



Louisiana Board of Pharmacy

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March 10, 2014

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

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

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2014-1 ~ Prescription Monitoring Program Delegates

Dear Senator Alario:

The Board has initiated the rulemaking process to amend the existing rules relative to the state prescription monitoring program. In compliance with Act 110 of the 2013 Legislature, these proposed rules will allow a prescriber or dispenser to appoint a delegate for the purpose of accessing and retrieving information from the prescription monitoring program database. In connection with this regulatory project, you should find the following documents in this packet:

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

As indicated in the solicitation, we will convene a public hearing on April 29, 2014 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 or 225.925.6481.

For the Board:

Malcolm J Broussard
Executive Director

cc: Chair, Senate Health & Welfare Committee
Via Email: APA.S-H&W@legis.la.gov
Speaker, House of Representatives
Via Email: APA.HouseSpeaker@legis.la.gov
Chair, House Health & Welfare Committee
Via Email: APA.H-H&W@legis.la.gov
Director, Community Outreach Services, La. Economic Development
Via Email: Witty@la.gov
Editor, *Louisiana Register*
Via Email: Catherine.Brindley@la.gov
Reference File

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PMP Office
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Notice of Intent

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

Prescription Monitoring Program Delegates (LAC 46:LIII.Chapter 29)

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.*), and pursuant to the provisions of Act 110 of the 2013 Legislature, the Louisiana Board of Pharmacy hereby gives notice of its intent to amend several sections within *Chapter 29 – Prescription Monitoring Program* of its rules, to allow prescribers and dispensers to appoint delegates for the purpose of accessing and retrieving information from the prescription monitoring program database.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII – Pharmacists

Chapter 29. Prescription Monitoring Program

Subchapter A. General Operations

§2901. Definitions

- A. As used in this Chapter, the following terms shall have the meaning ascribed to them unless the context clearly indicates otherwise:

...

Delegate – a person authorized by a prescriber or dispenser who is also an authorized user (as described in §2917 of this Chapter) to access and retrieve program data for the purpose of assisting the prescriber or dispenser, and for whose actions the authorizing prescriber or dispenser retains accountability.

...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1345 (July 2007), amended LR 36:755 (April 2010), effective September 1, 2010, amended LR 39:314 (February 2013), amended LR

...

Subchapter C. Access to Prescription Monitoring Information

§2917. Authorized Direct Access Users of Prescription Monitoring Information

- A. The following persons may access prescription monitoring information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar protected health information under federal and state law and regulation:

1. persons authorized to prescribe or dispense controlled substances or drugs of concern, and their delegates, for the purpose of providing medical or pharmaceutical care for their patients, or for verifying their prescription records;

...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR 39:315 (February 2013), amended LR

§2919. Registration Procedures for Authorized Direct Access Users

- A. Authorized users of prescription monitoring information, and their delegates, shall comply with the following requirements to register with the board, in order to receive the appropriate credentials to access prescription monitoring information.
1. The applicant shall successfully complete the program's orientation course, and attach evidence of same to his application to the program.
 2. The applicant shall file an application with the program, using the form supplied by the program for that purpose.
 3. The board shall verify the practitioner applicant is in possession of a valid license to prescribe or dispense controlled substances, or in the case of an agency applicant, the board shall verify agency representation.
 4. Upon verification of all requirements, the board shall issue the appropriate credential necessary to access prescription monitoring information.
 5. Upon receipt of information that an authorized user no longer possesses authority to prescribe or

dispense controlled substances, the program shall terminate the user's credentials to access prescription monitoring information. If or when the user's authority to prescribe or dispense controlled substances is reinstated, the program may reinstate the user's credentials to access prescription monitoring information.

6. Prescribers and dispensers approved for access shall be responsible for the enabling and/or disabling of access privileges for their delegates, as well as the supervision of their activities.

AUTHORITY NOTE: Promulgated by R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR

§2921. Methods of Access to Prescription Monitoring Information

- A. Prescribers and dispensers as well as their delegates, once properly registered, may solicit prescription monitoring information from the program concerning their patients, or for verifying their prescription records. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.

...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR 39:315 (February 2013), amended LR

§2923. Unlawful Use or Disclosure of Prescription Monitoring Information

- A. If the program receives evidence of inappropriate or unlawful use or disclosure of prescription monitoring information by an authorized user or his delegate, the program shall refer that user to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007), amended LR

**FAMILY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

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

IV. The effect on family earnings and family budget.

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

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

We anticipate 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 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
FOR ADMINISTRATIVE RULES**

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.

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

We anticipate no impact on household income, assets, and financial security.

II. 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.

III. The effect on employment and workforce development.

We anticipate no positive impact on employment and workforce development.

IV. The effect on taxes and tax credits.

We anticipate no impact 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 on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

**REGULATORY FLEXIBILITY ANALYSIS
FOR ADMINISTRATIVE RULES**

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 reporting requirements for small businesses.

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 for small businesses.

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

There are no changes in the reporting requirements for small businesses.

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.

