

## **Final 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 (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. 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.

# Louisiana Administrative Code

## Title 46 – Professional and Occupational Standards

### Part LIII: Pharmacists

#### Chapter 24. Limited Service Providers

##### Subchapter A. Durable Medical Equipment

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##### §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 & 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 thirty 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 thirty days. No special event pharmacy permit shall be valid for more than sixty 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 & Board Notice
    - a. When 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).