Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov

January 10, 2013

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

Electronic Mail – Read Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2013-1 ~ Compounding for Prescriber's Use

Dear Senator Alario:

The Board has initiated the rulemaking process to repeal the provisions of its rules that allow a pharmacy to compound preparations for a prescriber's use without a patient-specific prescription. In connection with this regulatory project, you should find the following documents in this packet:

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

As indicated in the solicitation, we will convene a public hearing on February 27, 2013 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 Broussard

Malcolm J Broussard
Executive Director

cc: Chair, Senate Health & Welfare Committee
Speaker, House of Representatives
Chair, House Health & Welfare Committee
Director, Community Outreach Services, La. Economic Development
Editor, *Louisiana Register*
Reference File

Notice of Intent

Department of Health and Hospitals
Board of Pharmacy

Compounding for Prescriber's Use

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 repeal certain provisions of its rules that permit pharmacies to compound medications intended for administration to a patient within a prescriber's office without the necessity of a patient-specific prescription. Further, the proposal seeks to prohibit a pharmacy from engaging in manufacturing activities within the prescription department of the pharmacy.

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, February 27, 2013 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

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

…

§2533. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:

…

Practitioner Administered Compounds ~~– products compounded by a licensed pharmacist, upon the medical order of a licensed prescriber for administration by a prescriber for diagnostic or therapeutic purposes.~~ Repealed.

…

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 29:2105 (October 2003), effective January 1, 2004, amended LR 39:

§2535. General Standards

A. – C. …

~~D. Compounding for Prescriber's Use. Pharmacists may prepare practitioner administered compounds for a prescriber's use with the following requirements:~~

~~1. an order by the prescriber indicating the formula and quantity ordered to be compounded by the pharmacist;~~

~~2. the product is to be administered by the prescriber and not dispensed to the patient; and~~

~~3. the pharmacist shall generate a label and sequential identification number for the compounded drug.~~ Repealed.

E. …

F. Labeling of Compounded Products.

1. …

~~2. All practitioner administered compounds shall be packaged in a suitable container with a label containing, at a minimum, the following information:~~

~~a. pharmacy's name, address, and telephone number;~~

~~b. practitioner's name;~~

~~c. name of preparation;~~

~~d. strength and concentration;~~

~~e. lot number;~~

~~f. beyond use date;~~

~~g. special storage requirements, if applicable;~~

~~h. assigned identification number; and~~

i. ~~pharmacist's name or initials.~~ Repealed.

G. Manufacturing Activities. No pharmacy shall engage in the manufacturing of drugs or drug products within the prescription department.

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 39:

§2537. Requirements for Compounding of Sterile Products

A. – F. …

G. Labeling.

~~1. All practitioner administered sterile compounds shall be packaged in a suitable container, and shall bear a label with the following minimum information:~~

~~a. pharmacy's name, address, and telephone number;~~

~~b. preparation name;~~

~~c. strength and concentration;~~

~~d. lot number;~~

~~e. beyond use date;~~

~~f. practitioner's name;~~

~~g. assigned identification number;~~

~~h. special storage requirements, if applicable; and~~

~~i. pharmacist's name or initials.~~ Repealed.

2. …

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 29:2106 (October 2003), effective January 1, 2004, amended LR 39:

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Malcolm J. Broussard
Executive Director

Phone: (225) 925-6481

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

Dept.: Health and Hospitals

Office: Board of Pharmacy

Title: Compounding for Prescriber's Use

Date Rule Takes Effect: May 20, 2013 (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)

It is estimated that implementation of the proposed rule will cost the agency $500 in FY 12-13 for printing costs.

