



# Louisiana Board of Pharmacy

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January 2, 2013

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

## CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Re: Report No. 2 of 3 for Regulatory Project 2012-5 ~ Institutional Pharmacies  
Report No. 2 of 3 for Regulatory Project 2012-7 ~ Security of Prescription Departments  
Report No. 2 of 3 for Regulatory Project 2012-8 ~ Controlled Dangerous Substance License for  
Non-Resident Distributors  
Report No. 2 of 3 for Regulatory Project 2012-9 ~ Controlled Dangerous Substances in  
Emergency Drug Kits  
Report No. 2 of 3 for Regulatory Project 2012-10 ~ Prescription Monitoring Program

Dear Senator Alario:

As we indicated in our first report to you on July 10, 2012, the Board is currently promulgating amendments to several different sections of its rules as described above. Subsequent to our Notices of Intent published in the July 20, 2012 edition of the Louisiana Register, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on August 27, 2012.

The Board received one verbal comment in support of the proposed rule, as published, relative to controlled dangerous substances in emergency drug kits (Project 2012-9), but no other comments or testimony for any of the other proposals identified above.

During their December 12, 2012 meeting, the Board considered all comments and testimony and determined that no revisions to the original proposals are necessary. Further, the Board has determined it appropriate to move forward with the proposals as published.

Appended to this letter, you should find copies of the Notice of Intent and full text of the proposed rule for each of the regulatory projects identified above.

Subject to review by the Joint Legislative Oversight Committee on Health and Welfare, the Board proposes to publish the original proposed rules as Final Rules in the February 20, 2013 edition of the Louisiana Register. If you have any questions about the enclosed information or our procedures, please contact me directly at [mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov) or 225.925.6481.

For the Board:

Malcolm J. Broussard  
Executive Director

## **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 and distributors 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 ( $\$50 \times 100 = \$5,000$ ).

### 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.