



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov)



January 10, 2013

Senator John A Alario, Jr, President  
Louisiana Senate  
PO Box 94183  
Baton Rouge, LA 70804-9183

## Electronic Mail – Read Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2013-2 ~ Hospital Off-Site Satellite Pharmacy

Dear Senator Alario:

The Board has initiated the rulemaking process to establish a new type of pharmacy permit for hospital off-site satellite pharmacies. In connection with this regulatory project, you should find the following documents in this packet:

- Notice of Intent & Solicitation of Comments
- Proposed Rule
- Fiscal & Economic Impact Statement
- Family Impact Statement
- Poverty Impact Statement
- Regulatory Flexibility Analysis

As indicated in the solicitation, we will convene a public hearing on February 27, 2013 to receive public comments and testimony on this proposal. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information, please contact me directly at [mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov) or 225.925.6481

For the Board:

Malcolm J Broussard  
Executive Director

cc: Chair, Senate Health & Welfare Committee  
Speaker, House of Representatives  
Chair, House Health & Welfare Committee  
Director, Community Outreach Services, La. Economic Development  
Editor, Louisiana Register  
Reference File

## **Notice of Intent**

### **Department of Health and Hospitals Board of Pharmacy**

#### Hospital Off-Site Satellite Pharmacy (LAC 46:LIII.1525)

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 its chapter of rules for hospital pharmacies to authorize the use of satellite pharmacies by pharmacies located within hospitals. The proposed rule identifies the credentialing requirements and standards of practice applicable to such satellite pharmacies.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding this proposed rule. A public hearing on this proposed rule is scheduled for Wednesday, February 27, 2013 at 9:00 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 12:00 noon that same day.

Malcolm J Broussard  
Executive Director  
Louisiana Board of Pharmacy

# Louisiana Administrative Code

## Title 46 – Professional and Occupational Standards

### Part LIII: Pharmacists

#### Chapter 15. Hospital Pharmacy

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#### §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 and Hospitals, or its successor, the location of which is physically separate from the location of the provider pharmacy.

...

Provider Pharmacy – a hospital pharmacy which provides administrative control, staffing as well as products and services to a hospital off-site satellite pharmacy.

...

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

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#### §1525. Hospital Off-Site Satellite Pharmacy

##### A. Issuance and Maintenance of Permit

1. A hospital pharmacy may establish a hospital off-site satellite pharmacy within a facility bearing the same hospital license number as the facility housing the provider pharmacy.
2. The provider pharmacy, acting through its pharmacist-in-charge, shall make application for the satellite pharmacy permit using a form and process specified by the board.
3. The applicant shall pay the fee for the initial issuance and renewal as specified in La. R.S. 37:1184.
4. Once issued, the satellite pharmacy permit shall expire at midnight on December 31 of each year, unless suspended or revoked earlier by the board.
5. The satellite pharmacy shall renew its permit using the form and process specified by the board.
6. The operation of a hospital off-site satellite pharmacy without a pharmacy permit, or with an expired permit, shall constitute a violation of La. R.S. 37:1241.A(12).
7. In the event a provider pharmacy sustains a change of ownership sufficient to require a new pharmacy permit, the hospital off-site satellite pharmacy shall also obtain a new pharmacy permit.
8. In the event a provider pharmacy closes permanently and surrenders its permit, the hospital off-site satellite pharmacy shall also close and surrender its permit.

##### B. General Requirements

1. The hospital off-site satellite 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/or controlled substances;
  - b. All areas where drugs and devices are stored shall be dry, well-lighted, well ventilated, and maintained in a clean and orderly condition, and more specifically, storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the United States Pharmacopeia (USP) and/or the 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 health care information shall be maintained in a manner that protects the integrity and confidentiality of such information.

2. The pharmacist-in-charge of the provider pharmacy shall be responsible for all pharmacy operations involving the hospital off-site satellite pharmacy including supervision of pharmacy personnel.
3. The hospital off-site satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times the hospital off-site satellite pharmacy is open for the transaction of business.
4. The hospital off-site satellite hospital pharmacy shall have a sufficient number of pharmacists on duty to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.
5. When the hospital off-site satellite pharmacy is closed or there is no pharmacist on duty, other individuals shall not have access to the hospital off-site satellite pharmacy except for temporary absences as provided for in Chapter 11 of these rules.
6. The provider pharmacy and the hospital off-site satellite pharmacy shall have:
  - a. the same owner; and
  - b. share a common electronic file or have the appropriate technology to allow access to sufficient information necessary or required to process a prescription or medical order.
7. The hospital off-site satellite pharmacy shall comply with the recordkeeping provisions identified in Chapter 11 of these rules.
8. The compounding of preparations in a hospital off-site satellite pharmacy shall be accomplished in compliance with the current federal standards applicable to such practices: USP Chapter 797, or its successor, for the compounding of sterile preparations, and USP Chapter 795, or its successor, for the compounding of non-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

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

Person Preparing Statement: **Malcolm J. Broussard**  
Executive Director  
Phone: **(225) 925-6481**  
Return Address: **3388 Brentwood Drive**  
**Baton Rouge, LA 70809-1700**

Dept.: **Health and Hospitals**  
Office: **Board of Pharmacy**  
Title: **Hospital Off-Site Satellite Pharmacy**  
Date Rule Takes Effect: **May 20, 2013 (est)**

SUMMARY  
(Use complete sentences)

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

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

It is estimated that implementation of the proposed rule will cost the agency \$500 in FY 12-13 for printing costs.

