Louisiana Board of Pharmacy

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

July 10, 2012

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

Re: Report No. 1 of 3 for Regulatory Project 2012-5 ~ Institutional Pharmacies
Report No. 1 of 3 for Regulatory Project 2012-6 ~ Interstate Remote Processing
Report No. 1 of 3 for Regulatory Project 2012-7 ~ Security of Prescription Departments
Report No. 1 of 3 for Regulatory Project 2012-8 ~ Controlled Dangerous Substance License for Non-Resident Distributors
Report No. 1 of 3 for Regulatory Project 2012-9 ~ Controlled Dangerous Substances in Emergency Drug Kits
Report No. 1 of 3 for Regulatory Project 2012-10 ~ Prescription Monitoring Program

Dear Senator Alario:

The Board has initiated the rulemaking process to amend several different sections of its rules. For each of the six projects identified above, you should find the following documents in this packet:

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

As indicated in the solicitation, we will convene a public hearing on August 27, 2012 to receive public comments and testimony on these proposals. 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 225.925.6481 or mbroussard@pharmacy.la.gov.

For the Board:

Malcolm J 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*

Pharmacy Program
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PMP Office
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Executive Office
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Notice of Intent

Department of Health and Hospitals
Board of Pharmacy

Controlled Dangerous Substance License for Non-Resident Distributors

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 §2705 of its rules to require the acquisition of a Louisiana Controlled Dangerous Substance (CDS) license by non-resident distributors prior to the distribution of controlled dangerous substances to any Louisiana purchaser.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 27. Controlled Dangerous Substances

...

§2705. Licenses and Exemptions

...

F. Manufacturers and Distributors

...

3. The sale or transportation of controlled substances within the State of Louisiana by manufacturers <u>and distributors</u> located outside the State of Louisiana shall require the possession of a valid CDS license issued by the board prior to the engagement of such activities.

...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2129 (October 2008), amended LR

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.

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.

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 amendment. A public hearing on this proposed amendment is scheduled for Monday, August 27, 2012 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

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

The proposed rule imposes an annual Controlled Dangerous Substances (CDS) licensing fee of $50 on non-resident distributors. As such, the Board estimates an increased revenue collection of approximately $5,000 per fiscal year from licensing fees to be paid by an estimated 100 non-resident distributors seeking to distribute controlled substances within the state ($50 x 100 = $5,000).

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

Other than the $50 annual CDS license fee assessed on non-resident distributors, the Board anticipates minimal additional costs for recordkeeping and reporting since most of the requirements can be accomplished electronically.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT

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

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:

VII. The establishment of less stringent compliance or reporting requirements for small businesses.

The reporting requirements for handlers of controlled substances are similar to those required for the federal credential required for such activities.

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

The schedules and deadlines for handlers of controlled substances are similar to those required for the federal credential required for such activities.

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

The reporting requirements for handlers of controlled substances are similar to those required for the federal credential required for such activities.

X. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

The operational standards are similar to those required for the federal credential required for such activities.

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

Since there are no exemptions at the federal level, there are none at the state level for handlers of controlled substances.

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: Controlled Dangerous Substance License for Non-Resident Distributors

Date Rule Takes Effect: December 1, 2012 (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 proposed rule imposes an annual Controlled Dangerous Substances (CDS) licensing fee of $50 on non-resident distributors. As such, the Board estimates an increased revenue collection of approximately $5,000 per fiscal year from licensing fees to be paid by an estimated 100 non-resident distributors seeking to distribute controlled substances within the state ($50 x 100 = $5,000).

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

Other than the $50 annual CDS license fee assessed on non-resident distributors, the Board anticipates minimal additional costs for recordkeeping and reporting since most of the requirements can be accomplished electronically.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

Malcolm J Broussard
Signature of Agency Head or Designee

Evan Brasseaux, Staff Director
Legislative Fiscal Officer or Designee

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

7/6/12
Date of Signature

June 20, 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).

We propose to amend the rule for controlled dangerous substances to require non-resident distributors to acquire a controlled dangerous substance license in order to distribute controlled dangerous substances to a Louisiana-based purchaser. 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.

When the Board promulgated its current chapter of rules for controlled substances, non-resident manufacturers distributing controlled dangerous substances to Louisiana-based purchasers were included in the list of entities required to acquire the controlled dangerous substances. Non-resident distributors should have been included in that list but were not. We seek to remedy that oversight through this proposed amendment.

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.

We can discern no measurable impact on the Board's expenditures, other than the printing costs of promulgation.

(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 Legislature has not appropriated the funds. The Board of Pharmacy operates purely on self-generated funds, and the Board has sufficient funds budgeted and available for the promulgation process.

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 its licensees 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 reporting and recordkeeping requirements are similar to the federal requirements, and both may be accomplished electronically. We anticipate minimal administrative costs beyond the annual $50 license fee.

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

We can discern no substantive effect on non-resident distributors that are small businesses.

(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 propose amendments.

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	$ 5,000	$ 5,000	$ 5,000
DEDICATED FUNDS	$ 0	$ 0	$ 0
FEDERAL FUNDS	$ 0	$ 0	$ 0
LOCAL FUNDS	$ 0	$ 0	$ 0
TOTAL	$ 5,000	$ 5,000	$ 5,000

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.

We can discern no impact on revenue collections of state and local governmental units.

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 persons directly affected by the proposed amendment are non-resident distributors shipping controlled dangerous substances to Louisiana-based purchasers. The proposed amendment will require them to obtain a Louisiana controlled dangerous substance license in order to ship such products into this state. The annual fee for the license is $50. The record-keeping and reporting requirements are similar to those already required by their resident state authority as well as the federal authority, and further, those requirements may usually be accomplished electronically.

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.

We are not able to estimate any impact on receipts or income resulting from this proposed amendment.

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.

We can discern no measurable 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

June 20, 2012
Date of Signature