



# Louisiana Board of Pharmacy

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January 2, 2013

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

## CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Re: Report No. 2 of 3 for Regulatory Project 2012-5 ~ Institutional Pharmacies  
Report No. 2 of 3 for Regulatory Project 2012-7 ~ Security of Prescription Departments  
Report No. 2 of 3 for Regulatory Project 2012-8 ~ Controlled Dangerous Substance License for  
Non-Resident Distributors  
Report No. 2 of 3 for Regulatory Project 2012-9 ~ Controlled Dangerous Substances in  
Emergency Drug Kits  
Report No. 2 of 3 for Regulatory Project 2012-10 ~ Prescription Monitoring Program

Dear Senator Alario:

As we indicated in our first report to you on July 10, 2012, the Board is currently promulgating amendments to several different sections of its rules as described above. Subsequent to our Notices of Intent published in the July 20, 2012 edition of the Louisiana Register, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on August 27, 2012.

The Board received one verbal comment in support of the proposed rule, as published, relative to controlled dangerous substances in emergency drug kits (Project 2012-9), but no other comments or testimony for any of the other proposals identified above.

During their December 12, 2012 meeting, the Board considered all comments and testimony and determined that no revisions to the original proposals are necessary. Further, the Board has determined it appropriate to move forward with the proposals as published.

Appended to this letter, you should find copies of the Notice of Intent and full text of the proposed rule for each of the regulatory projects identified above.

Subject to review by the Joint Legislative Oversight Committee on Health and Welfare, the Board proposes to publish the original proposed rules as Final Rules in the February 20, 2013 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](mailto:mbroussard@pharmacy.la.gov) or 225.925.6481.

For the Board:

Malcolm J. Broussard  
Executive Director

## **Notice of Intent**

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

#### Prescription Monitoring Program

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 *Chapter 29 – Prescription Monitoring Program* of its rules for the purpose of implementing the provisions of Acts 144 and 488 of the 2010 Legislature and Act 352 of the 2012 Legislature.

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:

...

*Dispenser* – a person authorized by this state to dispense or distribute to the ultimate user any controlled substance or drug monitored by the program, but shall not include any of the following:

(a) – (d) ...

(e) A veterinarian who dispenses negligible amounts of controlled substances or drugs of concern, as identified by rule.

...

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

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§2909. Advisory Council

A. The advisory council shall consist of the following members, each of whom may appoint a designee:

1 – 4. ...

5. The president of the Louisiana State Board of ~~Examiners of Psychologist; Veterinary Medicine;~~

6 – 25. ...

26. The president of the Louisiana Veterinary Medical Association.

...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1005.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), amended LR

Subchapter B. Data Collection

§2911. Reporting of Prescription Monitoring Information

A. ...

B. Each dispenser shall submit the required information by electronic means ~~on a frequency set by the board, which shall be no less than every fourteen days and no more than every seven days~~ as soon as possible but in no event more than seven days after the date of dispensing.

C. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), amended LR

## §2913. Required Data Elements

- A. The information submitted for each prescription shall include data relative to the identification of the following elements of the transaction, or alternative data as identified in the board's program user manual. To the extent possible, the data shall be transmitted in the format established by the American Society for Automation in Pharmacy (ASAP) Telecommunications Format for ~~Controlled Substances in May 1995~~ Prescription Monitoring Programs Standard Version 4.2 or a successor.
1. Prescriber Information
    - a. Last and first name of prescriber;
    - b. ~~Address of prescriber;~~
    - c. ~~Telephone number of prescriber;~~
    - d. United States Drug Enforcement Administration (DEA) registration number, and suffix if applicable, or in the alternative, the National Provider Identifier (NPI) number, as issued by the United States Centers for Medicare and Medicaid Services (CMS).
  2. Patient Information
    - a. Last and first name of human patient and middle initial or name if available, or in the event of a veterinary prescription, the client's name and patient's animal species;
    - b. Complete address of patient;
    - c. ...
    - d. ...
    - e. Gender code;
    - f. Species code.
  3. Prescription Information
    - a. ...
    - b. ...
    - c. ...
    - d. Number of refills authorized on original prescription and refill number;
    - e. ...
  4. Drug Information
    - a. ...
    - b. Name of drug quantity dispensed;
    - c. Dosage form of drug days supply;
    - d. ~~Strength of drug;~~
    - e. ~~Quantity dispensed.~~
  5. Dispenser Information
    - a. ~~Name of pharmacy or dispensing practitioner~~ DEA registration number, or in the alternative, the National Provider Identifier (NPI) number;
    - b. ~~Address of dispenser;~~
    - c. ~~Telephone number of dispenser;~~
    - d. ~~DEA registration number;~~
    - e. ~~National practitioner identification number.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), amended LR

