



Louisiana Board of Pharmacy

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



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 or 225.925.6481.

For the Board:

Malcolm J. Broussard
Executive Director

Notice of Intent

Department of Health and Hospitals Board of Pharmacy

Institutional Pharmacies

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 two sections of *Chapter 17 – Institutional Pharmacies*. In particular, the proposed amendments clarify provisions relative to pharmacies operated in hospitals and penal institutions.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 17. Institutional Pharmacy

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§1705. Institutional Pharmacy Permit

- A. An institutional pharmacy permit shall be required to operate a pharmacy department located within an institutional facility, other than a hospital or penal institution, for residents or patients of that institutional facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.
- B. Pharmacies operated within a hospital shall be operated in accordance with Chapter 15 of these regulations.
- C. Pharmacies operated within a penal institution shall be operated in accordance with Chapter 18 of these regulations.

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 29:2095 (October 2003), effective January 1, 2004, amended LR

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Subchapter D. ~~Drug Donations to Pharmacies in Penal Institutions~~ (repealed)

~~§1727. Medication Transfers~~

- ~~A. In facilities licensed by the Department of Health and Hospitals where United States Pharmacopeia (USP) storage requirements can be assured, prescription drugs, except controlled dangerous substances, dispensed in unit dose or in individually sealed doses may be transferred to a permitted institutional pharmacy located within a penal institution operated under the authority of the Department of Public Safety and Corrections for re-labeling and dispensing to that penal institution's patients, free of charge, pursuant to a valid prescription order.~~
 - ~~1. The pharmacist in charge of the institutional pharmacy located within a penal institution shall be responsible for determination of suitability of the product for reuse.~~
 - ~~a. No product where integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.~~
 - ~~b. A re-dispensed prescription medication shall be assigned the expiration date stated on the package.~~
 - ~~c. No product shall be re-dispensed more than one time.~~
 - ~~2. Pursuant to a voluntary agreement between the facility licensed by the Department of Health and Hospitals and an institutional pharmacy located within a penal institution operated under the authority of the Department of Public Safety and Corrections, prescription drugs, except controlled substances, may be transferred from the facility to the pharmacy provided the following procedures are satisfied:~~
 - ~~a. The physical transfer shall be accomplished by an individual authorized to do so by the institutional pharmacy located within a penal institution.~~
 - ~~b. The patient from whom the prescription medication was obtained shall document their consent for the donation; the consent shall be maintained on file in the facility.~~

- ~~e. The patient's name, prescription number, and any other identifying marks, shall be obliterated from the packaging prior to removal from the facility.~~
 - ~~d. The drug name, strength, and expiration date shall remain on the medication package or label.~~
 - ~~e. An inventory list of the drugs shall accompany the drugs being transferred. The list shall contain, at a minimum, the medication name, strength, quantity, and expiration date.~~
 - ~~f. Expired drugs shall not be transferred. In the event expired drugs are received by an institutional pharmacy located within a penal institution, the pharmacist in charge shall destroy them as required by law.~~
- ~~B. Under no circumstances may these transferred medications be re-distributed to another location.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:1408 (July 2008), repealed 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 these proposed amendments. A public hearing on these proposed amendments 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

No impact on state or local government revenue collections is anticipated as a result of the proposed rule change.

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

The proposed amendments will clarify that pharmacies located within hospitals and penal institutions shall be operated in compliance with separate chapters of rules already promulgated by the board. No impact on costs or benefits to directly affected persons is anticipated as a result of the proposed rule change.

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.

There are no reporting requirements associated with the proposed amendments.

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

There are no deadlines for reporting requirements associated with the proposed amendments.

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

There are no reporting requirements associated with the proposed amendments.

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

There are no design or operational standards in the proposed amendments.

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

The proposed amendments contain no new requirements.