



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

Controlled Dangerous Substances in Emergency Drug Kits

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 its rules to authorize pharmacies utilizing emergency drug kits at long term care facilities to place a portion of its inventory of controlled dangerous substances within such kits.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 17. Institutional Pharmacy

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Subchapter B. Emergency Drug Kits

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§1713. Emergency Drug Kit Requirements

A.– I. ...

J. The placement of controlled dangerous substances in an EDK in non-federally registered long term care facilities shall be deemed in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:

1. Controlled dangerous substances shall be stored in the EDK as deemed necessary and jointly approved by the pharmacist, medical director and the director of nursing services;
2. The source from which the controlled dangerous substances for EDKs are obtained shall be a pharmacy licensed by the Board in possession of a valid DEA registration and Louisiana CDS license.
3. The number of different controlled dangerous substances in a single EDK shall be limited to a maximum of eight (8) separate drug entities with not more than eight (8) single-use containers of each drug entity.
4. The EDK containing controlled dangerous substances shall be closed with a tamper proof seal and kept in a locked medication room, cart or closet.
5. Access to controlled dangerous substances stored in an EDK shall be limited to the pharmacist, a practitioner, the director of nursing services, or the registered nurse or licensed practical nurse on duty.
6. Controlled dangerous substances stored in an EDK shall be administered to a patient only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.21 or their successors.
7. A usage record shall be retained in the EDK for each separate drug included which shall be completed by the nursing staff when retrieving any controlled dangerous substance(s) from the EDK.
8. The pharmacist at the provider pharmacy shall receive and retain all completed usage records for a minimum of two years.
9. When the EDK is opened:
 - a. The pharmacist shall be notified by the facility within 24 hours; and
 - b. Shift counts shall be performed by the nursing staff on all controlled dangerous substances until the kit is resealed by the pharmacist.
10. Shift counts of the controlled dangerous substances contained in the EDK shall not be required when the EDK is sealed.
11. The pharmacist shall check the controlled dangerous substances in the EDK at least monthly and so document that check inside the kit.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004, amended LR

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Chapter 27. Controlled Dangerous Substances

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Subchapter F. Production, Distribution and Utilization

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§2743. Procurement Requirements

- A. ...
- B. ...
- C. Acquisition of Controlled Dangerous Substances by Institutional Facilities
 - 1. A Louisiana licensed pharmacy in possession of a valid Louisiana CDS license and DEA registration may include a portion of its controlled dangerous substance inventory within an emergency drug kit (EDK) placed in a non-federally registered institutional facility, but only under the following conditions:
 - a. The EDK bears a valid EDK permit issued by the board; and
 - b. The inclusion and management of controlled dangerous substances in such EDK shall comply with the provisions of Section 1713.J of these rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2148 (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 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. In addition, to the extent that state and local long-term care facilities elect to utilize emergency drug kits, the proposed amendments will allow them to add a maximum of 8 controlled dangerous substances (CDS) to those kits from the CDS list under R.S. 40:964. The costs of the controlled dangerous substances vary depending on the supplier and whether the drug is generic or brand name. The recordkeeping and reporting requirements associated with the controlled dangerous substances are similar to the federal mandates and will result in a minimal workload increase to state and local governmental units.

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

To the extent that private pharmacies elect to utilize emergency drug kits within private long-term care facilities, the proposed amendments will allow them to add a maximum of 8 controlled dangerous substances to those kits from the CDS list under R.S. 40:964. The costs of the controlled dangerous substances vary depending on the supplier and whether the drug is generic or brand name. The recordkeeping and reporting requirements associated with the controlled dangerous substances are similar to the federal mandates and will result in a minimal workload increase to directly affected persons or non-governmental groups.

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:

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

The recordkeeping and reporting requirements are similar to the federal mandates.

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

The schedules and deadlines are similar to the federal mandates.

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

The reporting requirements are similar to the federal mandates.

IV. 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 the federal mandates.

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 amendments.