Since the proposed rule allows flexibility for the prescriber and dispenser to appoint and dismiss their own delegates, there are no exemptions for small businesses in the proposed rule.

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, April 29, 2014 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

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: **Prescription Monitoring
Program Delegates**

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

Date Rule Takes Effect: **June 20, 2014 (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)

The Board has allocated \$500 for printing costs of the proposed rule in FY 2013-2014, and the same amount for printing of the final rule in FY 2014-2015. The proposed rule will result in no costs or savings to local governmental units. The proposed rule codifies the allowance of delegates to access prescription monitoring information in certain circumstances as per Act 110 of the 2013 Regular Session of the Louisiana Legislature.

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

There will be no impact on revenue collections of state or local governmental units from the proposed rule.

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

Prescribers and dispensers with authorized access to the prescription monitoring program database will be allowed to appoint delegates for the purpose of accessing and retrieving that information. The use of delegates could free up time for prescribers and dispensers for other tasks, including direct patient care, and further, could reduce the labor costs associated with such data retrieval tasks.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

Malcolm Broussard
Signature of Agency Head or Designee

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

March 6, 2014
Date of Signature

Evan Brassel, Staff Director
Legislative Fiscal Officer or Designee

3/7/14
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 amend several sections within *Chapter 29 – Prescription Monitoring Program* of its rules to enable authorized prescribers and dispensers with access privileges to appoint delegates for the purpose of accessing and retrieving information from the prescription monitoring program database. 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.

This rulemaking action is required by the provisions of Act 110 of the 2013 Legislature, which amended the Prescription Monitoring Program Law to authorize prescribers and dispensers with access privileges to appoint delegates for the purpose of accessing and retrieving information from the prescription monitoring program database. A copy of the enabling legislation is appended.

- 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 anticipate a modest expenditure of funds for the printing of the proposed and final rules.

(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 receives no appropriated funds from the legislature and operates totally on self-generated funds.

- 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. To the extent that all of the pharmacies licensed by the Board may meet the statutory definition of a small business, there are 1,832 pharmacies currently licensed by the Board.

(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 does not change the reporting, record keeping or other administrative requirements for compliance.

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

We anticipate a potentially positive impact on small businesses. A prescriber or dispenser with access privileges will be authorized to appoint delegates for the purpose of accessing and retrieving information from the prescription monitoring program database. This could reduce the amount of time the prescriber or dispenser must personally devote to such activities which could improve the rate of compliance.

(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 method 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 13-14</u>	<u>FY 14-15</u>	<u>FY 15-16</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 500	\$ 500	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
TOTAL	\$ 500	\$ 500	\$ 0
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 have allocated \$500 for the printing of the Notice of Intent and the same amount for the printing of the Final Rule.

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

<u>SOURCE</u>	<u>FY 13-14</u>	<u>FY 14-15</u>	<u>FY 15-16</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 500	\$ 500	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
TOTAL	\$ 500	\$ 500	\$ 0

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 has sufficient funds budgeted and available to complete the rulemaking project.

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.

To the extent that a local governmental unit employs a prescriber or dispenser and that authorized user currently performs the access and retrieval of information from the prescription monitoring program database, that user will be able to appoint a delegate for that purpose, which could reduce the labor costs associated with that activity.

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 13-14</u>	<u>FY 14-15</u>	<u>FY 15-16</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
TOTAL	\$ 0	\$ 0	\$ 0

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 anticipate no impact on the 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.

The beneficiaries of the proposed rule are those prescribers and dispensers with authorized access privileges for the prescription monitoring program database. The current rule requires such professionals to personally perform the computerized queries in the database. Although each query can be performed within a couple of minutes, the labor and time impact of a long list of patients requiring such queries could be substantial. The proposed rule will allow prescribers and dispensers to appoint delegates for the purpose of accessing and retrieving information from the prescription monitoring program database. The rule holds prescribers and dispensers accountable for the actions of their delegates with respect to the unlawful access, use or disclosure of prescription monitoring program information.

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 anticipate no impact from this proposed rule on receipts or income.

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 anticipate no impact from this proposed rule on competition or employment.



Signature of Agency Head or Designee

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

February 20, 2014

Date of Signature

ACT No. 110

Regular Session, 2013

HOUSE BILL NO. 355

BY REPRESENTATIVE LEBAS

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

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AN ACT

To amend and reenact R.S. 40:1007(E)(1), relative to access to prescription monitoring information; to add certain delegates to the persons authorized to access prescription monitoring information; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 40:1007(E)(1) is hereby amended and reenacted to read as follows:

§1007. Access to prescription monitoring information

* * *

E. The following persons, after successful completion of the educational courses identified in R.S. 40:1008, may access prescription monitoring information at no cost and in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar protected health information under federal and state law and regulation:

(1) Persons authorized to prescribe or dispense controlled substances or drugs of concern, or their delegates as defined by rule, for the purpose of providing medical or pharmaceutical care for their patients, or for verifying their prescribing records.

* * *

SPEAKER OF THE HOUSE OF REPRESENTATIVES

PRESIDENT OF THE SENATE

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____