



Louisiana Board of Pharmacy

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December 4, 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 2015-2 ~ Expiration Date of Schedule II Prescriptions

Dear Senator Alario:

The Board has initiated the rulemaking process to amend the Board's rules for controlled dangerous substances by changing the expiration date of prescriptions written for drugs listed in Schedule II of the list of controlled substances, from the current six months down to ninety days, as required by Act 865 of the 2014 Regular Session of the Louisiana Legislature. 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
- Provider Impact Statement
- Regulatory Flexibility Analysis
- Solicitation of Comments
- Fiscal & Economic Impact Statement
- Act 865 of the 2014 Regular Session of the Louisiana Legislature

As indicated in the solicitation, we will convene a public hearing on January 28, 2015 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: Pat.Witty@la.gov
Editor, *Louisiana Register*
Via Email: Reg.Submission@la.gov
Reference File

Notice of Intent

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

Expiration Date of Schedule II Prescriptions (LAC 46:LIII.2745 and 2747)

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 27 - Controlled Dangerous Substances* of its rules, in compliance with Act 865 of the 2014 Legislature, by changing the expiration date of prescriptions written for controlled substances listed in Schedule II, as indicated in §2745 and §2747, from six months to ninety days.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 27. Controlled Dangerous Substances

...

Subchapter F. Production, Distribution and Utilization

...

§2745 Prescriptions

...

F. Controlled Substances Listed in Schedule II

...

2. Expiration Date of Prescriptions

A prescription for a controlled substance listed in Schedule II shall expire ~~six months~~ ninety days after the date of issue. No pharmacist shall dispense any controlled substance pursuant to an expired prescription.

...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2149 (October 2008), amended LR

...

§2747 Dispensing Requirements

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B. Prescriptions for Controlled Substances Listed in Schedule II

...

3. Expiration Date

A pharmacist shall not dispense a prescription for a controlled substance listed in Schedule II more than ~~six months~~ ninety days after the date of issue of the prescription.

...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2152 (October 2008), amended LR

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

PROVIDER IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

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:

I. 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.

II. 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.

III. 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.

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 expiration date of prescriptions is applicable to all pharmacies regardless of size.

II. 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.

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

There are no exemptions to 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 standards in the proposed rule.

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.

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, January 28, 2015 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
(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 expiration date of prescriptions written for controlled substances listed in Schedule II, from six months to ninety days, as per Act 865 of the 2014 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)

The proposed rule directly affects prescribers of controlled substances listed in Schedule II, the pharmacies that dispense those prescriptions, and the patients that receive those medications. The proposed rule will change the expiration date of prescriptions for controlled substances listed in Schedule II, from six months to ninety days. Since such prescriptions cannot be called into a pharmacy, the prescriptions must be (1) written and then manually signed by the prescriber and given to a patient, or in the alternative, (2) electronically generated, signed, and transmitted to a pharmacy in accordance with federal security standards. Regardless of their method of communication, they cannot be refilled. Pharmacies will not be able to dispense such prescriptions more than ninety days after their date of issuance by the prescriber. Prescribers may incur minimal costs for generating a new prescription. In the event the prescriber elects to issue a written prescription, the patient may or may not incur a charge for an office visit to the prescriber, but there may also be transportation or other costs. In the alternative, the prescriber may elect to issue the prescription electronically directly to the pharmacy.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

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: **Expiration Date of C-II Prescriptions**
Return Address: **3388 Brentwood Drive**
Baton Rouge, LA 70809
Effective Date of Rule: **April 20, 2015 (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 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 expiration date of prescriptions written for controlled substances listed in Schedule II, from six months to ninety days, as per Act 865 of the 2014 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)

The proposed rule directly affects prescribers of controlled substances listed in Schedule II, the pharmacies that dispense those prescriptions, and the patients that receive those medications. The proposed rule will change the expiration date of prescriptions for controlled substances listed in Schedule II, from six months to ninety days. Since such prescriptions cannot be called into a pharmacy, the prescriptions must be (1) written and then manually signed by the prescriber and given to a patient, or in the alternative, (2) electronically generated, signed, and transmitted to a pharmacy in accordance with federal security standards. Regardless of their method of communication, they cannot be refilled. Pharmacies will not be able to dispense such prescriptions more than ninety days after their date of issuance by the prescriber. Prescribers may incur minimal costs for generating a new prescription. In the event the prescriber elects to issue a written prescription, the patient may or may not incur a charge for an office visit to the prescriber, but there may also be transportation or other costs. In the alternative, the prescriber may elect to issue the prescription electronically directly to the pharmacy.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

Malcolm J. Broussard
Signature of Agency Head or Designee

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

December 3, 2014
Date of Signature

Evan Brassel, Staff Director
Legislative Fiscal Officer or Designee

12/4/14
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 *Chapter 27 – Controlled Dangerous Substances* of its rules, specifically by amending the expiration date of prescriptions for controlled substances listed in Schedule II, as indicated in §2745.F.2 and §2747.B.3.

