



Louisiana Board of Pharmacy

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March 27, 2017

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

Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2016-4 ~ Standing Orders for Distribution of Naloxone

Dear Senator Alario:

As we indicated in our first report to you on January 9, 2017, the Board is currently amending its rules to allow pharmacists to distribute naloxone and other opioid antagonists pursuant to non-patient-specific standing orders issued by medical practitioners with prescriptive authority for naloxone, in compliance with Act 370 of the 2016 Legislature. Subsequent to our Notice of Intent published in the January 20, 2017 edition of the Louisiana Register, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on March 1, 2017.

We received no written comments or testimony prior to or during the public hearing. The Board has determined no revisions are necessary to the proposed rule as originally published, and further, determined it appropriate to move forward with the proposed rule.

You should find the following documents appended to this letter:

- Notice of Intent, as published in the January 2017 Louisiana Register
- Summary of Comments from March 1, 2017 Public Hearing
- Full text of proposed rule

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposed rule as a Final Rule in the May 20, 2017 edition of the Louisiana Register, with an immediate effective date. 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

cc: Chair, Senate Committee on Health and Welfare – APA.S-H&W@legis.la.gov
Speaker, House of Representatives – APA.HouseSpeaker@legis.la.gov
Chair, House Committee on Health and Welfare – APA.H-HW@legis.la.gov
Editor, Louisiana Register – Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health Board of Pharmacy

Standing Orders for Distribution of Naloxone (LAC 46:LIII.2541)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy hereby gives notice of its intent to add §2541 to its rules. As authorized by Act 370 of the 2016 Legislature, the proposed Rule will authorize pharmacists to distribute naloxone and other opioid antagonists pursuant to non-patient specific standing orders issued by any medical practitioner with prescriptive authority for naloxone.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

Subchapter D. Prescription Drugs

§2541. Standing Orders for Distribution of Naloxone and Other Opioid Antagonists

A. Given the current public health emergency relative to the misuse and abuse of opioid derivatives, public health officials have strongly recommended the widespread availability of naloxone and other opioid antagonists to addicts and their caregivers as well as first responders in the community.

B. For as long as naloxone and other opioid antagonists remain classified as prescription drugs by the federal Food and Drug Administration, pharmacists must secure a prescription or order from a prescriber with the legal authority to prescribe the drug product in order to dispense or distribute the drug product.

C. The Louisiana Legislature has adopted a number of laws designed to facilitate the distribution and dispensing of naloxone and other opioid antagonists beyond the person who would need the medication on an emergent basis to manage an opioid-related drug overdose, more specifically to first responders as well as caregivers and family and friends of potential patients.

1. Act 253 of the 2014 Legislature authorized prescribers to issue prescriptions for naloxone and other opioid antagonists to first responders, and further, authorized pharmacists to recognize such prescriptions as legitimate orders for the dispensing and distribution of naloxone and other opioid antagonist drug products, and further, authorized first responders to have and hold those drug products ready for administration in emergent conditions to manage opioid-related drug overdoses.

2. Act 192 of the 2015 Legislature authorized medical practitioners to prescribe naloxone or another opioid antagonist without having previously examined the individual to whom the medication would be administered, but only under certain conditions specified in the legislation, including the requirement for the prescriber to provide the recipient of the drug with all training and education required for the safe and proper administration of the drug product.

3. Act 370 of the 2016 Legislature authorized medical practitioners to issue nonpatient-specific standing orders to

pharmacists authorizing the distribution of naloxone and other opioid antagonists to anyone who might be in a position to assist a patient in the emergent management of an opioid-related drug overdose, but only in compliance with these rules.

a. A nonpatient-specific standing order for the facilitated distribution of naloxone or other opioid antagonist issued by a medical practitioner licensed by the state of Louisiana shall expire one year after the date of issuance.

b. A Louisiana-licensed pharmacist may distribute naloxone or other opioid antagonist according to the terms of the nonpatient-specific standing order issued by a Louisiana-licensed medical practitioner until the expiration date of the standing order. No pharmacist shall distribute naloxone or other opioid antagonist pursuant to a standing order more than one year after the date of issuance of the standing order.

c. Before releasing the naloxone or other opioid antagonist drug product to the recipient, the pharmacist shall verify the recipient's knowledge and understanding of the proper use of the drug product, including, at a minimum:

i. techniques on how to recognize signs of an opioid-related drug overdose;

ii. standards and procedures for the storage and administration of the drug product; and

iii. emergency follow-up procedure including the requirement to summon emergency services either immediately before or immediately after administering the drug product to the individual experiencing the overdose.

d. To comply with the recordkeeping requirements found elsewhere in the board's rules, the pharmacist shall attach a copy of the standing order to the invoice or other record of sale or distribution, and further, shall store these transaction documents with the other distribution records in the pharmacy.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:

Family Impact Statement

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.

1. The effect on the stability of the family. We anticipate no effect on the stability of the family.

2. The effect on the authority and rights of parents regarding the education and supervision of their children. We anticipate no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The effect on the functioning of the family. We anticipate no effect on the functioning of the family.

4. The effect on family earnings and family budget. We anticipate no effect on family earnings and the family budget.

5. The effect on the behavior and personal responsibility of children. We anticipate no effect on the behavior and personal responsibility of children.