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

No impact on state or local government revenue collections is anticipated as a result of the proposed rule change. The Board seeks to amend its existing rules to provide a new classification of pharmacy permit – hospital off-site satellite pharmacy – to be used by hospital pharmacies seeking to provide pharmacy products and services at its own distant campuses without the necessity of an additional full service pharmacy permit. The proposed rule identifies the new credentials, establishes credentialing requirements, and establishes the standards of practice for such satellite pharmacies. The credentialing requirements will be less strict for the off-site satellite pharmacy as opposed to the full service pharmacy permit. However, the fees will be the same as a full service pharmacy permit so there is no new anticipated revenue as a result of this rule change.

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

The proposed rule change may result in a reduction in costs associated with the recordkeeping and reporting requirements for satellite pharmacies as compared to full service pharmacies in hospitals or health systems.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

No effect on competition and employment is anticipated as a result of this proposed rule.

  
Signature of Agency Head or Designee

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

**December 21, 2012**  
Date of Signature

  
Legislative Fiscal Officer or Designee

**1/9/13**  
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

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

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

The Board seeks to amend its existing rules to provide a new classification of pharmacy permit – hospital off-site satellite pharmacy, to be used by hospital pharmacies seeking to provide pharmacy products and services at its own distant campuses without the necessity of an additional full service pharmacy permit. The proposed rule identifies the new credential, establishes credentialing requirements, and establishes the standards of practice for such satellite pharmacies. A copy of the Notice of Intent is appended.

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

As traditional hospitals evolve into health systems, progressing from single stand alone facilities to multiple campuses, hospital pharmacies need to adjust their medication distribution procedures accordingly. One of the challenges faced by licensees is the address specificity of the pharmacy permit – the pharmacy permit acquired by a hospital pharmacy authorizes medication distribution and dispensing services at the address noted on the permit. While this authority works for a single campus facility, it introduces limitations for multiple campus health systems. The Board proposes to allow a hospital pharmacy to establish a hospital off-site satellite pharmacy permit, which would allow a hospital pharmacy to establish one or more satellite pharmacies at one or more of its distant campuses. The proposed rule will not require the satellite pharmacy to possess the same physical space requirements (minimum 300 square feet) required of regular pharmacy permits. This and other features will allow the hospital pharmacy to centralize its medication distribution functions but still provide products and services to the distant campus effectively and efficiently.

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

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

The proposed rule change will not require any increase in the expenditure of funds by the Board.

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

(a)  Yes. If yes, attach documentation.

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

The Board operates totally on self-generated funds; we do not receive any appropriations from the legislature.

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

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

Given the criteria in the statutory definition of 'small businesses,' we are unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data. We do know there are 154 hospital pharmacies currently licensed in the state, ranging from small rural hospitals to large urban facilities.

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

The proposed rule change would not change any recordkeeping or reporting requirements, but it could simplify the process by centralizing all such activities under a single pharmacy permit instead of the potential multiple pharmacy permits.

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

**Given the absence of physical specifications, we envision minimal impact on small businesses.**

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

**We can discern no alternative methods of achieving the same purpose of the proposed rule.**

FISCAL AND ECONOMIC IMPACT STATEMENT  
WORKSHEET

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

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

<u>COSTS</u>	<u>FY 12-13</u>	<u>FY 13-14</u>	<u>FY 14-15</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$0
OPERATING EXPENSES	\$ 500	\$ 0	\$0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$0
OTHER CHARGES	\$ 0	\$ 0	\$0
EQUIPMENT	\$ 0	\$ 0	\$0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$0
<b>TOTAL</b>	<b>\$ 500</b>	<b>\$ 0</b>	<b>\$0</b>
POSITIONS (#)	0	0	0

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

We anticipate the printing costs for the implementation of the proposed rule to approximate \$500 (\$250 for the notice of intent and the same amount for the final rule).

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

<u>SOURCE</u>	<u>FY 12-13</u>	<u>FY 13-14</u>	<u>FY 14-15</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$0
AGENCY SELF-GENERATED	\$ 500	\$ 0	\$0
DEDICATED	\$ 0	\$ 0	\$0
FEDERAL FUNDS	\$ 0	\$ 0	\$0
OTHER (Specify)	\$ 0	\$ 0	\$0
<b>TOTAL</b>	<b>\$ 500</b>	<b>\$ 0</b>	<b>\$0</b>

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

The Board currently has sufficient funds budgeted and available to complete the promulgation process.

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

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

We can discern no impact on local governmental units from the proposed rule.

