Potpourri

Department of Health and Hospitals
Board of Pharmacy

Compounding for Prescriber's Use

The Board of Pharmacy ("Board") published a Notice of Intent to promulgate amendments to LAC 46:LIII.Chapter 25 in the January 20, 2013 edition of the Louisiana Register (LR 39:187-189). The notice solicited comments and testimony. As a result of its analysis of the comments and testimony received, the Board proposes to amend the original proposal by replacing the original language that would have repealed the authority of a pharmacy to compound any drug products for practitioner administration with language that will limit the authority of the pharmacy to compound drug products for practitioner administration up to ten percent of the total number of drug dosage units dispensed and distributed by the pharmacy on an annual basis.

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 substantive amendments to the original proposal. A public hearing on these proposed amendments is scheduled for Thursday, May 30, 2013 at 1:00 p.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 4:00 p.m. 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

…

Subchapter C. Compounding of Drugs

…

§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 – 3 …

4. A pharmacy may prepare such products not to exceed ten percent of the total number of drug dosage units dispensed and distributed by the pharmacy on an annual basis.

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 distributors, as documented by invoice or other communication from the distributor.

G. Labeling of Compounded Products.

1 – 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 23:1316 (October 1997), amended LR 29:2105 (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 13 for printing costs.

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

The Board seeks to amend 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 take safety precautions, the Board is amending its current rules to allow pharmacies to compound products without a patient-specific prescription as long as that activity does not exceed 10% of the pharmacy's total annual dosage units distributed or dispensed. As a result, 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, though the Board anticipates this loss in revenue to be minimal. The only other exception to these compounding restrictions is for compounding commercial products that are no longer publically available under Section 2535(F) of the Board's rules. Only commercial products that are temporarily unavailable as documented by invoice/communication from the distributor, or as provided by the federal Food & Drug Administration (FDA) and/or the American Society of Health-System Pharmacists, will be available for compounding under this provision.

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 more than 10% of its annual business via 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

John D. Cogan
Legislative Fiscal Officer or Designee

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

04-09-13
Date of Signature

April 9, 12013
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 amend 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. In order to take safety precautions, the Board is amending its current rules to allow pharmacies to compound products without a patient-specific prescription as long as they do not exceed 10% of the pharmacy's total annual dosage units distributed or dispensed. The only other exception to these compounding restrictions is for compounding commercial products that are no longer publically available under Section 2535(F) of the Board's rules. Only commercial products that are temporarily unavailable as documented by invoice/communication from the distributor, or as provided by the federal Food & Drug Administration (FDA) and/or the American Society of Health-System Pharmacists, will be available for compounding under this provision. 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. The federal FDA regulates drug manufacturers and requires their activities to comply with the safety standard known as Current Good Manufacturing Practices (cGMP). Pharmacies compounding medications are regulated by the Board, and their activities are required to comply with the safety standard known as USP Chapter 797, a less stringent standard than cGMP. 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. Drug products intended for use in the general population are typically manufactured according to cGMP standards, not the less stringent USP Chapter 797 standards. The Board seeks to mitigate the potential harm from preparation of drug products intended for use in the general population using the less stringent safety standard.

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 is amending its current rules to allow pharmacies to compound products without a patient-specific prescription as long as they do not exceed 10% of the pharmacy's total annual dosage units distributed or dispensed. As a result, 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, though the Board anticipates this loss in revenue to be minimal.

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 Board is amending its current rules to allow pharmacies to compound products without a patient-specific prescription as long as they do not exceed 10% of the pharmacy's total annual dosage units distributed or dispensed.

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 if these transactions exceed 10% of the pharmacy's annual business.

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

April 9, 2013

Date of Signature