



# Louisiana Board of Pharmacy

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



January 10, 2012

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

Re: Report No. 1 of 3 for Regulatory Project 2011-1 ~ Pharmacist-in-Charge (PIC) Requirements  
**Report No. 1 of 3 for Regulatory Project 2011-2 ~ Cognitive Services**  
Report No. 1 of 3 for Regulatory Project 2011-7 ~ Penal Pharmacy  
Report No. 1 of 3 for Regulatory Project 2012-1 ~ E-Communications  
Report No. 1 of 3 for Regulatory Project 2012-2 ~ Hospital Pharmacy  
Report No. 1 of 3 for Regulatory Project 2012-3 ~ Remote Processing of Medical Orders

Dear Senator Alario:

The Board has initiated the rulemaking process to amend six different sections of its rules. For each of the six projects identified above, you should find the following documents in this packet:

- Insertion Order for the Louisiana Register
- Notice of Intent
- Proposed Rule
- Fiscal & Economic Impact Statement
- Regulatory Flexibility Analysis
- Family Impact Statement

As indicated in the notice, we will convene a public hearing on February 28, 2012 to receive testimony and public comments on these proposals. We will summarize those comments and our responses thereto in our next report to you. If you have any questions or need additional information, please contact me directly at 225.925.6481 or [mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov).

For the Board:

Malcolm J. Broussard  
Executive Director

OFFICE OF THE STATE REGISTER INSERTION ORDER (eff.08/02)  
Claiborne Building 1201 North Third Street Suite 3-220 Post Office Box 9489  
Baton Rouge, LA 70804-9095 (225)342-5015 FAX (225)342-0284

RECEIVED

JAN 10 2011

(SUBMIT A SEPARATE INSERTION ORDER PER DOCUMENT)

OFFICE OF THE STATE REGISTER

EMERGENCY RULE  NOTICE OF INTENT  RULE  POTPOURRI

REFER TO INSTRUCTIONS ON REVERSE SIDE

This is your authority to publish in the (month) January, 20 12 *Louisiana Register* the document indicated above.

Board of Pharmacy

Office/Board/Commission promulgating this document

Malcolm J Broussard Executive Director

(name) (title)  
Name and title of person whose signature will appear in the publication (at the end of the document)

Health and Hospitals

Department under which office/board/commission is classified

Malcolm J Broussard 225.925.6481 225.922.0316

(name) (phone) (fax)  
Name, phone number, and FAX number of person to contact regarding this document

mbroussard@pharmacy.la.gov

E-mail address of contact person

Provide a short descriptive listing for this document to be used in the *Louisiana Register's* TABLE OF CONTENTS/INDEX (note: this description should match the fiscal statement title, if sending a Notice of Intent:

\*If sending a diskette, indicate the name of the file on diskette:

Cognitive Services

**Important:** If submitting both an Emergency Rule (ER) and a Notice of Intent (NOI) to be published this month, AND if the rule text in the ER is identical to the rule text in the NOI, check here:

Malcolm J Broussard  
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director

Print Name and Title of Agency Head or Designee

CERTIFICATION OF AVAILABLE FUNDS

DOCUMENT # \_\_\_\_\_

**ISIS AGENCY:** I certify the availability of fiscal year \_\_\_\_\_ appropriated funds for the payment of the above referenced publication and authorize the processing of an Interagency Billing with the following coding on the 30th of the month of the publication. Attach supplemental sheet for additional lines of coding.

AGENCY ORGANIZATION # OBJECT SUB-OBJECT REPORTING CATEGORY

**NON-ISIS AGENCY:** I certify the availability of fiscal year 11-12 appropriated funds for the payment of the above referenced publication and agree to place corresponding invoice in line for payment upon receipt.

Billing Address for Agencies:

Louisiana Board of Pharmacy

Agency Name

3388 Brentwood Drive

Street Address or Post Office Box

Baton Rouge LA 70809

City State Zip Code

Malcolm J Broussard 225.925.6481  
Signature of Agency Head or Designee - Phone #

Lines/Other Charges \_\_\_\_\_ Typesetting \$ \_\_\_\_\_ TOTAL \$ \_\_\_\_\_

## **Notice of Intent**

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

#### **LAC 46:LIII.525 – Cognitive Services**

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 create a new section of rules, §525 – *Cognitive Services*. The new rule will define cognitive (other than dispensing) services provided by a pharmacist for the benefit of Louisiana residents, and will require those pharmacists performing such services to possess a Louisiana pharmacist license.

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 Tuesday, February 28, 2012 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 5. Pharmacists**

...

**Subchapter B. Professional Practice Procedures**

...

**§525. Cognitive Services**

A. Definitions

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

Cognitive services – those acts and operations related to a patient’s drug therapy that are judgmental in nature, based on knowledge, and derived from empirical factual information. Such services may include, but are not necessarily limited to, the following:

- a. Drug regimen review, drug use evaluation and drug information.
- b. Provision of advice and counsel on drugs, the selection and use thereof to the facility, the patients therein, the health care providers of the facility regarding the appropriateness, use, storage, handling, administration, and disposal of drugs within the facility.
- c. Participation in the development of policies and procedures for drug therapy within the institution, including storage, handling, administration, and disposing of drugs and devices.
- d. Assuring the compliance with all applicable laws, rules, and regulations.

