permit to the sponsor of a special event, e.g., medical missions, to facilitate the dispensing of prescription medications to patients at the special event. The Rule establishes the general requirements and standards of practice for pharmacies operating with a special event pharmacy permit.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 24. Limited Service Providers
Subchapter A. Durable Medical Equipment
§2409. (Reserved)
Subchapter B. Special Event Pharmacy Permit
§2411. Special Event Pharmacy Permit

A. For good cause shown, the board may issue a special event pharmacy permit when the scope, degree, or type of pharmacy practice or service to be provided is of a special, limited, or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions as requested by the applicant and imposed by the board in cases where certain requirements or standards of practice may be waived.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1223.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:100 (January 2015).

§2413. General Requirements

A. Authority and Limitation

1. A special event pharmacy permit shall authorize the permit holder to procure and possess prescription and non-prescription drugs and devices, and hold such items for immediate administration directly to a patient and/or dispense such items to a patient for later use upon the order of a practitioner with prescriptive authority.

2. In the absence of a Louisiana controlled dangerous substance (CDS) license, the holder of a special event pharmacy permit shall not procure or possess any controlled dangerous substances.

B. Licensing Procedure

1. A person or other entity desiring to obtain a special event pharmacy permit shall complete the application form supplied by the board and submit it with any required attachments and the application fee to the board.

2. The applicant shall provide a complete physical address reflecting the location where the applicant will hold the drugs and devices and engage in the activity for which the permit is acquired. The board shall not issue more than one permit for the same physical space.

3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.

4. A person or other entity who knowingly or intentionally submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2).

5. Once issued, the special event permit shall expire 30 days thereafter. No person or other entity shall operate a special event pharmacy with an expired permit; the continued operation of a special event pharmacy with an expired permit shall constitute a violation of R.S. 37:1241(A)(12). Upon written request to the board, and with the concurrence of the board's president and executive director, the expiration date of the special event pharmacy permit may be extended up to an additional 30 days. No special event pharmacy permit shall be valid for more than 60 days.

C. Maintenance of Permit

1. A special event pharmacy permit shall be valid only for the person or other entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a special event pharmacy permit be valid for any premises other than the physical location for which it is issued.

2. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall not serve or be used as an additional or second permit.

D. Closure of Permit

1. At the conclusion of the special event, the permit holder shall terminate the dispensing and/or distribution of drugs and/or devices from the pharmacy.

2. Disposition of Inventory

a. Controlled Dangerous Substances Listed in Schedule II. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by an executed DEA Form 222, or its successor. Alternatively, these drugs shall be inventoried on the DEA Form 41 (registrant's inventory of drugs surrendered), or its successor, and then either returned to the regional DEA office or destroyed, but only pursuant to permission from the DEA or agent of the board. The permit holder shall retain triplicate copies of returns, transfers, and/or destructions.

b. Controlled Dangerous Substances Listed in Schedules III, IV, or V. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by appropriate inventory records. Alternatively, these drugs shall be inventoried on the DEA Form 41, or its successor, and then either returned to the

regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board.

c. All Other Prescription and Non-prescription Drugs and/or Devices. These items shall be returned to the supplier, transferred to an authorized registrant, or destroyed.

3. Surrender of Credentials and Board Notice

a. All drugs, devices, prescription records and other pharmacy records have been removed from the premises, the permit holder shall prepare and render a final closure notice to the board. The notice shall contain the following:

i. disposition and destination of all drugs and/or devices held by the pharmacy;

ii. disposition and destination of all prescriptions and medical orders dispensed or administered to patients;

iii. disposition and destination of all other pharmacy records, including acquisition, inventory, and disposition records for all drugs and/or devices;

iv. the commitment to store such records for no less than two years following the closure of the pharmacy, and further, to make any and all such records available for inspection by the board no later than 72 hours following a request from the board;

v. the certification that all signage indicating the presence of a pharmacy has been removed from the premises;

vi. the confirmation of the surrender of any federal DEA registration held by the pharmacy to the regional DEA office; and

vii. the original and all duplicate copies of the special event pharmacy, and if applicable, Louisiana CDS license.

b. The pharmacist-in-charge of the special event pharmacy permit has the primary responsibility for the proper closure of the pharmacy permit. However, in the event the pharmacist-in-charge fails to complete the task, then the permit holder shall be responsible for the proper closure of the pharmacy permit.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:100 (January 2015).

§2415. Standards of Practice

A. General Requirements

1. The special event pharmacy shall be of sufficient size and shall contain sufficient fixtures, equipment, and supplies commensurate with the scope of practice for that pharmacy, provided:

a. the pharmacy shall be of sufficient size to allow for the safe and proper storage of prescription drugs and, if applicable, controlled dangerous substances;

b. all areas where drugs and devices are stored shall be dry, well-lighted, well ventilated, and maintained at temperatures which will ensure the integrity of drugs prior to their dispensing as stipulated by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product labeling unless otherwise indicated by the board;

c. the pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the pharmacist is not present; and

d. prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.

2. The pharmacist-in-charge of the special event pharmacy shall be responsible for all pharmacy operations including supervision of all pharmacy personnel.

3. The pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times the pharmacy is open for the transaction of business.

4. The pharmacy shall have a sufficient number of pharmacists and/or other pharmacy personnel on duty to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

5. When the pharmacy is closed or there is no pharmacist on duty, other individuals shall not have access to the pharmacy except for temporary absences as provided for in Chapter 11 of these rules.

6. The special event pharmacy shall comply with the recordkeeping requirements identified in Chapter 11 of these rules.

7. The compounding of preparations in a special event pharmacy shall be accomplished in compliance with the current federal standards applicable to such practices: USP chapter 795, or its successor, for the compounding of non-sterile preparations and USP chapter 797, or its successor, for the compounding of sterile preparations.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:101 (January 2015).

Malcolm J. Broussard
Executive Director

1501#011

RULE

Department of Health and Hospitals
Bureau of Health Services Financing

Crisis Receiving Centers
Licensing Standards
(LAC 48:I.Chapters 53 and 54)

The Department of Health and Hospitals, Bureau of Health Services Financing has adopted LAC 48:I.Chapters 53 and 54 in the Medical Assistance Program as authorized by R.S. 36:254 and R.S. 28:2180.14. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Title 48
PUBLIC HEALTH—GENERAL
Part 1. General Administration
Subpart 3. Licensing and Certification
Chapter 53. Level III Crisis Receiving Centers
Subchapter A. General Provisions
§5301. Introduction

A. The purpose of this Chapter is to:

1. provide for the development, establishment, and enforcement of statewide licensing standards for the care of patients and clients in level III crisis receiving centers (CRCs);