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

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

<u>SOURCE</u>	<u>FY 12-13</u>	<u>FY 13-14</u>	<u>FY 14-15</u>
STATE GENERAL FUND	\$0	\$0	\$0
AGENCY SELF-GENERATED	\$0	\$0	\$0
DEDICATED FUNDS	\$0	\$0	\$0
FEDERAL FUNDS	\$0	\$0	\$0
LOCAL FUNDS	\$0	\$0	\$0
<b>TOTAL</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

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

The fee for the satellite pharmacy permit will be the same as the regular pharmacy permit. The advantage is for one type of permit over another and not the addition of more permits; therefore, we envision no change in the revenue collections for the Board or other local governmental units.

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

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

The groups directly affected by the proposed rule change are those hospital pharmacies located within hospitals or health systems operating on multiple campuses. To the extent there may be additional costs associated with maintaining multiple full service pharmacy permits at multiple campuses in lieu of maintaining satellite pharmacy permits at the same locations, there may be a reduction in such costs resulting from the simplification of the recordkeeping and reporting requirements for all pharmacies. We are not able to quantify such cost savings.

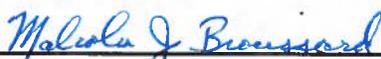
Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

We do not anticipate any impact on receipts or revenue resulting from this proposed rule.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

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

We envision no impact on competition or employment in the public or private sectors.

  
\_\_\_\_\_  
Signature of Agency Head or Designee

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

December 21, 2012  
\_\_\_\_\_  
Date of Signature

FAMILY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

Person Preparing

Statement: **Malcolm J. Broussard**  
**Executive Director**

Dept.: **Health and Hospitals**

Office: **Board of Pharmacy**

Telephone: **(225) 925-6481**

Title: **Hospital Off-Site Satellite  
Pharmacy**

Return Address: **3388 Brentwood Drive**  
**Baton Rouge, LA 70809-1700**

Date Rule

Takes Effect: **May 20, 2013 (est)**

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

I. The effect on the stability of the family.

**We can discern no effect on the stability of the family.**

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

**We can discern no effect on the authority and rights of parents regarding the education and supervision of their children.**

III. The effect on the functioning of the family.

**We can discern no effect on the functioning of the family.**

IV. The effect on family earnings and family budget.

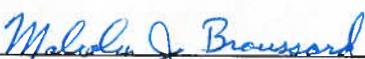
**We can discern no effect on family earnings or family budget.**

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

**We can discern no effect on the behavior and personal responsibility of children.**

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

**We can discern no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.**

  
\_\_\_\_\_  
Signature of Agency Head or Designee

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

**January 10, 2013**  
\_\_\_\_\_  
Date of Signature

POVERTY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

Person Preparing

Statement: **Malcolm J. Broussard**  
**Executive Director**

Dept.: **Health and Hospitals**

Office: **Board of Pharmacy**

Telephone: **(225) 925-6481**

Title: **Hospital Off-Site Satellite  
Pharmacy**

Return Address: **3388 Brentwood Drive**  
**Baton Rouge, LA 70809-1700**

Date Rule  
Takes Effect: **May 20, 2013 (est)**

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. The following statements will be published in the Louisiana Register with the proposed agency rule.

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

**We anticipate no impact from the proposed rule on household income, assets, or financial security.**

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

**We anticipate no impact from the proposed rule on early childhood development or preschool through postsecondary education development.**

III. The effect on employment and workforce development.

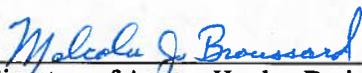
**We anticipate no impact from the proposed rule on employment or workforce development.**

IV. The effect on taxes and tax credits.

**We anticipate no impact from the proposed rule on taxes or tax credits.**

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

**We anticipate no impact from the proposed rule on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.**

  
\_\_\_\_\_  
Signature of Agency Head or Designee

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

**January 10, 2013**  
\_\_\_\_\_  
Date of Signature

REGULATORY FLEXIBILITY ANALYSIS  
FOR ADMINISTRATIVE RULES

Person Preparing

Statement: **Malcolm J. Broussard**  
**Executive Director**

Dept.: **Health and Hospitals**

Office: **Board of Pharmacy**

Telephone: **(225) 925-6481**

Title: **Hospital Off-Site Satellite  
Pharmacy**

Return Address: **3388 Brentwood Drive**  
**Baton Rouge, LA 70809-1700**

Date Rule

Takes Effect: **May 20, 2013 (est)**

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

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

The proposed rule change would not change any recordkeeping or reporting requirements, but it could simplify the process by centralizing all such activities under a single pharmacy permit instead of the potential multiple pharmacy permits.

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

There are no changes in the deadlines for compliance or reporting requirements.

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

There are no changes in the reporting requirements.

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

The proposed rule change eliminates the specific minimum physical specifications identified for full service pharmacy permits, so satellite pharmacies are free to select different design and operational standards.

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

There are no exemptions for small businesses in the proposed rule.

  
\_\_\_\_\_  
Signature of Agency Head or Designee

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

**January 10, 2013**  
\_\_\_\_\_  
Date of Signature