



Louisiana Board of Pharmacy

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July 9, 2015

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 2015-4 ~ Compounding for Office Use for Veterinarians

Dear Senator Alario:

The Board has initiated the rulemaking process to amend the Board's rules to allow pharmacies to compound medications for office use by veterinarians. You may recall we issued an Emergency Rule on this topic effective June 1; we now seek to make that rule permanent. 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

As indicated in the solicitation, we will convene a public hearing on August 26, 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-HW@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**

Compounding for Office Use for Veterinarians (LAC 46:LIII.2535)

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 §2535 of *Chapter 25 - Prescriptions, Drugs, and Devices* of its rules, to allow pharmacies to compound medications for office use, but only for veterinarians.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

...

Subchapter C. Compounding of Drugs

...

§2535. General Standards

A. – D. ...

E. Veterinarian Administered Compounds, also referred to as Pharmacy-Generated Drugs

1. Upon receipt of a valid non-patient-specific medical order from a licensed veterinarian, the pharmacy may compound a preparation intended for administration to an animal patient by the veterinarian.
2. These preparations may not be distributed to any other third party by the pharmacy, nor may these preparations be further re-sold or distributed by the veterinarian ordering the preparation from the pharmacy.
3. This authorization is primarily intended to facilitate the preparation of medications needed for emergency use in a veterinary office practice. Given the limited application of this authorization, which allows these products to be prepared using less rigorous standards applicable to compounding as opposed to the more rigorous standards applicable to manufacturing processes, the compounding pharmacy preparing these products shall be limited in the amount of such products they can prepare.
 - a. No Louisiana-licensed pharmacy may distribute any amount of practitioner administered compounds in excess of five percent of the total amount of drug products dispensed and/or distributed from their pharmacy.
 - b. The five percent limitation shall be calculated on a monthly basis and shall reference the number of dosage units.
 - c. For those Louisiana-licensed pharmacies located outside Louisiana, the total amount distributed and/or dispensed shall reference the pharmacy's total business within the state of Louisiana.

~~E. F. Compounding Commercial Products not Available.~~ A pharmacy may prepare a copy of a commercial product when that product is not available as evidenced by either of the following:

1. Products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health-System Pharmacists (ASHP).
2. Products temporarily unavailable from manufacturers, as documented by invoice or other communication from the distributor or manufacturer.

~~F. G. Labeling of Compounded Preparations.~~

1. For patient-specific compounded preparations, the labeling requirements of R.S. 37:1225, or its successor, as well as §2527 of this Chapter, or its successor shall apply.
2. For veterinarian administered compounds, the label shall contain, at a minimum, the following data elements:
 - a. pharmacy's name, address, and telephone number;
 - b. veterinarian's name;
 - c. name of preparation;
 - d. strength and concentration;
 - e. lot number;
 - f. beyond use date;
 - g. special storage requirements, if applicable;
 - h. identification number assigned by the pharmacy; and
 - i. name or initials of pharmacist responsible for final check of the preparation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR 41:97 (January 2015), 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 minimum standards for quality and safety for compounded medications are federal in origin and replicated in the Board's rules. There are no provisions for less stringent requirements for small businesses.

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

There are no reporting deadlines 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.

The proposed rule allows, but does not require, pharmacies to compound medications for office use for veterinarians. The existing rule stipulates the minimum standards for quality and safety, which mirror the federal standards.

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 Tuesday, August 26, 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 16. The proposed rule authorizes pharmacies to compound medications for office use for veterinarians according to standards and limitations identified in the proposed rule.

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 those pharmacies which elect to compound medications for office use for veterinarians. While the existing rule identifies the minimum standards for quality and safety, the proposed rule authorizes compounding drugs for office use for veterinarians but limits the amount of these medications that a pharmacy may compound to not exceed 5% of the total amount of drug products dispensed or distributed. The costs and benefits associated with compounding for office use for veterinarians are similar to those for compounding medications for patient-specific prescriptions.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

To the extent a pharmacy may elect to engage in the activity authorized by the proposed rule and develops a market for that activity, there could be a positive effect on employment.