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## 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 for the purpose of providing medical or pharmaceutical care for their patients, or for verifying their prescription records;
  2. Designated representatives from the professional licensing, certification, or regulatory agencies

of this state or another state charged with administrative oversight of those professionals engaged in the prescribing or dispensing of controlled substances or other drugs of concern.

- ...
5. Prescription monitoring programs located in other states, through a secure interstate data exchange system or health information exchange system approved by the board, but only in compliance with the provisions of R.S. 40:1007.G.

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

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### **§2921. Methods of Access to Prescription Monitoring Information**

- A. Prescribers and dispensers, 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.

B – D. ...

- E. Upon receipt of one of the following methods of application by local, state, out-of-state, or federal law enforcement or prosecutorial officials, the program may provide prescription monitoring information:

...

- H. Prescription monitoring programs located in other states may access prescription monitoring information from the program through a secure interstate data exchange system or health information exchange system approved by the board.

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

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## **Subchapter D. Reports**

### **§2925. Release of Prescription Monitoring Information to Other Entities**

- A. The program shall provide prescription monitoring information to public or private entities, whether located in or outside the state, for public research, policy, or educational purposes, but only after removing information that identifies or could reasonably be used to identify prescribers, dispensers, and individual patients or persons who received prescriptions from prescribers.

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

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## **Subchapter E. Exemptions**

### **§2931. Exemptions**

- A. ~~A veterinarian licensed by the Louisiana Board of Veterinary Medicine who dispenses, administers, and/or prescribes a controlled substance or drug to a client/patient within the scope of his practice is exempt from the provisions of the Prescription Monitoring Program as defined in these rules. Repealed.~~

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.

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.

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 these proposed amendments. A public hearing on these proposed amendments is scheduled for Monday, August 27, 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

## FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

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.

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

It is estimated that implementation of the proposed rule will cost the agency \$40,500 in FY 13. These costs consist of \$500 for printing expenses and \$40,000 for software modification to connect to the national prescription monitoring program (PMP) network in order to participate in the interstate exchange of prescription monitoring information as directed by Act 352 of 2012 and Act 488 of 2010. In addition, continuing network participation fees are estimated to cost approximately \$15,000 annually in future fiscal years.

### II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS

With this rule change, the Board will repeal the exemption of veterinarians from the prescription monitoring program under section 2931. As such, the Board estimates increased revenue collections of a minimum of \$22,500 per fiscal year from the assessment of the \$25 annual fee from the approximately 900 veterinarians currently holding a controlled dangerous substance license.

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

Veterinarians will now be required to pay the annual \$25 PMP fee. In addition, to the extent that Louisiana licensed pharmacies may need to upgrade their pharmacy dispensing information systems, some pharmacies may incur programming costs of an indeterminable amount to prepare their information systems to continue to report their eligible controlled substance dispensing transactions to the PMP database.

### IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT

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

## 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 recordkeeping requirements are similar to the federal mandates, and the reporting standards require consistency for meaningful use of the data.

### II. THE ESTABLISHMENT OF LESS STRINGENT DEADLINES FOR DEADLINES FOR COMPLIANCE OR REPORTING REQUIREMENTS FOR SMALL BUSINESSES

The schedules and deadlines require consistency for meaningful use of the data.

### III. THE CONSOLIDATION OR SIMPLIFICATION OF COMPLIANCE OR REPORTING REQUIREMENTS FOR SMALL BUSINESSES

The reporting standards require consistency for meaningful use of the data.

### IV. THE ESTABLISHMENT OF PERFORMANCE STANDARDS FOR SMALL BUSINESSES TO REPLACE DESIGN OR OPERATIONAL STANDARDS REQUIRED IN THE PROPOSED RULE.

The operational standards are similar to the federal mandates.

### 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 amendments.