Louisiana Board of Pharmacy

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March 3, 2015

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 2015-1 ~ Dispenser Reporting to Prescription Monitoring Program*

Dear Senator Alario:

As we indicated in our first report to you on December 4, 2014, the Board is currently amending its rules for the Louisiana Prescription Monitoring Program by changing the deadline by which pharmacies are required to report their controlled substance prescriptions to the PMP database, in compliance with Act 472 of the 2014 Regular Session of the Louisiana Legislature. Subsequent to our Notice of Intent published in the December 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 January 28, 2015.

We received no comments or testimony concerning the proposed rule prior to or during the public hearing. During their subsequent meeting on February 25, 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 December 2014 *Louisiana Register*
- Summary of Comments from January 28, 2015 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 April 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 Broussard

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

NOTICE OF INTENT

Department of Health and Hospitals
Board of Pharmacy

Dispenser Reporting to Prescription Monitoring Program
(LAC 46:LIII.2901 and 2911)

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 29, Prescription Monitoring Program, of its rules by updating the definition of drugs of concern in §2901 to remove tramadol drug products, and further, by revising the deadline by which pharmacies and other dispensers of prescriptions for controlled substances are required to report those transactions to the PMP database, as indicated in §2911.

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.

* * *

Drugs of Concern—drugs other than controlled substances as defined by Rule which demonstrate a potential for abuse, including any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, esters, ethers, isomers, and salts of isomers (whenever the existence of such salts, esters, ethers, isomers, and salts of isomers is possible within the specific chemical designation):

a. butalbital when in combination with at least 125 milligrams of acetaminophen per dosage unit.

b. 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 33:1345 (July 2007), amended LR 36:755 (April 2010), effective September 1, 2010, LR 39:314 (February 2013), LR 41:

Subchapter B. Data Collection
§2911. Reporting of Prescription Monitoring Information

A. Each dispenser shall submit to the board information regarding each prescription dispensed for a controlled substance.

B. Each dispenser shall submit the required information by electronic means no later than the next business day after the date of dispensing.

C. If the dispenser is unable to submit prescription information by electronic means, he may apply to the board for a waiver. The board may grant a waiver to that requirement; if so, the waiver shall state the format and frequency with which the dispenser shall submit the required information. The waiver shall expire one year after the date of issue, unless terminated sooner 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 33:1346 (July 2007), amended LR 39:314 (February 2013), LR 41:

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

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 removal of tramadol drug products from the definition of 'drugs of concern' is required by the scheduling of that drug by the federal government in Schedule IV of the federal list of controlled substances. All pharmacies, regardless of size, are required to comply with those federal requirements. The deadline to report prescription transactions to the PMP database is the same for all pharmacies, regardless of size.

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

3. The consolidation or simplification of compliance or reporting requirements for small businesses. There are no exemptions to the reporting requirements for small businesses.

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.

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

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. We anticipate minimal costs to the provider to implement the requirements of the proposed Rule.

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

There are no exemptions for small businesses. 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 Wednesday, January 28, 2015 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: Dispenser Reporting to Prescription Monitoring Program

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

The proposed Rule will result in a cost of approximately $2,000 for printing costs of the proposed and final Rules in FY 15. The proposed Rule changes the deadline by which dispensers of prescriptions for controlled substances must report those transactions to the Prescription Monitoring Program (PMP) database as per Act 472 of the 2014 Regular Session of the Louisiana Legislature. The proposed Rule also removes tramadol from the definition of a 'drug of concern' as made necessary by a scheduling action taken by the U.S. Drug Enforcement Administration in August of 2014.

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 NONGOVERNMENTAL GROUPS (Summary)

The proposed Rule directly affects pharmacies and other dispensers of prescriptions for controlled substances. The proposed Rule will change the deadline by which such dispensers are required to report their controlled substance prescription transactions to the PMP database, in conformance with Act 472 of the Louisiana Legislature – from no later than seven days after dispensing to no later than the next business day. Most dispensers use an automated reporting process to report their transactions to the database, and will now do so on a daily basis. The proposed Rule could create an indeterminable cost for any dispenser that does not use an automated reporting system or a minimal one-time cost to adjust the reporting schedules within the automated systems. Dispensers will make a one-time change to the tramadol record in their master drug file to indicate its status in Schedule IV.

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
1412#036

Evan Brasseaux
Staff Director
Legislative Fiscal Office

Louisiana Board of Pharmacy

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Summary of Testimony & Public Comments
re
Regulatory Project 2015-1 ~ Dispenser Reporting to Prescription Monitoring Program
at
January 28, 2015 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

Chapter 29. Prescription Monitoring Program

Subchapter A. General Operations

§2901. Definitions

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a. butalbital when in combination with at least 125 milligrams of acetaminophen per dosage unit.

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Subchapter B. Data Collection

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