- e. Provision of educational and drug information sources for the education and training of the facility health care professionals.
- f. Accepting responsibility for the implementation and performance of review of quality-related or sentinel events.

B. Practice

- 1. A pharmacist who provides cognitive services to Louisiana residents shall be licensed by the board.
- 2. Cognitive services provided from outside a permitted pharmacy may not include the physical dispensing of medication to patients.

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  
Dept.: **Health and Hospitals**  
Office: **Board of Pharmacy**  
Phone: **(225) 925-6481**  
Title: **Cognitive Services**  
Return Address: **3388 Brentwood Drive**  
**Baton Rouge, LA 70809-1700**  
Date Rule Takes Effect: **June 1, 2012 (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 11-12, for printing costs.

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

The proposed rule will require those pharmacists performing cognitive services for the benefit of Louisiana residents to possess a Louisiana pharmacist license. There is no measurable impact on revenue collections for state or local governmental units at this time. However, should out-of-state pharmacists decide to pursue the practice of cognitive services in the state of Louisiana in future, the Board's revenue will increase by approximately \$1,000 per application for licensure and \$100 annually per renewal.

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

The cost to out-of-state pharmacists to acquire the initial pharmacist license in Louisiana is approximately \$1,000, and the annual renewal fee is \$100.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

We can discern no measurable effect on competition or employment in this state.

  
Signature of Agency Head or Designee

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

December 20, 2011  
Date of Signature

  
Legislative Fiscal Officer or Designee

1-4-2012  
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 proposes to create a new rule defining cognitive services to be provided by a pharmacist for the benefit of Louisiana residents, and then require any pharmacist providing such services to possess a Louisiana pharmacist license.

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.

The Board has observed a trend of pharmacists located in other states and countries seeking to provide professional pharmacy services for the benefit of Louisiana residents. To facilitate that growing trend of services provided through electronic communications and still provide the protection to Louisiana residents afforded through state licensure, the Board seeks to identify those services and require those pharmacists to acquire a Louisiana pharmacist license.

- 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.

We can discern no measurable impact on the Board's expenditures, other than the printing costs of promulgation. Although there are costs to process licensure applications, those costs are offset by the application fees.

- (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 Legislature has not appropriated the funds. The Board of Pharmacy operates purely on self-generated funds, and the Board has sufficient funds budgeted and available for the promulgation process.

- 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. However, we can estimate the number using a specific classification of pharmacy permits; in particular, we do not believe the number of impacted small businesses would exceed 600.

- (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.

There are no reporting requirements or costs associated with the proposed rule.

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

We can discern no measurable effect on small businesses from the proposed rule.

- (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 11-12</u>	<u>FY 12-13</u>	<u>FY 13-14</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). We can discern no additional changes in the Board's costs.

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

<u>SOURCE</u>	<u>FY 11-12</u>	<u>FY 12-13</u>	<u>FY 13-14</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.

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 11-12</u>	<u>FY 12-13</u>	<u>FY 13-14</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.

We can discern no impact on revenue collections of state and 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.

To the extent any pharmacists located in other jurisdictions seek to provide the described services to Louisiana residents, the pharmacist would need to acquire a Louisiana pharmacist license prior to engaging in such activity. The cost of acquiring the initial pharmacist license is approximately \$1,000, depending on the method of licensure, and the annual renewal fee is \$100.

The licensure process requires the submission of application forms to document eligibility for the credential, as well as successful completion of the required licensure examinations. Depending on the licensure method, there may be a requirement for a personal interview. Finally, the Board conducts criminal background checks on all applicants, the process for which is prescribed in state pharmacy law.

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.

To the extent any pharmacists seeking to provide the described services submit applications for licensure to the Board, the Board would receive application fees, which would be used to offset the cost of processing the applications and issuing the licenses. We are not able to estimate or quantify any potential applications 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 can discern no measurable impact on competition or employment in the public or private sectors of this state, although it is possible the rule may facilitate competition or affect employment in other jurisdictions.

Malcolm J. Broussard  
Signature of Agency Head or Designee

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

December 20, 2011  
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: **Cognitive Services**

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

Date Rule  
Takes Effect: **June 1, 2012 (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 seeks to identify professional, non-dispensing services provided by pharmacists to Louisiana residents and then requires such pharmacists to possess a Louisiana pharmacist license.

The proposed rule places no compliance or reporting requirements for small businesses in this state.

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

There are no schedules or deadlines for reporting requirements in the proposed rule.

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

There are no reporting requirements in the proposed rule.

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

There are no design or operational standards in the proposed rule.

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

The proposed rule seeks to require any pharmacist providing cognitive services to any Louisiana resident to possess a Louisiana pharmacist license. The persons affected by the proposed rule would be pharmacists practicing in another state. It is possible businesses in another state that provide cognitive services to Louisiana residents may need to require their pharmacist to also obtain a Louisiana pharmacist license. In the absence of any other protections for Louisiana residents, the Board believes an exemption for pharmacists employed by small businesses in another state is not in the public's best interest.

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

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

December 20, 2011  
Date of Signature

FAMILY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

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

Dept.: **Health and Hospitals**  
Office: **Board of Pharmacy**  
Title: **Cognitive Services**  
Date Rule  
Takes Effect: **June 1, 2012 (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.

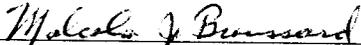
We can discern no effect on family earnings or family budget.

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

December 20, 2011  
Date of Signature