6. The ability of the family or a local government to perform the function as contained in the proposed Rule. We anticipate no effect on the ability of the family or a local government to perform the activity as contained in the proposed Rule.

Poverty Impact Statement

In accordance with section 973 of title 49 of the *Louisiana Revised Statutes*, there is hereby submitted a Poverty Impact Statement on the Rule proposed for adoption, repeal, or amendment.

1. The effect on household income, assets, and financial security. We anticipate no impact on household income, assets, and financial security.

2. The effect on early childhood development and preschool through postsecondary education development. We anticipate no impact on early childhood development or preschool through postsecondary education development.

3. The effect on employment and workforce development. We anticipate no impact on employment and workforce development.

4. The effect on taxes and tax credits. We anticipate no impact on taxes or tax credits.

5. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance. To the extent a child or other dependent has an addiction to opiates and is at risk of an opioid-related overdose, and to the extent the caregiver acquires naloxone to keep close at hand, the proposed Rule may improve the opportunity for positive outcomes from an opiate-related overdose event.

Small Business Analysis

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.

1. The establishment of less stringent compliance or reporting requirements for small businesses. The proposed Rule does not contain any reporting requirements for small businesses.

2. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses. There are no reporting deadlines for businesses in the proposed Rule.

3. The consolidation or simplification of compliance or reporting requirements for small businesses. There are no reporting requirements for businesses in the proposed Rule.

4. 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 required in the proposed Rule.

5. 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.

Provider Impact Statement

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a Provider Impact Statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities.

1. The effect on the staffing level requirements or qualifications required to provide the same level of service. We anticipate no effect on the staffing level requirements or

the qualifications for that staff to provide the same level of service.

2. The total direct and indirect effect on the cost to the provider to provide the same level of service. We anticipate no impact on the total direct and indirect effect on the cost to the provider to provide the same level of service.

3. The overall effect on the ability of the provider to provide the same level of service. We anticipate no effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments to Malcolm J. Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding this proposed Rule. The deadline for the receipt of all comments is 12 p.m. that same day.

Public Hearing

A public hearing on this proposed Rule is scheduled for Wednesday, March 1, 2017 at 9 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.

Malcolm J. Broussard
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: **Standing Orders for Distribution of Naloxone**

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The estimated implementation costs to the Louisiana Board of Pharmacy are approximately \$1,500 (\$750 in FY 17 and \$750 in FY18) for the notice and rule publication costs. There are no estimated implementation savings to the state or local government units through promulgation of the proposed rule change. The proposed rule change will allow pharmacists to distribute naloxone and other opioid antagonists pursuant to non-patient specific standing orders issued by medical practitioners with prescriptive authority for naloxone.

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

There will be no impact on revenue collections of state or local governmental units from the proposed rule.

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

The proposed rule change is anticipated to affect persons with an addiction to opioid drug products and that do not currently have access to naloxone. Naloxone is an effective antidote medication that reverses the respiratory depression resulting from an opioid overdose event. Currently, naloxone can be dispensed with a prescription however many addicts do not have primary care providers. The proposed rule change will allow anybody with an opioid addiction to receive naloxone from a pharmacy pursuant to a standing order.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will have no impact on competition or employment.

Malcolm J. Broussard
Executive Director
1701#031

Evan Brasseaux
Staff Director
Legislative Fiscal Office



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Summary of Testimony & Public Comments
re
Regulatory Project 2016-4 ~ Standing Orders for Distribution of Naloxone
at
March 1, 2017 Public Hearing

No comments or testimony were received for this regulatory project.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

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Subchapter D. Prescription Drugs

§2541. Standing Orders for Distribution of Naloxone and Other Opioid Antagonists

- A. Given the current public health emergency relative to the misuse and abuse of opioid derivatives, public health officials have strongly recommended the widespread availability of naloxone and other opioid antagonists to addicts and their caregivers as well as first responders in the community.
- B. For as long as naloxone and other opioid antagonists remain classified as prescription drugs by the federal Food and Drug Administration, pharmacists must secure a prescription or order from a prescriber with the legal authority to prescribe the drug product in order to dispense or distribute the drug product.
- C. The Louisiana Legislature has adopted a number of laws designed to facilitate the distribution and dispensing of naloxone and other opioid antagonists beyond the person who would need the medication on an emergent basis to manage an opioid-related drug overdose, more specifically to first responders as well as caregivers and family and friends of potential patients.
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 3. Act 370 of the 2016 Legislature authorized medical practitioners to issue nonpatient-specific standing orders to pharmacists authorizing the distribution of naloxone and other opioid antagonists to anyone who might be in a position to assist a patient in the emergent management of an opioid-related drug overdose, but only in compliance with these rules.
 - a. A nonpatient-specific standing order for the facilitated distribution of naloxone or other opioid antagonist issued by a medical practitioner licensed by the State of Louisiana shall expire one year after the date of issuance.
 - b. A Louisiana-licensed pharmacist may distribute naloxone or other opioid antagonist according to the terms of the nonpatient-specific standing order issued by a Louisiana-licensed medical practitioner until the expiration date of the standing order. No pharmacist shall distribute naloxone or other opioid antagonist pursuant to a standing order more than one year after the date of issuance of the standing order.
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 - d. To comply with the recordkeeping requirements found elsewhere in the Board's rules, the pharmacist shall attach a copy of the standing order to the invoice or other record of sale or

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