



Louisiana Board of Pharmacy

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November 18, 2014

Senator John A Alario Jr., President
Louisiana Senate
PO Box 94183
Baton Rouge, LA 70804

Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2014-6 ~ Special Event Pharmacy Permit

Dear Senator Alario:

As we indicated in our first report to you on September 9, 2014, the Board is currently amending its rules to create a new classification of pharmacy permit intended to authorize the establishment of a pharmacy for a limited period of time, e.g., medical missions. Subsequent to our Notice of Intent published in the September 20, 2014 edition of the Louisiana Register, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on October 30, 2014.

We received no comments or testimony concerning the proposed rule prior to or during the public hearing. During their subsequent meeting on November 13, the Board determined no revisions were necessary to the proposed rule as originally published, and further, determined it appropriate to move forward with the proposed rule.

You should find the following documents appended to this letter:

- Notice of Intent, as published in the September 2014 Louisiana Register
- Summary of Comments from October 30, 2014 Public Hearing
- Full text of proposed rule

Subject to review by the Joint Legislative Oversight Committee on Health and Welfare, the Board proposes to publish the original proposed rule as a Final Rule in the January 20, 2015 edition of the Louisiana Register. 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-H&W@legis.la.gov
Editor, Louisiana Register – Reg.Submission@la.gov
Reference File

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 40:

§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 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.

NOTICE OF INTENT

**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 hereby gives notice of its intent to amend Chapter 24, Limited Service Providers, of its rules by adding Subchapter B, Special Event Pharmacy Permit. The proposed 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 proposed Rule establishes the general requirements and standards of practice for pharmacies operating with a special event pharmacy permit.

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 40:

§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 40:

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. We anticipate 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. We anticipate 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. We anticipate no effect on the functioning of the family.

4. The effect on family earnings and family budget. We anticipate no effect on family earnings and the family budget.

5. The effect on the behavior and personal responsibility of children. We anticipate 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. We anticipate 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. We anticipate no impact on household income, assets, and financial security.

2. The effect on early childhood development and preschool through postsecondary education development. We anticipate no impact early childhood development or preschool through postsecondary education development.

3. The effect on employment and workforce development. We anticipate no positive impact on employment and workforce development.

4. The effect on taxes and tax credits. We anticipate no impact on taxes or tax credits.

5. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance. To the extent a medical mission operates a pharmacy as part of their mission, it is possible they may receive needed prescription medication at the mission instead of taking those prescriptions to an existing commercial pharmacy.

Small Business Statement

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. The proposed rules are flexible for the establishment of a pharmacy for a

limited period of time. As long as the standards for security, environmental integrity, and confidentiality are maintained, the permit owner has flexibility on how to achieve those requirements.

2. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses. There are no schedules or deadlines or reporting requirements in the proposed Rule.

3. The consolidation or simplification of compliance or reporting requirements for small businesses. There are no reporting requirements in the proposed Rule.

4. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule. There are no design standards in the proposed Rule. The permit owner has flexibility on how to achieve the operational standards.

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 because the proposed Rule provides flexibility in how the pharmacy achieves the operational standards.

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. We anticipate 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. To the extent the sponsor of a medical mission operates a pharmacy as part of their special event, that pharmacy could be operated for a lower cost than a routine commercial pharmacy.

3. The overall effect on the ability of the provider to provide the same level of service. We anticipate no effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments to Malcolm J. Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Thursday, October 30, 2014 at 9 a.m. in the board office. At that time, 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 noon that same day.

Malcolm J. Broussard
Executive Director

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES
RULE TITLE:**

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

The proposed rule will result in a cost to the Board of Pharmacy of approximately \$2,000 for printing costs of the proposed and final rules in FY 15. The proposed rule establishes a new type of pharmacy permit for special events of a temporary nature.

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

There will be no material impact on revenue collections of state or local governmental units from the proposed rule. The proposed rule change addresses special event permits that are requested on an infrequent basis.

**III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO
DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL
GROUPS (Summary)**

The proposed rule directly affects those organizations sponsoring medical missions or other similar types of special events. The proposed rule establishes a new type of pharmacy permit that can be operated for a limited period of time. The proposed rule provides operational standards for the security and environmental integrity of the medications as well as for the integrity and confidentiality of prescriptions and other healthcare information, but provides flexibility to the permit holder in how those standards are to be achieved. That flexibility can reduce the start-up and operating costs of the pharmacy.

**IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT
(Summary)**

The proposed rule will not have any effect on competition or employment.

Malcolm J. Broussard
Executive Director
1409#044

John D. Carpenter
Legislative Fiscal Officer
Legislative Fiscal Office



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Summary of Testimony & Public Comments
re
Regulatory Project 2014-6 ~ Special Event Pharmacy Permit
at
October 30, 2014 Public Hearing

There were no comments received prior to or during the public hearing.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

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Subchapter A. Durable Medical Equipment

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§2409. (Reserved)

Subchapter B. Special Event Pharmacy Permit

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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.

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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.

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 - 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.
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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.
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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.

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