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

The Board seeks to repeal certain provisions of its current rules relative to the compounding of medications by pharmacies intended for administration by practitioners in their offices without the necessity of a patient-specific prescription. Some of these pharmacies specialize in the large-scale preparation of practitioner-administered compounds as opposed to compounding medications pursuant to patient-specific prescriptions, which has been tied to the spread of fungal meningitis in other states. Although the statutory definition of 'compounding' in the Louisiana Pharmacy Practice Act [La. R.S. 37:1164(5)] requires pharmacies to receive patient-specific prescriptions, the Board's current rules permit pharmacies to prepare practitioner-administered compounds without the necessity of a patient-specific prescription. In order to eliminate this discrepancy and to take safety precautions, the Board is repealing the provisions regarding compounding without a patient-specific prescription until a new rule can be developed with the necessary safeguards in place. Until this new rule is established, the Board will lose any revenue received from permitting ($150 each) and renewal fees ($125) associated with pharmacies choosing to solely distribute non-patient-specific compounded medication.

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

The proposed rule change will require a compounding pharmacy to receive a patient-specific prescription prior to compounding medications intended for administration to a patient within a practitioner's office. It is estimated that pharmacies that currently produce compound medications for practitioners without use of patient-specific prescriptions will lose the revenue associated with that book of business. For smaller compounding pharmacies, this loss of revenue can be significant, though the amount is indeterminable. It is possible for a pharmacy to continue distributing compound medications without patient-specific prescriptions if it has obtained a manufacturing permit through the Food & Drug Administration (FDA); however, this costs $525,000 for the overall permit registration and $98,000 per individual compound drug registration.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

Malcolm J Broussard
Signature of Agency Head or Designee

Josh D. Carpenter
Legislative Fiscal Officer or Designee

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

1/9/13
Date of Signature

December 17, 2012
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 seeks to repeal certain provisions of its current rules relative to the compounding of medications by pharmacies intended for administration by practitioners in their offices without the necessity of a patient-specific prescription. 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.

The Board has taken note of the recent tragedies associated with fungal meningitis traced to contaminated medications dispensed by a compounding pharmacy in Massachusetts. That pharmacy was licensed to do business in Louisiana, although none of the cases – to date – have been located within the state. Further, the Board has learned there are other similar types of pharmacies operating across the country that are also licensed to do business in this state. Some of these pharmacies specialize in the large-scale preparation of practitioner-administered compounds as opposed to compounding medications pursuant to patient-specific prescriptions. Although the statutory definition of 'compounding' in the Louisiana Pharmacy Practice Act [La. R.S. 37:1164(5)] requires pharmacies to receive patient-specific prescriptions, the Board's current rules permit pharmacies to prepare practitioner-administered compounds without the necessity of a patient-specific prescription.

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 proposed rule change will not require any increase in the expenditure of funds by the Board.

(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; we do not receive any appropriations from the legislature.

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.

(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 change would not change any reporting requirements, but it would require a change in the type of record required to be maintained by the pharmacy. Instead of a purchase order from the prescriber to the pharmacy, the proposed rule change would require the prescriber to issue a patient-specific prescription to the pharmacy in order to authorize the compounding of the medication.

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

Given the absence of physical specifications and the ability to accommodate a different type of record authorizing the compounding activity, we envision minimal impact on small businesses in this respect. Otherwise, a pharmacy can obtain a manufacturer's permit from the FDA at a cost of $525,000 and $98,000 per individual compound drug registration.

(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 methods 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?

COSTS	FY 12-13	FY 13-14	FY 14-15
PERSONAL SERVICES	$ 0	$ 0	$0
OPERATING EXPENSES	$ 500	$ 0	$0
PROFESSIONAL SERVICES	$ 0	$ 0	$0
OTHER CHARGES	$ 0	$ 0	$0
EQUIPMENT	$ 0	$ 0	$0
MAJOR REPAIR & CONSTR.	$ 0	$ 0	$0
TOTAL	$ 500	$ 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.

We anticipate the printing costs for the implementation of the proposed rule to approximate $500 ($250 for the notice of intent and the same amount for the final rule).