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: **Malcolm J. Broussard** Dept.: **Health and Hospitals**
Executive Director
Phone: **(225) 925-6481** Office: **Board of Pharmacy**
Return Address: **3388 Brentwood Drive** Title: **Compounding for Office Use**
Baton Rouge, LA 70809 **for Veterinarians**
Effective Date of Rule: **October 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 16. The proposed rule authorizes pharmacies to compound medications for office use for veterinarians according to standards and limitations identified in the proposed rule.

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

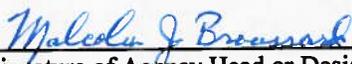
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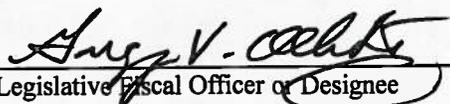
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IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

To the extent a pharmacy may elect to engage in the activity authorized by the proposed rule and develops a market for that activity, there could be a positive effect on employment.


Signature of Agency Head or Designee

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


Legislative Fiscal Officer or Designee

7/9/2015
Date of Signature

July 9, 2015
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 25 – Prescriptions, Drug, and Devices* of its rules, specifically §2535, to authorize pharmacies to compound medications for office use for veterinarians. 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.

Prior to the 2012 tragedy from compounded medications in pharmacies, the Board's rules allowed pharmacies to compound medications for office use by all practitioners. When the U. S. Congress passed the Drug Quality & Security Act of 2013, that federal law prohibited pharmacies from compounding medications for office use, and the Board subsequently modified its rules in January 2015 to prohibit pharmacies from compounding medications without a patient-specific prescription, which also excludes compounding medications for office use by practitioners. With subsequent guidance from the federal Food & Drug Administration that the federal law only applies to the compounding of medications for human use, several veterinarians approached the Board requesting a restoration of the authority for a pharmacy to compound medications for office use for veterinarians. The proposed rule will restore the authority for pharmacies to compound medications for office use but only for veterinarians.

- 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 of approximately \$2,000 for the printing of the proposed and final rules. Those funds are budgeted and available from self-generated agency funds.

- (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 1,951 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 reporting, record keeping and other administrative costs required for the compounding of medications for office use is similar to those for the compounding of medications for patient-specific prescriptions. Pharmacies engaged in compounding activities are familiar with these procedures and costs.

- (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 15-16</u>	<u>FY 16-17</u>	<u>FY 17-18</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 FY 16.

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

<u>SOURCE</u>	<u>FY 15-16</u>	<u>FY 16-17</u>	<u>FY 17-18</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.

The proposed rule will not result in any cost savings to 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 15-16</u>	<u>FY 16-17</u>	<u>FY 17-18</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 will directly affect any pharmacy electing to engage in the practice of compounding medications for office use for veterinarians. While other portions of the existing rule stipulate the minimum standards for quality and safety of the compounded medication, the proposed rule imposes a limitation on the amount of such medication that can be compounded for office use for a veterinarian: no pharmacy may distribute any amount of compounded medication intended for office use for veterinarians in excess of five percent of the total amount of drug products dispensed and distributed from that pharmacy, as calculated using dosage units on a monthly cycle. The proposed rule also specifies the data elements to be included in the labeling of such compounded preparations.

The process, record keeping, reporting, and other costs required for the compounding of medications for office use is similar to those for the compounding of medications for patient-specific prescriptions. Pharmacies engaged in compounding activities are familiar with these procedures and costs. To the extent a pharmacy elects to expand their existing compounding practice to include this new authority, there may be additional costs of a similar nature as their existing practice.

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 a pharmacy elects to engage in the practice of compounding medications for office use for veterinarians, the proposed rule could have a positive effect on sales, receipts, and revenue at that pharmacy. Given the multiple factors associated with developing a new market, it is not possible to provide an estimate of the financial impact from the 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.

To the extent a pharmacy elects to engage in the practice of compounding medications for office use for veterinarians, and further, is able to develop a market for that activity, the proposed rule could have a positive effect on employment at that pharmacy.



Signature of Agency Head or Designee

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

July 9, 2015

Date of Signature