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

The proposed rule is necessary to comply with Act 865 of the 2014 Louisiana Legislature, which imposed a ninety-day expiration date on prescriptions for controlled substances listed in Schedule II. This date is shorter than the six-month expiration date indicated in the current rules. A copy of the legislation is appended to the Notice of Intent.

- 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 Board anticipates an expenditure 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 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 1,904 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.

Pharmacies and other dispensers of prescriptions for controlled substances will need to make one-time modifications to the master drug file in their dispensing information systems, to shorten the current expiration date for prescriptions for all drug products listed in Schedule II, from the current six months to ninety days.

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

The Board anticipates a minimal, if any, impact on small businesses.

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

There are no alternative methods for achieving the 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 14-15</u>	<u>FY 15-16</u>	<u>FY 16-17</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 2,000	\$ 0	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
TOTAL	\$ 2,000	\$ 0	\$ 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.

The Board has allocated \$2,000 for the printing of the Notice of Intent and the Final Rule in the current fiscal year.

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

<u>SOURCE</u>	<u>FY 14-15</u>	<u>FY 15-16</u>	<u>FY 16-17</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 2,000	\$ 0	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
TOTAL	\$ 2,000	\$ 0	\$ 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 a local governmental unit operates a pharmacy, the staff will need to make a one-time change to the master drug file in their dispensing information system, to change the expiration date of prescriptions for all drug products listed in Schedule II, from six months to ninety days.

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 14-15</u>	<u>FY 15-16</u>	<u>FY 16-17</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.

Since the proposed rule does not impact fees, the Board discerns no impact on the revenue collections of state and local governmental units from the proposed rule.

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 proposed rule directly affects prescribers of controlled substances listed in Schedule II, the pharmacies that dispense those prescriptions, and the patients that receive those medications. The proposed rule will change the expiration date of prescriptions for controlled substances listed in Schedule II, from six months to ninety days. Since such prescriptions cannot be called into a pharmacy, the prescriptions must be (1) written and then manually signed by the prescriber and given to a patient or caregiver, or in the alternative, (2) electronically generated, signed, and transmitted to a pharmacy in accordance with federal security standards. Regardless of their method of communication, they cannot be refilled. Pharmacies will not be able to dispense such prescriptions more than ninety days after their date of issuance by the prescriber.

Prescribers may incur minimal costs for generating a new prescription. In the event the prescriber elects to issue a written prescription, the patient may or may not incur a charge for an office visit to the prescriber, but there may also be transportation or other related costs. In the alternative, the prescriber may elect to issue the prescription electronically directly to the pharmacy.

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.

The proposed rule will not have any impact on receipts or revenue.

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.

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



Signature of Agency Head or Designee

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

December 3, 2014
Date of Signature

SENATE BILL NO. 496

BY SENATOR HEITMEIER

1 AN ACT

2 To amend and reenact R.S. 40:978(A) and to enact R.S. 40:978(E) and (F), relative to
3 prescriptions; to provide for the limited dispensing of certain controlled substances;
4 to provide for accessing the Prescription Monitoring Program in certain situations;
5 and to provide for related matters.

6 Be it enacted by the Legislature of Louisiana:

7 Section 1. R.S. 40:978(A) is hereby amended and reenacted, and R.S. 40:978(E) and
8 (F) are hereby enacted to read as follows:

9 §978. Prescriptions

10 A. Except when dispensed or administered directly by a medical practitioner
11 or administered by a person authorized to administer by such practitioner, other than
12 a pharmacist, to an ultimate user, no controlled dangerous substance included in
13 Schedule II, which is a prescription drug as determined under the Louisiana Revised
14 Statutes, of 1950, may be dispensed or administered without either the written
15 prescription of a practitioner, or an electronic prescription order as provided by
16 federal law or regulation, except that in emergency situations, as prescribed by the
17 department by regulation, such drug may be dispensed or administered upon oral
18 prescription reduced promptly to writing and filed by the pharmacist. Prescriptions
19 shall be retained in conformity with the requirements of R.S. 40:976. No prescription
20 for a Schedule II substance may be refilled **nor may such prescription be filled**
21 **more than ninety days after the date of the prescription.**

22 * * *

23 **E.(1) The pharmacist shall not dispense more than a ten-day supply at**
24 **a dosage not to exceed the United States Food and Drug Administration's**
25 **approved labeling for the medication if the prescriber for such medication is not**
26 **licensed by the state of Louisiana, and the medication is an opiod derivative**

1 Schedule II or an opioid derivative Schedule III controlled dangerous substance.
 2 The dispensing pharmacist shall notify the prescriber of the supply dispensed
 3 and the cancellation of the remainder of the prescription.

4 (2) Within sixty days of the dispensing of a medication pursuant to
 5 Paragraph (1) of this Subsection, such a medication shall not be dispensed again
 6 for the individual by a prescriber not licensed by the state of Louisiana.

7 F. A prescriber shall access the Prescription Monitoring Program prior
 8 to initially prescribing any Schedule II controlled dangerous substance to a
 9 patient for the treatment of non-cancer-related chronic or intractable pain.

 PRESIDENT OF THE SENATE

 SPEAKER OF THE HOUSE OF REPRESENTATIVES

 GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____