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

SOURCE	FY 12-13	FY 13-14	FY 14-15
STATE GENERAL FUND	$ 0	$ 0	$0
AGENCY SELF-GENERATED	$ 500	$ 0	$0
DEDICATED	$ 0	$ 0	$0
FEDERAL FUNDS	$ 0	$ 0	$0
OTHER (Specify)	$ 0	$ 0	$0
TOTAL	$ 500	$ 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 currently has sufficient funds budgeted and available to complete the promulgation process.

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.

We can discern no impact on local governmental units from the proposed rule.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

SOURCE	FY 12-13	FY 13-14	FY 14-15
STATE GENERAL FUND	$0	$0	$0
AGENCY SELF-GENERATED	DECREASE	DECREASE	DECREASE
DEDICATED FUNDS	$0	$0	$0
FEDERAL FUNDS	$0	$0	$0
LOCAL FUNDS	$0	$0	$0
TOTAL	DECREASE	DECREASE	DECREASE

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.

The Board will lose any revenue received from permitting ($150 each) and renewal fees ($125) associated with pharmacies choosing to solely distribute non-patient-specific compounded medication.

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 groups directly affected by the proposed rule change are the compounding pharmacies which have been supplying compounded preparations directly to prescribers for use in their offices without the necessity of a patient-specific prescription, but most often in response to purchase orders. The proposed rule will require the compounding pharmacy to first receive a patient-specific prescription from the prescriber before preparing the medication for delivery to the prescriber's office

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 the prescriber provides the patient-specific prescription to the compounding pharmacy then we envision no impact on revenue for the compounding pharmacy. In the event the prescriber is unable or unwilling to provide a patient-specific prescription, it is possible the compounding pharmacy could experience a loss in 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.

Since all compounding pharmacies licensed to do business in the state must follow the same rules, we envision no impact on competition or employment in the public or private sectors.

Malcolm J Broussard

Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director

Typed Name and Title of Agency Head or Designee

December 17, 2012

Date of Signature

FAMILY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement:	Malcolm J. Broussard Executive Director	Dept.:	Health and Hospitals
		Office:	Board of Pharmacy
Telephone:	(225) 925-6481	Title:	Compounding for Prescriber's Use
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809-1700	Date Rule Takes Effect:	May 20, 2013 (est)

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 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.

Malcolm J Broussard
Signature of Agency Head or Designee

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

January 10, 2013
Date of Signature

POVERTY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Malcolm J. Broussard
Executive Director

Telephone: (225) 925-6481

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

Dept.: Health and Hospitals

Office: Board of Pharmacy

Title: Compounding for Prescriber's Use

Date Rule Takes Effect: May 20, 2013 (est)

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. The following statements will be published in the Louisiana Register with the proposed agency rule.

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

We anticipate no impact from the proposed rule on household income, assets, or financial security.

II. The effect on early childhood development and preschool through postsecondary education development.

We anticipate no impact from the proposed rule on early childhood development or preschool through postsecondary education development.

III. The effect on employment and workforce development.

We anticipate no impact from the proposed rule on employment or workforce development.

IV. The effect on taxes and tax credits.

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

Malcolm J Broussard
Signature of Agency Head or Designee

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

January 10, 2013
Date of Signature

REGULATORY FLEXIBILITY ANALYSIS
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Malcolm J. Broussard
Executive Director

Telephone: (225) 925-6481

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

Dept.: Health and Hospitals

Office: Board of Pharmacy

Title: Compounding for Prescriber's Use

Date Rule Takes Effect: May 20, 2013 (est)

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 will not change any reporting requirements, but it will require a change in the type of record to be maintained by the pharmacy. Instead of a purchase order from the prescriber to the pharmacy, the proposed rule change will require the prescriber to issue a patient-specific prescription to the pharmacy in order to authorize the compounding of the medication.

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.

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

There are no changes in the reporting requirements.

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 change. The operational standard for the type of document to be received in the pharmacy will change from a purchase order to a patient-specific prescription.

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 rule.

Malcolm J. Broussard
Signature of Agency Head or Designee

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

January 10, 2013
Date of Signature